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DG(SANTE) 2024-8038

FINAL REPORT OF AN AUDIT  
OF  
CYPRUS  
CARRIED OUT FROM 9 TO 19 APRIL 2024  
IN ORDER TO  
EVALUATE THE SYSTEM OF OFFICIAL CONTROLS RELATING TO MICROBIAL  
SAFETY OF FOOD OF NON-ANIMAL ORIGIN

*In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.*

### ***Executive Summary***

*This report describes the outcome of an audit in Cyprus which took place from 9 to 19 April 2024 by the Directorate-General for Health and Food Safety of the European Commission.*

*The objectives of this audit were to assess the system of official controls in the area of food hygiene to prevent microbiological contamination in food of non-animal origin and to assess the system of official controls in the area of traceability of sprouts and seeds intended for sprouting, including applicable microbiological criteria and the approval of sprout-producing establishments.*

*The report concludes that there is a system in place for official controls on food of non-animal origin covering all production stages, supported by a monitoring plan and suitable laboratory capability.*

*Good progress was observed in improving the official controls system since the previous audit, however, its effectiveness is impacted by:*

- the fact that the existing procedures regarding reporting of non-compliances are not implemented, to the point that official reports portray a situation of compliance, when this is not always the case;*
- an incomplete knowledge of inspectors in some control areas, concerning pre-requisites, monitoring and verification in the context of Hazard Analysis and Critical Control Points and requirements related to *Listeria monocytogenes* in ready-to-eat foods.*

*The report contains recommendations to the competent authority to address the identified shortcomings.*

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## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
<b>BTSF</b>	Better Training for Safer Food
<b>CA(s)</b>	Competent Authority(ies)
<b>CCA(s)</b>	Central Competent Authority(ies)
<b>DG Health and Food Safety</b>	Directorate-General for Health and Food Safety of the European Commission
<b>DoA</b>	Department of Agriculture
<i>E. coli</i>	<i>Escherichia coli</i>
<b>EFSA</b>	European Food Safety Authority
<b>EU</b>	European Union
<b>FBO(s)</b>	Food Business Operator(s)
<b>FNAO</b>	Food of non-animal origin
<b>HACCP</b>	Hazard Analysis and Critical Control Points
<i>L. monocytogenes</i>	Listeria monocytogenes
<b>NRL</b>	National Reference Laboratory
<b>PHS</b>	Public Health Services
<b>PT</b>	Proficiency tests
<b>RASFF</b>	Rapid Alert System for Food and Feed
<b>RTE</b>	Ready-to-eat
<b>SGL</b>	State General Laboratory of the Republic of Cyprus
<b>STEC</b>	Shiga toxin-producing <i>Escherichia coli</i> <sup>(1)</sup>

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<sup>(1)</sup> The EFSA scientific opinion on the risk posed by pathogens in food of non-animal origin uses the term VTEC-Verocytotoxin-producing *Escherichia coli*, while the term STEC is used in the EFSA Scientific Opinion on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds. The term STEC is also used in Regulation (EC) No 2073/2005.

## 1 INTRODUCTION

This audit took place in Cyprus from 9 to 19 April 2024. It formed part of the planned work programme of the European Commission’s Directorate-General for Health and Food Safety (DG Health and Food Safety) and comprised two auditors from DG Health and Food Safety and was accompanied by an observer from the European Free Trade Association’s Surveillance Authority.

A remote opening meeting was held on 9 April with representatives from the competent authorities (CAs): Ministry of Agriculture, Rural Development and Environment (Department of Agriculture – DoA), Ministry of Health (Public Health Services – PHS and State General Laboratory of the Republic of Cyprus – SGL).

At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit team and the control systems were described by the authorities. A representative of the central competent authorities (CCA) accompanied the auditor for the duration of the audit.

## 2 OBJECTIVES AND SCOPE

The objectives of the audit were to evaluate:

- the system of official controls in the area of food hygiene to prevent microbiological contamination in food of non-animal origin (FNAO);
- the system of official controls in the area of traceability of sprouts<sup>(2)</sup> and seeds intended for sprouting, including applicable microbiological criteria and the approval of sprout-producing establishments.

In terms of scope, the audit reviewed the official controls for food hygiene to prevent microbiological contamination in FNAO, including seeds intended for sprouting and sprouts. This covered a review of the planning and implementation of official controls, control procedures and sampling performance. The implementation of official controls over operators’ obligations included: cultivation of fruit and vegetables (consumed raw), cut fruits and vegetables, sprout-producing establishments and retailers.

In pursuit of these objectives, the following sites were visited:

**Table 1: Audit visits and meetings**

<i>Visits / meetings</i>	<i>Comments</i>	
<b>Competent Authorities (CAs)</b>		
Central level	2	Opening (remote) and Closing Meeting – representatives of CAs

<sup>(2)</sup> ‘Sprouts’ means the product obtained from the germination of seeds and their development in water or another medium, harvested before the development of true leaves and which is intended to be eaten whole, including the seed.

<i>Visits / meetings</i>	<i>Comments</i>	
<b>Laboratories</b>		
Public	1	SGL
<b>Food Business Operators (FBOs)</b>		
Sprout-producing establishment	1	Sprouts (not approved yet)
Soft fruit production	2	Strawberries
Vegetable production	2	Green leafy vegetables
Processors of FNAO	3	Cut fruits and vegetables

### 3 LEGAL BASIS

The audit was carried out under the general provisions of the European Union (EU) legislation and, in particular, Articles 116, 117 and 119 of Regulation (EU) 2017/625 of the European Parliament and of the Council. Full legal references are provided in Annex 1 of this report. Legal acts quoted in this report refer, where applicable, to the last amended version.

### 4 BACKGROUND

FNAO is consumed in a variety of forms and is a major component of most meals. These food types have the potential to be associated with large disease outbreaks in the EU. In particular:

- May 2011: a major outbreak of Shiga toxin-producing *Escherichia coli* (STEC) O104:H4 in sprouted seeds. 4 000 people were reported ill with symptoms and the outbreak resulted in the deaths of 56 people;
- 2012: a major outbreak of Norovirus in frozen strawberries from China. 11 000 people (mainly children) were reported ill with symptoms;
- 2018-2020: a major outbreak of Hepatitis A in frozen strawberries, most likely from Egypt. 65 people were reported ill with symptoms.

The European Food Safety Authority (EFSA) concluded in a scientific opinion that the top-ranking food/pathogen combination was leafy greens eaten raw and *Salmonella spp.*, followed by (in equal rank) bulb and stem vegetables and *Salmonella spp.*, tomatoes and *Salmonella spp.*, melons and *Salmonella spp.*, and fresh pods, legumes or grain and pathogenic *Escherichia coli* (*E. coli*).

More details can be found at: <http://www.efsa.europa.eu/en/efsajournal/doc/3025.pdf>.

In view of the number of large outbreaks and the high number of Rapid Alert System for Food and Feed (RASFF) notifications concerning products of non-animal origin, DG Health and Food Safety decided to undertake an audit series in Member States on FNAO.

This was the second audit to Cyprus on this topic.

The first audit took place on 2014 (DG (SANTE) 2014-7171).

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 RELEVANT NATIONAL LEGISLATION**

#### **Legal requirements**

Article 291 of the Treaty on the Functioning of the EU; Article 1(3) of Regulation (EC) No 852/2004.

#### **Findings**

1. The national legislation implemented for official controls in the food sector is described in the Country Profile for Cyprus at:  
<https://ec.europa.eu/food/audits-analysis/country/profile/download/416>.

*Guide to Good Agricultural Practices and to Good Hygiene practices*

#### **Department of Agriculture (DoA)**

2. DoA has issued a Guide to Good Hygiene Practices at the primary production of FNAO to assist producers who do not have their own guide to follow. This has been published on DoA's website at:  
<https://www.moa.gov.cy/moa/da/da.nsf/All/83821970DF1CC1D4C225879D0042EA4E?OpenDocument>.
3. In addition, DoA has published a Guide to Good Agricultural Practices in the official national journal of the Republic of Cyprus. Within this guide, there are guidelines for the use of recycled water.

#### **Public Health Services (PHS)**

4. Further to the guides to Good Manufacturing Practices regarding specific categories of food businesses, a specific guide was developed intended for FBOs for which the Regulation (EC) No 2073/2005 on microbiological criteria is applied. This guide is available on PHS's website and disseminated to all implicated FBOs who are strongly advised to consult the guide to receive relevant information/knowledge in order to fulfil their obligations derived from the above-mentioned Regulation.

#### **Conclusion on relevant national legislation and guidelines**

5. There is national legislation in place complementing the directly applicable EU legislation, supported by guidelines. This enables the CAs to establish official controls in the area of food hygiene to prevent microbiological contamination along the food chain of FNAO.

## **5.2 COMPETENT AUTHORITIES**

### **Legal requirements**

Articles 4, 5 and 6 of Regulation (EU) 2017/625.

### **Findings**

6. There is a cooperation agreement between PHS and DoA (the two CCAs in the scope of the audit), which clarify the areas for which both CCAs have competency. This is clarified in a circular describing the responsibilities of PHS and DoA, which also includes how communication between the two authorities is organised.

### **DoA**

7. DoA, of the Ministry of Agriculture, Rural Development and Environment, is the CCA for the official controls of microbiological contamination prior to and during harvest of fresh fruits and vegetables.
8. The performance of comprehensive official controls of FNAO at the primary production (field) level is the sole responsibility of DoA.
9. Official controls, in term of official inspections and official samples, are carried out at local level by four different legislative control units. At the time of the audit, each unit included two inspectors in charge of official controls and one coordinator in charge of supervision.

### **PHS**

10. PHS is the CCA responsible for official controls post-harvest and at sprout-producing establishments, as described in the national legislation “Food (Control and Sale) Law of 1996 to 2014”.
11. Official controls when products are harvested by a primary producer and packed in the same place, are the responsibility of DoA, whereas if products are harvested by more than one producer and packed in a separate facility, the official controls are the responsibility of PHS. There is an agreement between PHS and DoA that PHS controls packers that fall under that category of having products from more than one primary producer. The packers are registered with PHS.

### **Training of official staff**

12. Each CCA (DoA and PHS) is responsible for their own staffing, in terms of number, qualifications, training programme and tools. Relevant staff include specialists in various disciplines, such as scientific personnel, as well as administrative staff and laboratory staff with chemical/technical/biological training.



## **DoA**

13. Regarding primary production, from 2020 to date, there have been approximately 30 inspectors authorised in Cyprus. However, official controls regarding the scope of this audit, are conducted by only 8 to 10 inspectors.
14. Training on the provisions of Regulation 852/2004 for primary production was carried out in March 2020, in which 48 people participated. This included staff from DoA and from Cyprus Agricultural Payment Organisation (in the context of cross compliance).
15. Further training included Better Training for Safer Food (BTSF) in which three people (authorised Inspectors) participated in 2022 and two more will be following the relevant courses in 2024.
16. However, the inspectors were not adequately trained and provided with specific tools to properly identify all non-compliances and to register them in the official reports (see paragraphs **52** to **55**).

## **PHS**

17. A total number of 88 inspectors are posted in the central, district and rural offices of PHS, who are authorised to enforce all pieces of legislation for which PHS have competency.
18. Training includes BTSF courses, internal training (within one or more districts), induction training (newly appointed staff) and cascade training sessions by inspectors who have attended BTSF courses (district level).
19. All training material is uploaded on the E-Collaboration platform (working platform accessible by all PHS's staff). In 2021 and 2022 the training activities were limited to the participation of 4 inspectors in BTSF, whereas in 2023, 62 inspectors participated in internal trainings regarding microbiological criteria for Regulation (EC) No 2073/2005.
20. However, the inspectors were not adequately trained and provided with specific tools to properly identify all non-compliances and thus enforce the EU Legislation (see paragraphs **61** to **64**).

## **Audit / Supervision**

21. This audit framework covers all areas of consumer health protection. All specialist areas are audited over a period of 5 years. Audits covering topics related to microbial safety are incorporated in various vertical audits related to food safety.
22. The area of microbiological risks in FNAO at primary production, in the scope of this audit, was last covered in 2018. Regarding processed FNAO, in the scope of this audit, the area of microbiological risks has not yet been covered.

23. Regarding supervision, DoA has a system in place whereby the district office is responsible for checking and validating each official report. The CA stated that this ensures the homogeneity of the inspections at district level. No on-site activity (e.g. witness inspections) was in place at the time of this audit. However, DoA informed the audit team that a procedure will be set to verify that from now on, inspectors respect the procedures, both in terms of regarding on non-compliances, and requesting appropriate corrective actions within defined deadlines (see paragraphs 53 to 57).
24. PHS has a system of supervision that includes on-site joint inspection (supervisor and district inspectors) at least once a year for every inspector. However, the system failed to adequately identify, and thus to rectify shortcomings (in particular regarding cross-contamination and the assessment of the Hazard Analysis and Critical Control Points – HACCP), during regular official controls (see paragraphs 62 to 64).

#### **Conclusions on competent authorities**

25. The CAs are designated for all stages of FNAO production and for sprout-producing establishments. These provide good bases for the implementation of the official control system.
26. The training systems are not able to deliver specific competency to staff, which has an impact on the implementation of official controls.
27. There is a system for supervision in place. However, it failed to identify shortcomings in the implementation of the procedures.

### **5.3 OFFICIAL CONTROLS**

#### *5.3.1 Registration and approval of food business operators*

##### **Legal requirements**

Article 6 of Regulation (EC) No 852/2004; Article 2 of Regulation (EU) No 210/2013; Articles 10(2), 138(1), 138(2)(c)-(j), 138(3), 138(4) and 148 of Regulation (EU) 2017/625.

##### **Findings**

###### Registration

###### DoA

28. DoA uses the Registry of Cyprus Agricultural Payment Organisation and other registries kept by DoA, such as those for greenhouse, edible flowers and microgreens producers.
29. For the registration of certain primary producers in the registries that are kept by DoA (e.g., microgreens producers, production of seeds intended for sprouting), an application form is provided. It is noted that the registration is completed without prior official con-

trol.

30. The CAs informed the audit team that the registries track plots with details of the crops produced. Through the payment agency it is possible to connect the plots to the farms.

### **PHS**

31. FNAO FBOs must be registered in the Director of Medical and Public Health Services Registry. There is a specific procedure for the registration of all food businesses, regardless of the type/category of business. It is noted that the registration is completed without prior official control.
32. The official inspection is carried out after the registration of a business; an inspector performs an official control and fills out the relevant first official control report and the class of risk is assigned.

### **Approval of sprout-producing establishments**

### **PHS**

33. At the time of the audit, there was one sprout-producing establishment in the process of being approved.
34. Procedures are in place for the approval of sprout-producing establishments. Sprout-producing establishments will register and then apply for approval. PHS has a specific comprehensive checklist for sprout-producing establishments. An official control will be carried out using the checklist and based on the result a decision on approval will be taken.

### **Importers that are importing and distributing risky produce**

35. The CA informed the audit team that trade and import (from outside the EU) companies were registered in the central registry, as importers of FNAO. As importers, they are under official control of PHS.

### ***5.3.2 Planning of official controls***

### **Legal requirements**

Article 17 of Regulation (EC) No 178/2002; Articles 9, 10 and 65 of Regulation (EU) 2017/625.

### **Findings**

### **DoA**

36. The primary producers are separated into three risk categories according to the species that they cultivate. The categories are “high-risk”, “medium-risk” and “low-risk”. The high-risk category includes cultivations such as leafy greens, soft-fruits, tomatoes, melons, watermelons and producers of seeds for sprouting that have high microbiological

risk according to EFSA opinions; the medium-risk category includes products that may be eaten raw but are not evaluated by EFSA; the low-risk category includes other products such as cereals and potatoes.

37. One producer may be included in one or two or all three categories. The higher risk category will determine the frequency of official control. For the year 2024, the sample size chosen for official control from each risk category was as follows:
- High-risk category – 4%;
  - Medium-risk category – 1%;
  - Low-risk category – at least one producer per district.
38. The risk analysis as described above, is presented in more detail in instructions provided each year to the inspectors. The annual programme is sent to the legislation control unit and it includes the number of inspections per risk category.
39. The FBOs in the scope of this audit are all in the high-risk category. A specific checklist, developed at central level based on the European guidelines <sup>(3)</sup>, is available to all inspectors.
40. There is a procedure in place for non-compliances. However, the procedure does not provide instructions on the immediate actions to be taken regarding a product, when cases of potential direct contamination (cross-contamination) of the food are found during an official inspection (see paragraphs **53** to **57**).

### **PHS**

41. A risk categorisation system for food businesses (including FNAO) is described in the Code of Practice on the classification of food businesses based on risk and the determination of the frequency of official controls. The Code of Practice, in conjunction with the risk assessment form, is used by the inspectors in order to determine the frequency of official controls for each FBO. Relevant data (e.g. total points, risk category and official controls frequency) is uploaded on the E-Collaboration platform.
42. The frequency of official controls/risk category is updated either after five official controls (inspections) or every two years, whichever comes first. Apart from this, the frequency of official controls can be updated whenever a change in the FBO may substantially affect the risks, taking the following criteria into consideration:
- identified risks (crops, foodstuffs, activities, distribution, consumer's categories, etc.);
  - the past performance of an FBO in terms of compliance with food law and its history with regard to the results of official controls carried out (including information indicating that consumers may be misled, in particular as to the nature, identity, properties, composition, quantity, shelf life, country of origin or place of origin, the method of preparation or production of the food);

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<sup>(3)</sup> Commission notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene. O. J. 2017/C 163/01.

- the reliability and results of self-checks carried out by FBOs.
43. For each of the above parameters a score is given, the total score of which determines the risk classification and the frequency of official controls for each FBO. However, for the FBOs in the scope of this audit, the frequency of official inspections is at least three times per year.
  44. Depending on the type of business and on the relevant legislation, a complementary checklist is used. In particular, in the scope of this audit, specific checklists are available for:
    - producers of ready-to-eat (RTE) pre-cut fruit and vegetables;
    - sprout-producing establishments.
  45. When a non-compliance is detected during an official inspection (either during the first official control after registration or any subsequent official control), the actions to be taken are described in a procedure for non-compliances.
  46. However, the procedure does not provide specific instructions on the actions to be taken regarding the product when cases of potential direct contamination of food are found during an official inspection (see paragraph 63).
  47. The CAs informed the audit team that the application of Commission Regulation (EC) No 2073/2005 is assessed by inspectors during official controls of FBOs producing RTE products, and the requirement regarding the implementation of environmental tests for *Listeria monocytogenes* (*L. monocytogenes*) by the FBOs is enforced.

### 5.3.3 Implementation of official controls

#### Legal requirements

Articles 9(1)(d), 14 and 44(1) of Regulation (EU) 2017/625; Articles 4 to 8, and Annexes I and II of Regulation (EC) No 852/2004; Article 18 of Regulation (EC) No 178/2002; Article 3 of Regulation (EU) No 208/2013; Regulation (EU) 2020/2235; Article 1 and Annex I of Regulation (EC) No 2073/2005.

#### Findings

##### DoA

48. For the implementation of official controls relating to FNAO at the primary production level, the following sectors within DoA are involved:
  - Plant Health and Marketing Standards Agricultural Products Sector (policy making):
    - i. Preparation of annual inspection programme based on risk analysis (number of controls and samples per district);
    - ii. Preparation of guidelines for inspectors, checklists, protocols with other entities/authorities;

- iii. Upkeep of records in the Register of FBOs;
  - iv. Carries out training of inspectors;
  - v. Suggest to the Director measures to be taken in case of non-conformities.
- Legislation Control Sector, implementing legislation (inspectors):
    - vi. Carry out official controls and sampling;
    - vii. Have direct communication with the operators that are involved;
    - viii. Follow up of any non-compliances and provide further feedback to the Plant Health and Marketing Standards Agricultural Products Sector.
49. Additionally, a monitoring programme is implemented in cooperation with the SGL. Samples of fresh fruits and vegetables are being taken prior to and during harvesting and analysed for *E. coli* and *Salmonella*.

### **PHS**

50. PHS are responsible for the implementation and enforcement of legislation, including the control of FNAO:
- Food businesses manufacturing, producing, importing, distributing and selling of FNAO throughout the food chain, except primary producers;
  - All FNAO throughout the food chain, except primary production;
  - All foodstuffs of animal origin and composite products at retail level except fresh meat.

### **DoA**

#### *Primary producers*

51. The audit team visited four different farms in three separate districts (two different local CAs). The inspectors informed the audit team that an assessment of the procedures on good manufacturing practices, good hygiene practices and good farming practices is part of the official controls.
52. In all cases, the specific checklist prepared at central level was used by the inspectors. Many points relevant to the official controls of microbiological risks in FNAO, such as: irrigation water, type of irrigation, manure, workers' health, product handling, and traceability are included. However, other important points, such as hand-washing facilities and field toilets, are not included in the checklist, but in additional documentation provided to the inspectors by the CCA.
53. All of these farms have been inspected previously and non-compliances have not been recorded by the inspectors in their official reports.
54. During this audit, the inspectors detected a number of non-compliances such as: poor hygiene conditions of toilets and hand-washing facilities, presence of birds inside the greenhouses, absence of protection papers in the crates used for harvested products.

55. However, the fact that crates containing products are regularly in direct contact with the floor in one packing room as well as the fact that there is no identification regarding the crates and their use, were both overlooked by the inspectors during the audit.
56. During the audit, the inspectors recorded the non-compliances identified and deadlines for their correction were imposed. However, for cases of direct contamination of the product, such as a birds' nest on the inside roof of the greenhouse and a crate containing tomatoes located on the floor, no immediate action regarding the product was requested.
57. The CAs informed the audit team that the procedure for non-conformities states that an inspector has the power to demand corrective actions to be taken. However, no immediate action was taken during the audit in order to segregate the potentially contaminated product observed.

## PHS

### *Sprout-producing establishment*

58. The audit team verified the official procedures and checklist in place at one sprout-producing establishment and found them to be satisfactory. Approval has not yet been granted. Production is for testing purposes only (see paragraph 77).

### *Processors (cut fruits and vegetables)*

59. The audit team visited three different processors of pre-cut fruits and vegetables in three separate districts (three different local CAs).
60. The inspectors informed the audit team that they verify the sampling plans and analyses carried out by FBOs. The FBOs visited used accredited laboratories for the analyses of their samples.
61. Regarding sampling of surfaces for *L. monocytogenes*, the CAs informed the audit team that there are official instructions available, and that all inspectors have thorough expertise regarding *L. monocytogenes*, in particular concerning their obligation to verify compliance of FBOs with Article 5(2) of Regulation (EC) No 2073/2005. However, during the audit, the CA overlooked the fact that environmental samples for *L. monocytogenes* from food contact surfaces were taken after cleaning <sup>(4)</sup> and not during operations.
62. The auditors observed inspections being carried out at the high care areas and, in part, at the non-high care cutting areas at all FBOs. Several non-compliances were detected and recorded by the inspectors, mainly related to structural problems. However, condensation issues, crates and boxes with direct contact with the floor, knives not properly managed, workers' behaviour, identified by the inspectors during the audit, were rarely recorded in the official reports from previous years.

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<sup>(4)</sup> Guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*, Version 3 – 20/8/2012.

63. At one FBO, the audit team did not observe evidence of any actions taken by the inspectors to address a potentially contaminated product.
64. In addition, the verification of HACCP is mainly related to the presence of a flow-chart instead of a verification of the hazard analysis, the appropriateness of the critical limits and its validation and the presence of monitoring procedures.

Other control systems

65. One farm and two processors, visited by the audit team, were certified under a private quality scheme. This was a requirement by their customers. Both FBOs were audited by buyers several times per year.

**DoA**

66. Private quality assurance schemes are not taken into account for the planning of official controls.

**PHS**

67. The reliability and results of self-checks carried out by the FBOs, are taken into account for the official controls carried out by PHS.

**Conclusions on official controls**

68. There is a system in place for the registration of farms and for processors of FNAO, and for the approval of sprout-producing establishments, that enables the CAs to identify FBOs for the purpose of official controls.
69. In line with Article 9(1)(a) and (d) of Regulation (EU) 2017/625, risks associated with the goods are taken into account to establish the frequency of official controls, both by DoA and PHS, which is a good base for the risk-based official controls.
70. Regarding primary production, non-compliances, when identified, were not recorded and, in case of on-the-spot detected risks, no immediate action is taken, thus affecting the official control system and enforcement of the legislation.
71. Regarding processing plants, non-compliances, in particular those with regard to cross-contamination and HACCP, are rarely identified and, when identified, are not always recorded, thus affecting the official control system and enforcement of the legislation.
72. The requirements of Article 5(2) of Regulation (EC) No 2073/2005 regarding environmental sampling for *L. monocytogenes* are not properly enforced and this could lead to an underestimation of this risk.



## 5.4 OFFICIAL SAMPLING PROCEDURES

### Legal Requirements

Articles 34 and 35 of Regulation (EU) 2017/625; Annex I, Chapter 1 of Regulation (EC) No 2073/2005.

### Findings

73. Official sampling of FNAO is carried out based on a guideline on sampling within the framework of a national monitoring plan. Samples for microbiological investigations are also taken in cases of suspicion or outbreaks.
74. During the period 2021-2023, 656 official samples of FNAO were taken and analysed for microbiological investigation.
75. Since 2015, there is a monitoring programme in place for the microbiological investigation of fresh salad vegetables, and fruits from primary production stage. Between 27 and 38 samples were taken per year during the period of 2021-2023 within the scope of the monitoring programme and analysed for *Salmonella* spp. *L. monocytogenes* and *E. coli*. There were no non-compliant samples detected.
76. Regarding processed FNAO, in the interest of this audit, between 60 and 70 samples were taken per year during the period of 2021-2023 (mainly at retail level) within the scope of the monitoring programme and analysed for *Salmonella* spp. and *E. coli*. Between 2021 and 2023, one *Salmonella* contaminated sample was detected (retail level).
77. In 2023, six samples of sprouted seeds were analysed for STEC in a pilot project carried out by the sprout-producing establishment (not approved yet – see paragraph 58) and the SGL.
78. Official samples are analysed for the main foodborne pathogens like *Salmonella* spp., *L. monocytogenes* (qualitative and quantitative analyses) but not routinely for STEC/VTEC (analysis for STEC is carried out on FNAO samples, in which high numbers of *Escherichia coli* have been enumerated, and in some cases of food poisoning investigation). Testing for viruses<sup>(5)</sup> is not yet part of the national monitoring programme because the official laboratory is not yet ready to implement the method.

### Conclusions on official sampling procedures

79. There are detailed procedures in place for official sampling for the microbiological analy-

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<sup>(5)</sup> EFSA – SCIENTIFIC REPORT. Tracing of food items in connection to the multinational hepatitis A virus outbreak in Europe. EFSA Journal 2014; 12(9); 3821;  
Food-borne diseases associated with frozen berries consumption: a historical perspective, European Union, 1983 to 2013. Euro Surveillance. 2015; 20(29);  
Foodborne viruses: Detection, risk assessment, and control options in food processing. International Journal of Food Microbiology 285 (2018) 110 – 128.

sis of FNAO. These support reliable analytical results.

80. However, contrary to the opinion of the scientific community regarding microbiological risks in soft berries, testing for viruses has not been a part of the national monitoring programme.

## 5.5 LABORATORY PERFORMANCE

### Legal Requirements

Articles 5(1)(d), 34 to 42, 100 and 101 of Regulation (EU) 2017/625.

### Findings

81. The evaluation of the laboratory performance is based on a review of documentation and records pertinent to the audit scope, and interviews of and discussions with representatives of the CAs via videoconference. The CAs stated that the laboratories are adequately staffed and that personnel are appropriately trained for the activities performed.
82. Official analyses of FNAO are carried out by SGL, the official government laboratory for chemical, biological/microbiological and toxicological control, under the supervision of the Ministry of Health. SGL is accredited according to EN ISO/IEC 17025:2017 by the Cypriot national accreditation body CYS-CYSAB. The most recent re-accreditation was granted in December 2023.
83. SGL comprises 19 specialised laboratories including the Food Microbiology Laboratory which is the national reference laboratory (NRL) for *L. monocytogenes* and the NRL for coagulase-positive staphylococci. The NRLs for STEC, *Salmonella* spp. and foodborne viruses are part of the Laboratory for Control of Food of Animal Origin, under the supervision of the Ministry of Agriculture, Rural Development and Environment Veterinary Services. The scopes of the NRLs for STEC and for foodborne viruses only cover food of animal origin.
84. The accreditation of SGL covers methods for analyses required for the official control of FNAO in the scope of the audit (detection and enumeration of *L. monocytogenes*, detection of *Salmonella* spp., enumeration of *Bacillus cereus* and *E. coli*). Methods for the detection of STEC are implemented in the laboratory but are not yet performed under accreditation. The STEC method has been verified for sprouts and pre-cut vegetables according to ISO 16140-3 and the laboratory intends to have it fully verified by 2025. The ISO method for the detection of foodborne viruses (Norovirus and Hepatitis A virus) has been introduced but it is not currently fully implemented for routine diagnostic.
85. Analyses are done using mainly standardised CEN/ISO-methods. SGL participated in the food microbial proficiency tests (PT), arranged by the European Reference Laborato-

ry of *L. monocytogenes* (EU-RL *L. monocytogenes*) and commercial providers of PTs, all with satisfactory results.

#### **Conclusion on laboratory performance**

86. There is a laboratory for the microbiological investigation of official samples in place, with the capacity to provide reliable analytical results for the detection of foodborne pathogens relevant for the scope of the audit. However, the lack of accredited methods for STEC and viruses could have an impact on the reliable investigation of FNAO <sup>(6)</sup>.

## **5.6 RAPID ALERT SYSTEM FOR FOOD AND FEED**

### **Legal Requirements**

Article 50 of Regulation (EC) No 178/2002; Article 66(5) of Regulation (EU) 2017/625; Chapter 3, Section I of Regulation (EU) 2019/1715.

### **Findings**

87. The Head of PHS is the national contact point for RASFF. When unsafe foodstuffs are found at regional or local level, information is forwarded to the official in charge of the district, who in turn notifies the Head of PHS. If it is necessary, the Head of PHS notifies other relevant authorities, and conducts a risk assessment as to whether the information should be submitted to the EU via the RASFF platform.
88. In line with Article 50 of Regulation (EC) No 178/2002 on the rapid alert system, responsibilities are defined, and procedures laid down in the relevant guidelines. Also, a communications network has been established for exchanging information between the national contact point and the relevant CAs.
89. The notifications evaluated by the audit team were handled in a correct and timely manner. The CA and inspectors demonstrated how the information was transmitted from the national contact point to the relevant staff. The measures taken included administrative measures, inspections, sampling, traceability actions, withdrawals, recalls, destruction and press releases.

#### **Conclusion on RASFF**

90. There is a comprehensive system in place for dealing with RASFF notifications effectively.

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<sup>(6)</sup> In their response to the draft report CAs explained that, regarding STEC, the fact that the method has been verified for pre-cut vegetables and sprouts supports the reliability of the analytical results in samples of these particular food types. The negative results, that are so far obtained, are in agreement with the absence of any reported clinical STEC incidents in Cyprus during the last years.

## 6 FOLLOW-UP OF FORMER AUDITS OF DG HEALTH AND FOOD SAFETY

91. The table below summarises the follow-up to the relevant recommendations made in report DG(SANTE) 2014/7171-MR Final.

<i>No</i>	<i>Previous</i>	<i>Assessment</i>
1.	Ensure that all establishments (farms) producing food are registered as required by Article 6 of Regulation 852/2004.	<b>Addressed</b> <i>See findings: 28, 29 and 30.</i>
2.	Ensure that potential risks arising at primary production, including at the growing stage, are taken into account in the development of risk-based planning of official controls in line with Article 9(1) of Regulation (EU) 2017/625.	<b>Addressed</b> <i>See findings: 36, 37, 38 and 39.</i>
3	Ensure that CAs responsible for official controls on primary production of FNAO carry these out in accordance with documented procedures, as required by Article 12 of Regulation (EU) 2017/625, which contain information and instruction relevant for the controls performed.	<b>Addressed</b> <i>See findings: 48 and 52.</i>
4	Ensure that official controls of FNAO include the assessment of good farming practices in the field of hygiene as required by Article 14 of Regulation (EU) 2017/625.	<b>Addressed</b> <i>See finding: 51.</i>

### Conclusion on follow-up of former audits of DG Health and Food Safety

92. Good progress was noted in respect of the implementation of the official controls system on FNAO since the previous audit. The action plan to address the four recommendations made in the previous report have been implemented satisfactorily.

## 7 OVERALL CONCLUSIONS

There is a system in place for official controls on FNAO covering all production stages, supported by a monitoring plan and suitable laboratory capability.

Good progress was observed in improving the official controls system since the previous audit, however, its effectiveness is impacted by:

- the existing procedures regarding reporting of non-compliances are not implemented, to the point that official reports portray a situation of compliance, when this is not al-

ways the case;

- incomplete knowledge of inspectors in some control areas, concerning pre-requisites, monitoring and verification in the context of HACCP and requirements related to *L. monocytogenes* in RTE foods.

## **8 CLOSING MEETING**

A closing meeting was held on 19 April with representatives of CAs involved. At this meeting the audit team presented the preliminary findings and conclusions of the audit. These were acknowledged by the representatives of the CAs present at the meeting.

## 9 RECOMMENDATIONS

The competent authority is invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below. With regard to those non-compliances noted in the audit report which did not result in a recommendation being made, the competent authority is, nevertheless, requested to address these. The effectiveness of the actions taken to address such non-compliances will be assessed in future audits on this topic.

No.	Recommendation
1	<p>The competent authorities should provide effective training and technical support (including work instructions), to ensure effective and appropriate official controls, including microbiological risks, as required by Article 5(1)(e)(f) and 5(4) of Regulation (EU) 2017/625.</p> <p><i>Recommendation based on conclusion: 26.</i></p> <p><i>Associated findings: 16 and 20.</i></p>
2	<p>To ensure that official controls of processors, producing ready-to-eat food of non-animal origin, include the effective control of the measures implemented by the food business operators to reduce the risk associated with <i>Listeria monocytogenes</i>, as required by Article 5(2) of Regulation (EC) No 2073/2005.</p> <p><i>Recommendation based on conclusion: 72.</i></p> <p><i>Associated finding: 61.</i></p>
3	<p>To ensure that following identification of non-compliances, appropriate measures are taken to ensure that the operator concerned remediates the non-compliance and prevents further cases of such non-compliance, as required by Articles 137 and 138 of Regulation (EU) 2017/625.</p> <p><i>Recommendation based on conclusions: 70 and 71.</i></p> <p><i>Associated findings: 56, 57 and 63.</i></p>
4	<p>To implement the existing procedures to verify the effectiveness and appropriateness of official controls, ensuring that inspection reports provide evidence of both adequacy and quality of those controls, in accordance with Articles 5(1) and 13 of Regulation (EU) 2017/625.</p> <p><i>Recommendation based on conclusions: 27, 70 and 71.</i></p> <p><i>Associated findings: 23, 24, 53 and 62.</i></p>

The competent authority's response to the recommendations can be found at:

[http://ec.europa.eu/food/audits-analysis/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2024-8038](http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2024-8038)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 210/2013	OJ L 68, 12.3.2013 p. 24 – 25	Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council.
Reg. 2017/625	OJ L 95, 7.4.2017 p. 1 – 142	Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation).
Reg. 2019/1715	OJ L 261, 14.10.2019 p. 37 – 96	Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components.
Reg. 178/2002	OJ L 31, 1.2.2002 p. 1 – 24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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.
Reg. 852/2004	OJ L 139, 30.4.2004 p. 1, Corrected and re-	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
	published in OJ L 226, 25.6.2004, p. 3	April 2004 on the hygiene of foodstuffs.
Reg. 208/2013	OJ L 68, 12.3.2013 p. 16 – 18	Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts.
Reg. 2020/2235	OJ L 442, 30.12.2020 p. 1 – 409	Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC.
Reg. 2073/2005	OJ L 338, 22.12.2005 p. 1 – 26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.