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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
SWEDEN
FROM 18 SEPTEMBER 2018 TO 27 SEPTEMBER 2018
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 a DG Health and Food Safety audit in Sweden which took place from 18 September to 27 September 2018 under the provisions of Regulation (EC) No 882/2004 of the European Parliament and the Council of 29 April 2004.

The objectives of the audit were to assess:

- *the system of official controls in the area of food hygiene to prevent microbiological contamination in the production of food of non-animal origin, notably as frozen products and sprouts and seeds intended for sprouting;*
- *the extent to which the corrective actions submitted to the Commission services in response to the recommendations of the previous Directorate-General for Health and Food Safety audit report of 2015 have been implemented and their effectiveness in addressing the identified shortcomings.*

Overall, a risk-based control system for official controls on food of non-animal origin is in place. There is a system for registering primary producers and for the approval of sprout-producing establishments. This facilitates the implementation of a risk-based approach to official controls including microbial risks associated with food of non-animal origin.

Regarding official samples, the appropriate laboratory capability and capacity is available.

Significant shortcomings were identified in relation to the registration of food business operators and approval of sprout-producing establishments. The approval system does not ensure that non-compliances have been rectified before that approval is granted. In addition, the official control system presents a number of gaps, notably related to provision of specific instructions, technical support and staff training. As a result, official controls cannot be implemented correctly and effectively, resulting in poor controls. This impacts on the enforcement, where non-compliances are hardly detected and when detected are rarely followed-up. A number of these shortcomings were equally reflected in the outcome of an internal audit performed by the Central Competent Authority in June 2018, and which found little corrective action since the previous internal audit, in 2014.

Thus, non-compliant products might be undetected and the correct application of the relevant legislation might not be enforced, resulting in placing on the market of non-compliant products which may present a health risk.

In respect of the follow-up to the previous audit, certain actions have not been effective in addressing the identified shortcomings. Overall, the audit had to conclude that there has been limited improvement compared to what was found previously.

The report makes recommendations to the competent authorities aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CA(s)	Competent Authority(ies)
CAB(s)	County Administrative Board(s)
CCA(s)	Central Competent Authority(ies)
CCP	Critical Control Point
DG Health and Food Safety	Directorate-General for Health and Food Safety of the European Commission
EFSA	European Food Safety Authority
EU	European Union
EURL	European Union Reference Laboratory
E. coli	*Escherichia coli*
FBO(s)	Food Business Operator(s)
FNAO	Food of Non Animal Origin
GAP	Good Agriculture Practices
HACCP	Hazard Analysis and Critical Control Points
ISO	International Organisation for Standardization
LIMS	Laboratory Information Management System
MANCP	Multi Annual National Control Plan
MEI	Ministry of Enterprise and Innovation
MUP(s)	Municipal Authority(ies)
NFA	National Food Agency
NRL	National Reference Laboratory
RASFF	Rapid Alert System for Food and Feed
STEC	Shigatoxin Producing *Escherichia coli*
VTEC	Verocytotoxin Producing *Escherichia coli*

1 INTRODUCTION

The audit took place in Sweden from 18 September to 27 September 2018 as part of the Directorate-General for Health and Food Safety (DG Health and Food Safety) planned work programme. The audit team comprised two auditors from DG Health and Food Safety and one national expert.

Representatives from the central competent authority (CCA) the National Food Agency (NFA) accompanied the audit team for the duration of the audit. An opening meeting was held on 18 September 2018 with the CCA and competent authorities (CAs). At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit team and the control system was described by the authorities.

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);
- Evaluate the system of official controls in the area of traceability of sprouts and seeds intended for sprouting, including applicable microbiological criteria, the approval of sprout-producing establishments and import controls;
- Verify the extent to which the guarantees and the corrective actions submitted to the Commission services in response to the recommendations of previous DG Health and Food Safety audit report of 2015[1] on the same subject have been implemented and enforced by the CAs.

In terms of scope, the audit reviewed the official controls for food hygiene to prevent microbiological contamination in primary production of FNAO, including seeds intended for sprouting and sprouts. The audit reviewed planning and implementation of official controls, control procedures and sampling performance.

The implementation of official controls over FBO obligations included: cultivation of fruit and vegetables (consumed raw), frozen vegetables, cultivation of seeds for sprouting (if applicable), sprout-producing establishments, internet sales of sprouts and seeds for sprouting, retailers and importers of seeds for sprouting, and the handling of non-conforming products.

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

Audit visits and meetings

Visits / meetings	Comments
Competent Authorities	

[1] Ref. DG(SANTE)/2015-7459–MR–FINAL, published on the Commission's website at: http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3657.

Central	2	Opening and closing meeting with representatives of CCA and CAs
Regional	2	County Administrative Boards (CABs) in the regions visited
Local	2	Municipal authority (MUP) inspectors
Laboratories		
Public	1	NFA laboratory
Establishments		
Soft Fruit	2	1 raspberry producer 1 strawberry producer
Leafy Green Vegetable	1	Large scale farm with outdoor production
Processor Frozen Vegetables	2	1 frozen berry processor 1 frozen green vegetables processor
Sprout-producing Establishments	3	Approved establishments
Importer of seeds for sprouting	1	Importer and sprout-producing establishment
Internet sellers	2	Registered sellers of seeds for sprouting

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation, in particular Article 45 of Regulation (EC) No 882/2004.

A full list of the EU legal instruments relevant to the scope of this audit is provided in Annex I to this report. Legal acts quoted refer, where applicable, to the last amended version.

4 BACKGROUND

The European Food Safety Authority (EFSA) adopted scientific opinions on the risk posed by FNAO which may be viewed at: http://www.efsa.europa.eu/en/publications/efsajournal.htm.

EFSA noted that FNAO is consumed in a variety of forms, and is a major component of almost all meals. These food types have the potential of being associated with large outbreaks, as seen in 2011, with the Verocytotoxin-producing *Escherichia coli* (VTEC) O104. A comparison of the incidence of human cases linked to consumption of FNAO and of food of animal origin was carried out to provide an indication of the relative incidence between these two groups of foods. Using data from 2007 to 2011, FNAO was associated with 10% of outbreaks, 26% of cases, 35% of hospitalisations and 46% of deaths. If the data from the 2011 VTEC O104 outbreak is excluded, FNAO was associated with 10% of outbreaks, 18% of cases, but only 8% of hospitalisations and 5% of deaths.

The top ranking food/pathogen combinations were:

• leafy greens eaten raw as salads/*Salmonella spp.* and norovirus;

• bulb and stem vegetables; tomatoes; melons; sprouts/*Salmonella spp.;*

• fresh pods, legumes or grains/pathogenic *Escherichia (E.) coli*.

EFSA adopted several scientific opinions on the public health risk posed by pathogens that may contaminate FNAO. In general, as regards specific mitigating options to reduce the risk for humans posed by pathogens in FNAO, EFSA concluded that: appropriate implementation of food safety management systems including Good Agricultural Practices (GAP), Good Hygiene Practice and Good Manufacturing Practice should be the primary objective of operators producing the relevant crops. These food safety management systems should be implemented along the farm to fork continuum and should aim at the control of a range of microbiological hazards.

The risk factors for the contamination of the crops assessed at primary production with different pathogens at growing stages are likely to include the following:

- Environmental factors, in particular climatic conditions (e.g. heavy rainfall) which may increase the transfer of pathogens from sewage or sewage effluents to irrigation water sources or fields.
- Use of untreated or insufficiently treated manure or compost. Use of sewage-contaminated agricultural water, either for irrigation or for application of agricultural chemicals such as fungicides.
- Contact with animal reservoirs (domestic or wild) gaining access to fields.
- Contamination and cross-contamination by harvesters, food handlers and equipment at harvest or post-harvest.

EFSA adopted a scientific opinion on the risk posed by Shiga toxin-producing *E coli* (STEC) and other pathogenic bacteria in seeds and sprouts, after the outbreaks of STEC in May 2011 in the EU. The EFSA report can be found at:

http://www.efsa.europa.eu/en/efsajournal/pub/2424.htm

Consumption of sprouts was identified as the most likely origin of the May 2011 outbreaks. Over 4,000 human cases were reported and 55 people died. In its opinion EFSA concluded that the contamination of seeds with bacterial pathogens was the most likely initial source of sprout associated outbreaks. Due to the high humidity and the favourable temperature during sprouting, bacterial pathogens present on dry seeds can multiply on the sprouts.

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

5 FINDINGS AND CONCLUSIONS

5.1 RELEVANT NATIONAL LEGISLATION

Legal requirements

Article 291 of the Treaty on the Functioning of the EU.

Findings

1. The national legislation in place in relation to the implementation of the EU provisions in the scope of this audit is:

   - LIVSFS 2005:20: Regulations on the hygiene of foodstuffs that lays down details about hygiene, registration and approval of FBOs;
   - Livsmedelsförordning (2006:813) The Food Ordinance, concerning the designation of CAs for registration, approval and official controls;
   - LIVSFSF 2005:21 The Food Administration's regulations on public food inspection, concerning official control of food;
   - Livsmedelslag 2006:804: the food act that complements the EU food law and lays down provisions on infringements and sanctions.

2. The NFA has a working group to develop and update national guidelines for FBOs and CAs. A national guide on GAP for safe production of field vegetables and berries is published. The guide was presented to the audit team. It includes requirements to prevent microbiological contamination at primary production.

3. National guides to good hygiene practices are reported to the Commission.

Conclusions on Relevant National Legislation and Guidelines

4. National legislation is in place in line with relevant EU legislation and a National Guide for GAP is available, addressing the prevention of risks of microbiological contamination in FNAO.

5.2 Organisation and Implementation of Official Controls

5.2.1 Designation of CAs and Resources for Official Control

Legal requirements

Article 4(1) of Regulation (EC) No 882/2004.

Findings

5. An overview of how control systems are organised in Sweden (based on information supplied by the CCA) is provided in the Country Profile: http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=SE

6. The NFA, which report to the Ministry of Enterprise and Innovation (MEI), is the CCA for official food control including primary production of FNAO at harvest and pre-harvest stage. The National Reference Laboratory (NRL) for food is part of NFA.

7. The NFA tasks are to issue regulations, instructions and guidelines on how official controls should be conducted, establishing the Multi Annual National Control Plan (MANCP), and developing risk classification systems. NFA is the contact point for RASFF.

8. Furthermore, the NFA co-ordinates the official control system, conducts risk assessments and compiles the annual reports on food controls from the CAs.

9. The NFA provides e-learning courses for different legislative areas for CAs and FBOs. Training is also organised on request or in combination with joint national control projects. However, NFA informed the audit team that no specific training on requirements applicable to sprouts and seeds for sprouting has been organised in the last five years. The inspectors met during the visits confirmed that they had not received specific training on sprouts and seeds for sprouting.

10. The 21 CABs which report to the MEI are the regional CAs and are responsible for official controls of FBOs in primary production of FNAO at harvest and pre-harvest stage, including sprout-producing establishments. The 260 MUPs which are independent authorities are the local CAs and are responsible for control of FBO of FNAO in all steps of production after primary production, including control of retailers, internet sales and importers. If a sprout-producing establishment is importing seeds for sprouting, the control of this activity falls under the responsibility of the CAB. NFA, which is reporting to the MEI, leads coordinates and follow up the official control of food at national, regional and local level. NFA issue regulations and guidelines for the official control at all levels. Results from the official controls performed are reported to NFA.

11. Each CA is responsible for ensuring that the authority has a sufficient number of qualified and trained staff, facilities, equipment and documented procedures available to be able to perform official controls according to the requirements in Regulation (EC) No 882/2004.

12. During the field visits, it was stated by most of the CAs, that staff shortage prevents them from following-up non-compliances in a timely manner (see point 37).

Conclusions on Designation of CAs and Resources for Official Control

13. CAs in the context of this audit are designated. However, their role in providing specific training and ensuring sufficient number of qualified staff was not fulfilled, thus weakening the system of official controls.

5.2.2 Registration / Approval of Food Establishments

Legal requirements

Article 6 of Regulation (EC) No 852/204, Article 2 of Regulation (EU) No 210/2013 and Article 31 of Regulation (EC) No 882/2004

Findings

5.2.2.1 Registration of Primary Producers / Food Establishments

14. The CABs are responsible for the registration of primary producers. The MUPs are responsible for all other FBOs. A guidance document for registration of FBOs has been prepared by the NFA.

15. No derogation of direct supply, by the producer, of small quantities of primary products as described in Article 1 of Regulation (EC) No 852/2004 is foreseen for FNAO.

16. PRIMÖR is the national electronic system for the registration of all primary producers including FNAO and sprout-producing establishments. All CABs have access to the system. The primary producers are obliged to provide information relating to the produce being produced, the volume of production and the main activity within primary production and sub activities at the time of registration. The primary producer may also give additional information about third party certification schemes used and approval or certification according to these systems. This information is part of the risk assessment for the planning and implementation of official controls.

17. From the data obtained by NFA from the CABs, in 2017 there were 1,371 primary producers of FNAO registered in PRIMÖR, in the scope of this audit. At CAB level it is estimated that 13.5% of all primary producers are not registered yet, including primary producers of FNAO. The CABs stated that mainly small producers are not registered. The NFA informed the audit team that missing registrations are caused by uncertainty of the CABs which primary producers would need to be registered or not. Therefore, NFA plans to improve current guidance regarding registration of primary producers and make it more detailed.

18. There is no national register for FNAO food establishments after the primary production level. The MUPs have own register and registration forms. These are based on the requirements of the national legislation.

19. The NFA confirmed that internet sellers of seeds for sprouting and garden centres selling seeds for sprouting are obliged to be registered as FBOs. The NFA has made an investigation regarding current registrations at the level of MUP. Currently 21 out of 26 identified sellers of seeds for sprouting are registered.

5.2.2.2 Approval of Sprout-Producing Establishments

20. According to the information provided by the NFA, at the time of the audit, there were five sprout producing establishments located in two different regions. All five have been approved, listed and published on the NFA website.

21. The CABs are the responsible CAs for approval of sprout-producing establishments. The procedure starts with receiving an application for approval, which is followed by an inspection. If the FBO complies with the requirements of Regulation (EC) No 852/2004, Annex I and Regulation (EU) No 210/2013, a preliminary approval for three months is issued to the sprout-producing establishment.

22. Based on their procedures, the CABs have to perform a physical inspection on the requirements quoted above before giving an approval.

23. The audit team verified the approval files of the five sprout-producing establishments and noticed that one FBO produced three months without approval until the definite approval was granted, and with the preliminary approval having expired (see point 68). Three out of the five establishments were visited by the audit team. In two cases out the three visited, the approvals were granted even when several non-compliances were not yet corrected since previous controls.

Conclusions on Registration of Food Establishments and Approval of Sprouting Establishments

24. Procedures are in place for the registration of primary producers in a national electronic database at CAB level and for the registration of all other food establishments at MUP level. However, by estimation on a national level, at least 13.5% of primary producers, including FNAO, are not registered and not all garden centres selling seeds for sprouting are registered yet. Thus, not all FBOs are under official controls.

25. There is a system in place for approval of sprouting establishments aimed at ensuring that applicant FBO met the relevant regulations, but this system does not ensure that non-compliances has been rectified before that approval is granted.

5.2.3 Organisation and Scope of Official Controls

Legal requirements

Article 17 of Regulation (EC) No 178/2002 and Articles 3 of Regulation (EC) No 882/2004

Findings

26. The system of official controls in FNAO is described in the MANCP. The current version covers the period 2018-2021 (www.nkpwebben.se).

27. NFA introduced a risk categorisation which consists of two systems, one for primary production, the second for FBOs after primary production. Both systems take into account the risks and other relevant factors associated with different types of produce.

5.2.3.1 Primary Producers – Cultivation and Sprout-Producing Establishments

28. The table below shows the official controls performed in 2016 and 2017 regarding primary production of FNAO in the scope of the audit (and 2018 for sprout-producing establishments). From 2016 to 2017 the number of controls was increased.

Table 1: *Primary Producers of FNAO and Official Controls data*

Year	Establishments	PP of FNAO intended to be eaten raw	Nr of Inspections carried out	Nr of official samples taken	Nr of non-compliant samples
2016	FNAO Primary Producers	1.163	36	1	0
	Sprout-producing establishments	4	1	0	0
2017	FNAO Primary Producers	1.371	66	2	0
	Sprout-producing establishments	4	2	0	0
2018	Sprout-producing establishments	5	3	1	0

29. The NFA has introduced a system for the risk classification of FBOs and the

prioritisation, planning and selection of controls. It is a point-based system, which consists of a priority module and an experience module. The priority module takes into account the significant risks in each sector of primary production, the total production volume per sector and the producers' possibility to reduce or minimise the risks in primary production in comparison with the possibility to risk reduction in later stages in food chain.

30. The priority module divides the 28 sectors of primary production in four priority classes, where 1 is high risk and 4 is low risk. Outdoor production of leafy green vegetables and indoor / outdoor production of berries are placed respectively in priority class 1 and 2. Sprout-producing establishments are in priority class 3: however, if an effective process for decontamination of seeds in in place (see *paragraph 5.2.4.3*), the risk is lowered to priority class 4.

31. The experience module takes into account if primary producers implement a private quality assurance system assessed by the NFA and the Swedish Board of Agriculture. The control priority for these FBOs is lower compared to FBOs who do not have an assessed quality assurance system.

32. The priority module and experience module is combined in a priority-experience matrix which is used both for classification the FBOs and for prioritisation and planning of the control. The system takes into account the CAs' experiences from previous controls. On a national basis, the majority of the FBOs selected for controls shall be in the highest category. Based on experiences from previous controls, the CA can adjust the classification and reduce or increase the control priority of a unique FBO. The CA can also adjust the control priority for a sector, based on regional variations and experiences from previous controls of FBOs within the sector.

33. The system of risk categorisation for primary production is integrated in PRIMÖR which is used for the control planning by the CAs. The PRIMÖR database can either randomly select the establishments to be inspected or a manual selection can be done by CABs. The audit team observed, however, that CABs are autonomous when they plan their control priorities. In one of the CAB visited, the audit team noted that the inspection plan was drawn up by using the specific FBO production volume as a corrective criterion and only big glass-house producers were inspected despite the fact that their risk ranking was lower than other producers which have not been chosen for official controls (e.g. outdoor leafy green producers).

34. The control category is not directly related to the inspection frequency. NFA informed the audit team that not all sectors must be controlled each year, but establishments in all sectors must be controlled over a five-year-period. Each CAB must have a multi-annual planning covering all sectors relevant in the county. Regular follow-ups are needed to ensure that the plan is followed.

35. However, NFA informed the audit team that in August 2018 a new project started with the purpose to develop and implement a model for prioritisation and planning at national level instead of at regional level. This will be implemented in the next

MANCP. The frequency for official controls will be then established at central level. It's a joint project between NFA, Swedish Board of Agriculture and the CABs. It should result in a multiannual control planning defining the control frequents for each sector in primary production. Thus, the control should be more effectively and equal and the prioritisation will be the same in all CABs.

36. The table below shows the controls done in 2017 in the four CABs visited. The audit team noted that the available data for 2018 showed a higher number of official controls (19 planned and 15 implemented). However, the percentage of non-compliances did not change from 2017 to 2018. Generally, non-compliances were mainly related to staff hygiene procedures.

Table 2: *Data regarding Official Controls in the CABs visited*

CABs Visited	Nº of FBOs Registered	Nº of Controls in 2017				
		Planned	Implemented	Not Planned	Total	With Non-Compliances
1	149	7	6	5	11	4
2	26	0	0	0	0	-
3	6	1	1	0	1	0
4	35	3	0	0	0	-

Table includes FBOs with main production of soft berries or leafy green vegetables (in and outdoor)

37. Regarding farms, the CABs informed the audit team that, due to staff shortages, no follow up took place yet for the non-compliances from 2017 and 2018. However, no action plan or other evidence related to the correction of the deficiencies has been requested from the FBOs by the CABs. The NFA informed the audit team that this lack on follow-up could affect the effectiveness of the official controls.

5.2.3.2 Control of Importers of Seeds for Sprouting

38. FBOs who import seeds for sprouting must, as well as FBOs who import FNAO in general, register their establishment at the MUPs. The FBOs are placed in a risk class depending on their activities, the type of product, labelling, inspection history and assessment from the local authority. The NFA informed the audit team that NFA has no information if inspections of importers within the scope of this audit have been performed in the last three years, since importers are not defined as a unique type of establishment in the reporting system.

39. The NFA informed the audit team that it has no knowledge of the number of importers in Sweden since these FBOs are reported by the MUP's to the NFA under the general categories "Warehousing and distribution and Wholesale".

5.2.3.3 Control of Food Business Operators after Primary Production

40. MUPs are responsible for these controls. The current system for risk classification of FBOs after primary production consists of a risk module, an experience module and an information module. It is a point-based system, which focuses on microbiological risks related to the activities in the establishment.

41. According to the risk module, freezing of vegetables and berries are ranked as a low risk. The experience module takes into account the results from previous controls, the need to control labelling and traceability. The system also takes into account the size of the establishment and the amount of food produced. All of these factors generate a score which defines the number of hours for official control. The CA then converts the resulting hours into the control frequency. More risky or complex activities will add up to more hours for performing controls. Inspection frequency varies from yearly to every third year.

Conclusions on Organisation and Scope of Official Controls

42. There is an official control system in place covering primary production, supported by relevant IT tools for assessing risks and for the associated planning of controls, in compliance with the provisions of Article 3(1) of Regulation (EC) No 882/2004. However, the lack of follow-up undermines the effectiveness of the official controls.

43. Based on the risk assessment and guidance at national level issued by the NFA, each CAB plans the specific controls based on their own risk assessment relevant for the operators in their region and the crops grown. The fact that CABs can introduce corrective factors could leave out higher risk classified FBOs from official controls thus weakening the efficiency of the official control system.

5.2.4 Implementation of Official Controls over FBO's Obligations

Legal requirements

Article 10(2)(b)(i), 10(2)(c) and 10(2)(d), and Article 15(1) of Regulation (EC) No 882/2004, Articles 4, Article 5, Article 6, Article 7, Article 8, Annex I and Annex 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) No 211/2013, Article 1 and Annex I of Regulation (EC) No 2073/2005

Findings

5.2.4.1 Cultivation

44. The audit team observed three inspections of primary producers of FNAO in two different CABs. A leafy green vegetable and two soft berry producers have been visited. All three were third part certified and two of them in the last three years were already inspected in the scope of this audit with minor non-compliances not related to the scope of this audit. One out of the three producers performed regular microbiological analytical tests on irrigation water and on finished produce.

45. All inspections included a number of factors for preventing microbiological risks in

FNAO. During such inspections the inspectors used NFA guidelines and a generic checklist. The inspection focussed on documentary checks and field visits. All key elements relating to microbial risks were addressed and, where possible, checked adequately on the field and included, health status of workers, staff hygiene in food handling, hygiene facilities (field toilets, hand washing), availability of instructions in the relevant languages for the staff, prevention of wild animals to enter fields, irrigation water, use of chemical and organic fertilisers and sampling and analysis of final products. The inspectors also described how they would undertake a traceability exercise at such an establishment.

46. At the CABs visited some inspectors stated that they take into account the reports from private certification bodies during their controls. However, there is no evidence of such statement in the reports and the checklists do not contain points related to this aspect.

47. The NFA informed the audit team of a study project on irrigation water: "Contamination of ready to eat vegetables contaminated with irrigation water – risk-based guidelines and consensus in the surveillance." The project was financed by the Swedish Civil Contingencies Agency and was performed in 2015-2017.

48. The purpose of the project was to gather knowledge on microbiological risks and quality of irrigation water used in the cultivation of berries and ready to eat vegetables. During the project, samples were taken at different water sources and irrigation systems at 20 different primary products. Analyses were done for E. *coli*, STEC, *Salmonella*, *Campylobacter* and *Clostridium perfringens*.

49. The NFA guidelines underline that in case of production, harvesting and packaging of primary products, potable water or clean water shall be used where appropriate in order to avoid contamination of food.

50. In line with NFA's guidelines and national guidelines for good hygiene practices, the farms need a water risk analysis in order to identity hazards, minimise and prevent the risk for contamination of the products and equipment. Origin of the water, condition of use (type of irrigation and crops) and justification of the presence or absence of a sampling plan have to be indicated in their risk assessment.

51. For the risk assessment, when a drip irrigation system is used, the CABs do not require specific microbiological tests, regardless of the origin of the water. Whereas, in case of an overhead water sprinkler system, microbiological analyses are required. However, inspectors and NFA did not clarify based on which microbiological parameters the quality of irrigation water was assessed[2].

52. At one CAB visited, for the water risk assessment the inspectors informed the audit team that the microbiological parameters settled in the European guidelines for primary production of FNAO[3] are used.

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[2] In their response to the draft report the Competent Authority noted that regarding use of potable water, the microbiological criteria in the national legislation LIVSFS 2001:30 are recommended to be used, according to NFA:s guidelines.

[3] Commission notice on guidance document on addressing microbiological risks in fresh fruits and vegetables

53. At one leafy green vegetable farm visited, an overhead sprinkler irrigation system with water from ten different wells was used. The FBO tested the water supply for microbiological parameters every year as part of the third party certification scheme. On the other hand, the two soft-berries growers that used a drip irrigation system and took the water either from an open basin or from a river did not test water for microbiological parameters.

54. The NFA and the CABs informed the audit team that regarding irrigation water, both FBOs are in compliance with the recommendations in NFA guidelines and the national guide to good hygiene practices.

55. However, during the field visit to the strawberries grower, in addition to the drip irrigation system, the inspectors noticed the use of an overhead water sprinkler system to temper the temperature during hot days. For this operation the FBO stated that water from a well (70m deep) is used.

56. For this well there was no risk assessment in place which is not in line with the recommendations in NFA guidelines. This non-compliance was noticed by the CAB which will require regular microbiological analyses and a new water risk assessment.

57. During the field visits to the leafy green vegetable grower, the inspectors noticed deficiencies regarding the cleaning of the field toilet and the fact that hand-washing facilities were not available in the field.

58. During the field visits to the strawberries grower, field toilets were not available. The FBO explained to the inspectors that due to the fact that the picking season was almost over, field toilets were no longer in place.

59. However, in the previous official control none of these non-compliances have been reported by the official reports. In addition, the use of generic checklists does not help inspectors in performing official controls and does not help inspectors in identifying which point have been checked during the previous inspection.

60. The NFA informed the audit team that such generic checklists in primary production of FNAO are the same all over Sweden.

5.2.4.2 Sprout-Producing Establishments

61. Inspections of sprout producing establishments are performed by CAB inspectors. The reports from previous inspections were available and the checklists used were attached to the reports.

62. Regarding the preliminary tests for the seeds for sprouting, according to Regulation (EU) No 2073/2005, Annex I, Chapter 3, point 3.3 (A), the NFA in their guidelines[4] introduced an alternative method for these preliminary tests, involving 60 sub-samples of 50g each per 3kg in total.

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at primary production through good hygiene. 2017/C 163/01.

[4] Guidelines on provisions applicable to sampling, traceability requirements and certification for the purpose of official controls of sprout-producing establishments.

63. The method is considered by the NFA statistically equivalent to the one in the Regulation due to the fact that it is based on an obsolete legislative proposal – SANCO/10038/2012 r1bis – before the new set of legislation on sprout testing was introduced.

64. The audit team underlined that NFA's arguments are very weak considering that the sample size (3kg) indicated in this obsolete proposal was refused and decided to be modified as it is in the actual regulation. In addition, the idea to take 50g per bag (considering the normal size of a bag of seeds for sprouting, 20/25kg), reduce the possibility to have a stratified sampling and the chance to miss a pathogen inside the bag during the sampling procedure itself could be high.

65. The NFA informed the audit team that based on its guidelines[3], a sprout-producing establishment could apply for the derogation of sampling and analysing, according to Regulation (EC) No 2073/2005 (see *paragraph 5.2.4.3*).

66. The NFA informed the audit team that, currently, the five approved sprout-producing establishments in Sweden have a decontamination step for the seeds before sprouting and two of them have been granted the derogation (see point 65).

67. In two different CABs the audit team observed three inspections at three different sprout-producing establishments. The inspectors informed the audit team that one of them has been granted the derogation (see points 65 and 70).

68. One sprout-producing establishment visited imported seeds for sprouting. This FBO received a conditional approval from 27/04/2016 valid for three months. It was inspected almost six months later and received a final approval on 14/10/2016 with several non-compliances still open. On 11/05/2017 the FBO received a re-approval due to a major change. The packing line had been moved to another facility. The last inspection dated 30/08/2018. Moreover, between 26/07/2016 and 14/10/2016 the FBO continued the activity without a valid approval. The CAB justified this gap with a lack of resources to perform official controls.

69. The second sprout-producing establishment visited was approved in line with the CAB procedure in 2015 and underwent official controls on 03/02/2017, 13/06/2017 and 29/09/2017. At the time of the audit only European seeds for sprouting were used.

70. The third sprout-producing establishment sprouts only seeds from third countries. The NFA informed the audit team that for this FBO the CAB has granted a derogation of sampling according to Regulation (EC) 2073/2005 in line with NFA guidelines (*see paragraph 5.2.4.3*). In this CAB, the control frequency for such establishments was established as every second year.

71. This last FBO was first inspected for approval on 1/09/2015 when the inspectors required additional information concerning procedures (cleaning, decontamination of the seeds) and addressed several non-compliances. After receiving the required information the CAB issued a conditional approval on 17/09/2015, valid for three months. This conditional approval was based on the documentation received without an onsite visit.

72. On 11/12/2015 the CAB granted a final approval to this FBO after an inspection with no non-compliances. The approval included the derogation on preliminary tests of seeds for sprouting based on Regulation (EC) No 2073/2005 and on guidelines of NFA (*see paragraph 5.2.4.3*). No non-compliances were noticed by the CAB at this time. However, the CAB inspectors did not provide evidence regarding how derogation has been granted to the FBO.

73. On 12/04/2017 this FBO received its last inspection from the CAB. No non-compliances were noticed by the inspectors. The FBO received a new approval due to a change in the company name on 5/09/2018 without inspection (done at the office).

74. A detailed checklist based on Regulation Nos (EU) 208/2013, 210/2013, 211/2013 and (EC) 2073/2005 in order to facilitate the official control was available in one CAB and used by the inspectors. Whereas, in the other CAB a generic checklist, the same used for farms, was in place and non-compliances regarding specific aspects of sprout production noticed during inspections cannot be reported in such a checklist. The inspectors admitted that this checklist could not guide or help in performing official controls at sprout-producing establishments.

75. In the two sprout-producing establishments visited that operated without the derogation the sampling procedure for the preliminary tests of seeds for sprouting was in line with NFA Guidelines, 60 sub-samples of 50g each for a final 3kg of seeds to be tested and regularly preliminary tests for the seeds were available since the end of 2017 as well as the monthly tests of the finished product as required by Regulation (EC) No 2073/2005.

76. One FBO explained to the official inspectors and to the audit team that preliminary testing of batches of seeds of small varieties (limited quantities) are done as a mixture in order to limit the costs and keep the production of small varieties profitable. However, the CAB concluded that this procedure was not in line with their provisions (EU legislation and NFA guidelines[3]).

77. During the three on-site visits, non-compliances concerning structure and hygiene have been partly noticed by the inspectors. By checking the inspection history in the reports, the audit team noticed that in two cases out of the three, many of these non-compliances were detected earlier but still are recurrent, even if follow-up inspections were performed. The inspectors did not provide an explication.

78. During the visits the audit team and the inspectors observed examples of potential direct contamination of seeds and sprouts: a worker who handled the bags touched the seeds already decontaminated without cleaning his hands or changing his gloves. The same worker touched the bottom of the container, which had contact with the floor without cleaning his hands. Condensation dripping directly on the sprouts, no protection for windows was in place; seeds in open bags in the storage, cleaning machinery and chemicals close to the open seed bags.

79. In addition, during the third visit, the audit team noticed several non-conformities that were not otherwise detected by the CAB, regarding cleaning and structures (e.g. broken floor tiles, dusty surfaces, doors not effective against pests or rodents, unidentified

seeds in production).

80. Despite the fact that during the shadow visits non-compliances have been noticed by the inspectors, no immediate actions have been taken by these inspectors to prevent direct contamination of the sprouts.

81. In addition, during the visit at the two FBO that used imported seeds, the inspectors did not notice the absence of valid import certificates for seeds from third countries according to Regulation (EC) 211/2013. One FBO imports regularly seeds (four times per year) from third countries and no valid import certificates were made available to the audit team. Moreover, the phytosanitary certificate explicitly mentions that such seeds were not intended for sprouting.

82. Inspectors from the CABs accepted all certificates provided by the FBO (phytosanitary certificates, organic farming certifications) without making a correct assessment. The inspectors explained to the audit team that, due to a lack of training they were not aware of the requirements of the certificate as required by the Regulation.

83. The fact that there had not been a valid import certificate to date for the imported consignments was not noticed by the CAB inspectors.

84. The official representing the NFA informed the audit team that they not know how a valid import certificate in line with Regulation (EU) No 211/2013 should look.

5.2.4.3 Decontamination of Seeds for Sprouting

85. According to the NFA, thermal decontamination (pasteurisation) of the seeds is considered to be an effective treatment to manage microbiological risks, and in particular to eliminate *Salmonella* and STEC. This is based on a study published by Bari *et al.*[5]

86. However, this study concluded that the thermal decontamination (treatment by soaking seeds in hot water at 85 °C for 10 to 40 seconds) reduce the bacterial load in a range of two to 3.7 log10 cycles but it is not a method to get completely sterile or pathogen-free seeds.

87. NFA informed the audit team that based on its guidelines, a FBO could apply for the derogation of sampling and analysing, according to Regulation (EC) No 2073/2005 provided that the FBO has in place:
    - a decontamination procedure of the seeds before sprouting;
    - a satisfactory quality assurance plan based on hazard analysis and critical control points (HACCP) principles and;
    - six months of satisfactory preliminary tests of seeds done in line with Regulation (EC) No 2073/2005.

88. The NFA informed the audit team that FBOs that were granted the derogation must, as verification of the effectiveness of the decontamination process, test the sprouts for *Salmonella* and *E.coli* at least once a month. STEC analysis is not obligatory. The

[5] Bari *et al*., *Journal of Food Protection*, **73**, 752-757.

monthly frequency for sprout analyses is still compulsory. These FBOs could also reduce the frequency of the preliminary test of seeds according to Regulation (EC) No 2073/2005.

89. The NFA explained to the team that this derogation applies to:
    - the preliminary tests of seed for sprouting as stated in Regulation (EU) No 2073/2005, Annex I, Chapter 3 (3.3) (B) and;
    - to the analytical parameters for the produced sprouts as described in Regulation (EU) No 2073/2005, Annex I, Chapter 1, footnote 23. In particular, under this derogation, sprouts only need to be tested for *Salmonella spp* and *E. coli*. There is no need to test for STEC.

90. The NFA explained to the audit team that according to the definition of sprouts, the seed is a natural part of the sprout. Therefore, NFA interpreted footnote 23 of Annex I to Regulation (EC) No 2073/2005[6] as meaning that the microbiological criteria for sprouts do not apply to seeds that undergo pasteurisation or chemical decontamination before sprouting. This is on condition that the pasteurisation or decontamination eliminates *Salmonella spp*. and STEC effectively, and the food business operator has methods for checking and verifying that the process has the intended effect. The CAB also has to grant its approval for a business to be allowed to apply the exemption from the microbiological criteria as specified in footnote 23 of the above Regulation.

91. The audit team pointed out that footnote 23 applies to sprouts that have received an effective treatment to eliminate *Salmonella* and STEC, and not to the seeds. Moreover, there are big differences for the detection of STEC according to ISO/TS 13136 and *E. coli*, mainly in the sensitivity of the method (detection of STEC is performed with a combined cultural and molecular based method and the detection/enumeration of *E. coli* with a cultural based method).

92. The NFA explained to the audit team that the sprout-producing establishment must have in place:
    - relevant background information;
    - documented procedure for seeds' decontamination which minimise the risks for *Salmonella spp* and STEC;
    - defined Critical Control Points (CCP) with proper critical limits (time and temperature correlation to achieve the pasteurisation);
    - documented satisfactory analytical results for *Salmonella spp* and STEC;
    - documented procedures for control of the CCPs;
    - procedures for handling non-compliances;
    - staff training;
    - corrective actions to be taken if a CCP is exceeded;
    - a documented sampling program to verify the effectiveness of the process and;

[6] '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.

- monthly frequency of analysis for the finished product.

93. The decontamination procedure (pasteurisation) was checked by the audit team at:
    - one sprout-producing establishment where derogation has not been granted and the audit team noticed that temperature / time of the treatment was not controlled;
    - one sprout-producing establishment, where derogation was granted but there was no pasteurisation process ongoing.

94. The procedure, verified in one case by the audit team and, described in the other by the FBO to the audit team, was the following:
    - 20 / 25kg of seeds were washed in cold water and rinsed, then;
    - the seeds were soaked in approximately 100l of water initially at 80 °C, then;
    - left for a time that went from a few seconds in the case observed to 1 minute in the case described. Water temperature measurements were performed before to soak the seeds. No measurements of the water temperature during and after soaking were performed.

95. The actual temperature of the treatment was less than 80 °C. In particular, the operating conditions were far from what was described in the literature by Bari *et al*. (see point 86).

96. However, in the sprout-producing establishment visited, which gained of the derogation, the audit team observed that:
    - there was no evidence of established monitoring procedures, proper records for CCPs, critical limits, preventive and corrective actions as recommended by NFA;
    - critical limits were expressed as a range, contrary to HACCP requirements where a critical limit must have a specific value;
    - the monthly frequency of own microbiological tests as required by EU legislation and NFA guidelines was not respected;
    - the NFA referred to Regulation (EC) No 2073/2005, Chapter 1, footnote 23 "*Excluding sprouts that have received a treatment effective to eliminate Salmonella spp. and STEC"* to exclude sprouts from being analysed for STEC. However, without validation it is not possible to conclude on the effectiveness of such a treatment;
    - the audit team could not obtain evidence confirming that the effect of the decontamination procedure was verified by the FBO and assessed by the CABs.

97. In addition, the six months of satisfactory preliminary tests of seeds carried out in line with Regulation (EC) No 2073/2005 were not available to the audit team. However, the CAB stated that such analytical reports had been checked and assessed as satisfactory. Thus, the derogation has been granted.

98. The CAB did not take immediate action to correct the non-compliances concerning sampling and analysis of seeds and sprouts and the absence of food safety procedures.

99. The NFA informed the audit team that, based on its guidelines, six months of satisfactory preliminary testing of seeds carried out in line with Regulation (EC)

2073/2005 are sufficient to show that this method is effective for eliminating *Salmonella spp.* and STEC. Nevertheless, Bari *et al*[5] in their publication indicated that extensive validation studies are necessary to verify the reproducibility of the results obtained in their study and that the amount of seeds processed affects the ability of this treatment to eliminate bacteria.

5.2.4.4 Freezing Establishments

100. Freezing establishments are ranked as a low risk and a yearly number of inspection hours are allocated depending of their size. Official samples were not foreseen for this type of establishment.

Table 3: *Freezing Establishments in the MUP visited and Official Controls data*

MUPs Visited	Nº of FBOs Registered Frozen Veg	Nº of Controls in 2018				
		Planned	Implemented	Not Planned	Total	With Non-Compliances
1	1	1	1	1*	2	1*
2	-	-	-	-	-	-
3	1	1	1	1*	2	1*
4	-	-	-	-	-	-

**Controls performed during this audit*

101. The audit team visited two different freezing establishments in two different MUPs from two different regions.

102. The first visit was at a small-scale freezing plant for soft-berries produced on the own farm. The MUP informed the audit team that the first inspection was performed on 6/09/2018.

103. This was the only freezing establishment for FNAO under this MUP's responsibility. For this plant two hours inspection / year are foreseen according to the annual control plan. The inspectors explained to the audit team that it means, in terms of frequency, one inspection every year.

104. The second visit was performed to a freezing establishment of vegetables. 50% of the blanched vegetables were intended for direct human consumption. Yearly official control reports were available since 2015 with no non-compliances. The last inspection was performed in June 2018 with no non-compliances detected.

105. The CA informed the audit team that this was the only freezing establishment for FNAO in their MUP. This plant has seven hours inspection / year and this means, in terms of frequency, one inspection every year.

106. This FBO performs regular microbiological tests focused on the clean area (after blanching) and on the lines dedicated to ready to eat production. There were weekly

analyses of final products, water and environmental swabs. Concerning *Listeria* and *Salmonella* no major non-compliances were found. Concerning *E.coli*, some non-compliance related to floors in the production area has been detected.

107. The official reports were available for both establishments. In one case some minor non-compliances regarding procedures were reported. Checklists were not attached to the reports.

108. A generic checklist is in place. However, during the witnessed inspections no checklists were used by the MUP inspectors who followed their guidelines which included the main requirements to prevent microbiological contamination. In the guidelines there are no specifying requirements for freezing establishments of FNAO.

109. In one case, some minor non-compliances regarding procedures, cleaning and hygiene at the warehouse were noticed by the MUP. However, the poor hygiene at the production facilities (e.g. disorder, wooden pallets, product packages placed directly on the ground and condensation on the ceiling of the cold store) were not considered as non-compliances by the MUP.

110. In the other case, during the visit, non-compliances concerning potential direct contamination of food were correctly noticed by the inspectors. The same team from MUP had performed the last inspection in June 2018 with no non-compliances detected and the FBO informed the audit team that procedures and facilities have not changed since. However, these inspectors did not take immediate action. In addition, other non-conformities like excessive rime in the cold store with cardboard boxes and the storage of waste in the middle of edible products were not noticed by the MUP. As there was no record of non-compliances, no corrective actions were initiated.

5.2.4.5 Internet Sellers of Seeds for Sprouting

111. In two MUPs the inspectors informed the audit team that they did not receive specific training on seeds for sprouting and that was the first inspection they perform concerning seeds for sprouting.

112. MUPs use generic checklists with no specific requirements for seeds for sprouting. The MUPs confirmed that they were not aware of which certificates they have to look at for imported seeds and that they were not aware of the specific requirement for labelling (e.g. taxonomic name required).

5.2.4.6 Non-Compliant Products

113. The central CA informed the audit team that non-compliant products are handled according to Article 19 (destruction and change of intended use) and Article 20 (special treatment) of Regulation (EC) No 882/2004.

114. The central CA also stated that in case of non-compliant FBOs or products, proportionate and dissuasive administrative measures and penalties are in place along the FNAO food chain. In some cases, the FBO is required to provide documentary evidence of corrective measures or a follow-up visit may be required to verify the

implementation of the measures. Where an FBO does not agree that there is a non-compliance or where corrective measures are not adequately taken, the CAs have a wide range of administrative sanctions available to ensure compliance including injunctions, prohibitions and administrative fines.

115. Some examples of follow-up actions were available for sprout-producing establishments. However, there was no evidence of their effectiveness due to the recurrence of the same non-compliances. No evidence of follow-up actions was available for other FBOs in the scope of this audit.

116. Before the closing meeting, the CAs informed the audit team that enforcement measures have been taken concerning the absence of import certificates in two sprout-producing establishments. In particular, bans from placing sprouts obtained from seeds without import certificates on the market were issued. Likewise, the batches of seeds for sprouting without import certificates were also blocked as unfit for use.

Conclusions on Implementation of Official Controls over FBO's Obligations

117. The official control system presents a number of gaps, notably related to provision of specific instructions (i.e. how to check import certificates for seeds intended for sprouting) and staff training. As a result, official controls cannot be implemented correctly and effectively. This impact on the enforcement, where non-compliances are hardly detected and, when detected, are rarely followed-up. Thus, non-compliant products might be undetected and the correct application of the relevant legislation might not be enforced.

118. The inspectors were not able to verify the import certificates of seeds intended for the production of sprouts imported from Third Counties because they were not familiar with them and with the requirements established in the Regulation (EU) No. 211/2013. This result in seeds intended for sprouting imported without a valid certificates. Thus, seeds are imported without guaranties regarding hygienic production provided by the exporting countries, representing a potential risk for the consumers.

119. The CA did not verify effectively compliance with the rules and criteria laid down in Regulation (EC) No 2073/2005 or NFA Guidelines in accordance with Regulation (EC) No 882/2004. Thus, non-compliant products might go undetected on the market and this could pose a health risk for the consumers.

120. The NFA in its guidelines excluded STEC from the parameters to be analysed in sprouts by FBOs which gained of the derogation by CAs, contrary to what required by Regulation (EC) No 2073/2005, Annex I, Chapter 1, due to a misinterpretation of the footnote 23 of such regulation. Thus, sprouts which would be contaminated with STEC would go undetected and would represent a risk for the consumers.

121. The NFA, in its guidelines, considers a treatment effective in eliminating pathogens based only on verification analysis of the finished product (sprouts) without requiring its validation, thus confusing verification with validation. Validation[7] differs from

[7] CAC / GL 69 – 2008. Guidelines for the Validation of Food Safety Control Measures.

monitoring and verification. Validation of a CCP requires an in-plant study to ensure that a critical limit, that is supported by literature or advised by CAs, is controlling the identified hazards under the operating conditions of the plant, especially when these conditions are different from what is described in the literature. In-plant studies for microorganisms usually rely on indicator organisms and require inoculation of the products to complete the study[8]. The studies should be statistically designed to ensure the required reduction of the hazard and an appropriate number of samples need to be collected to demonstrate its robustness (i.e. the paper of Bari *et al*.[5]).

5.2.5 Official Sampling Procedure

Legal requirements

Article 11 of Regulation (EC) No 882/2004 and Annex I, Chapter 1 of Regulation (EC) No 2073/2005

Findings

122. The NFA informed the audit team that there are no national routine monitoring or surveillance programmes for microbiological hazards in FNAO. Official sampling may, however, be performed on project basis to obtain general information of the microbiological status of certain FNAO products, in case of suspicion or outbreaks.

123. The table below shows the data provided by NFA regarding official microbiological samples of FNAO analysed for pathogen virus and microorganisms. Official samples are mainly taken at the stage after primary production.

Table 4: *Official Samples*

Year	Project / Survey	Verification of FBO own control	Outbreaks / complaints	Other	Total	Findings
2016	11	6	34	22	73	0
2017	14	4	23	15	56	1 Norovirus Frozen berries

124. During 2016 two MUPs had control projects covering STEC in FNAO consumed raw and in 2017 one MUP had a control project covering *E. coli*, *Staphylococcus aureus* and others in FNAO consumed raw.

125. In two different CABs, the audit team observed a sampling demonstration of sprouts

[8] In their response to the draft report the Competent Authority noted that NFA agrees that sprout producers need to validate decontamination treatments (time / temperature combinations or chemical treatments) which are used for different types of seeds and that the current guidelines need to be revised to better describe this. The Codex guideline (CAC / GL 69 – 2008) acknowledges a range of approaches to validation, which may be used independently or in combination, as appropriate. Apart from approaches mentioned here, there is also a possibility to e.g. base the validation on a "collection of data during operating conditions in the whole food operation". The NFA will consider which validation approaches that are most appropriate and update the guidelines accordingly.

and of strawberries at the production site. The inspectors demonstrated satisfactory knowledge of general sampling requirements. The sample packaging, sample transportation and the sampling protocol were set up in a way to prevent any adulteration.

Conclusions on Official Sampling Procedures

126. There are no national routine monitoring or surveillance programs for microbiological risks in food of non-animal origin in place. However, the official sampling procedure ensures the integrity of the samples for microbiological analyses.

5.2.6 Laboratory Performance

Legal requirements

Articles 4(2)(c), Article 11(1), Article 12(1), (2) and (3) and Article 33 of Regulation (EC) No 882/2004

Findings

General

127. The NFA is designated as NRL for STEC and food-borne viruses. Recently, the laboratory has been assigned as European Reference Laboratory for food-borne viruses. The laboratory has a comprehensive quality management system in place and is accredited according to International Organisation for Standardization (ISO), EN ISO 17025:2005 under a flexible scope of accreditation since 2018. The accreditation comprises, inter alia, EN ISO/TS 13136:2012 for STEC and EN ISO 15216-1:2016 resp. ISO/TS 15216-2:2013 for norovirus and hepatitis A virus analysis by SWEDAC.

Technical equipment and staffing situation

128. The laboratory building is properly designed. In general, the technical layout follows the forward flow principle as required for molecular analysis. The waste material from the real-time instruments is being transported to the sample preparation area.

129. The technical equipment includes real-time polymerase chain reaction (PCR) machines, and next generation Illumina MySeq DNA sequencing instruments meeting the current standards.

130. The laboratory has no laboratory information management system (LIMS) installed. Sample labelling and tracking through the process is mostly based on Excel files and written documentation. The audit team was informed that a LIMS will be implemented in the near future.

131. The resource is adequate for the numbers of samples to be analysed. The scientific personnel is dedicated and committed and demonstrated in-depth knowledge of all relevant analytical aspects.

Sample processing

132. Sample handling and sample processing follows clear structures with designated areas

for every step in which the responsibilities are clearly designated.

133. Minor deficiencies concerning the hygiene and temperature of the cold store for samples at the sample reception were noticed. The laboratory staff stated that the storage would be used only in exceptional circumstances, and the samples would stay in their original packaging.

134. The audit team focussed on the molecular analysis of FNAO for food-borne viruses and STEC. Both methods followed international standards in general. According to the methods in place, improvements of some weak points of the international standards were undertaken and validated, this leads to highly reliable analytical results.

135. At present, for FNAO only samples taken for outbreak investigations are analysed. In 2018, 6 samples for E-STEC and 3 for Virus.

Conclusions on Laboratory Performance

136. The laboratory has the capacity in terms of staff, equipment and procedures to fulfil its role as NRL for STEC and food-borne viruses.

5.2.7 Procedures for Performance and Reporting of Control Activities

Legal requirements

Article 8 and Article 9 of Regulation (EC) No 882/2004

Findings

137. Official controls can be undertaken by one or more inspectors depending on a number of factors, such as type of control, geographical location and safety issues. Inspections of FBOs in primary production are normally unannounced and are free of charge. Inspections carried out later in the food chain are covered by fees. Inspectors had checklists covering microbial risks and used them during the inspections observed. Follow-up inspections are charged to the FBO. A report is prepared after every inspection and the FBO receives a copy of the report including recommendations and deadlines.

138. The NFA performs audits at the CABs. There is a five-year audit plan which includes shadow controls. In the last three years, one internal audit regarding FNAO has been performed (June 2018) in one CAB. This audit also included the follow-up of an audit conducted in the same CAB in 2014. The 2018 audit report was presented to the audit team.

139. In the report the NFA described a number of shortcomings in the control system of the CAB:

- registration of primary producers is incomplete;
- lack of knowledge of inspectors;
- lack of a system to ensure consistency in the verification process;
- lack of a comprehensive system to verify that deficiencies were detected by food

businesses and the detection of deficiencies detected during official control;
- lack of follow-up to the objectives of the effectiveness of the control;
- inspections were not always risk-based.

140. The NFA concluded that: "*Food control at the level of primary production in the CAB audited was so low prioritise that the majority of the requirements examined from the Regulation (EC) No 882/2004 as well as parts of the Swedish regulations LVFS 2005:21 were not met. The non-compliances noticed during the 2014 NFA's audit were not corrected according to the CAB action plan submitted at the time*".

141. There was no evidence of timely follow-up by the NFA to verify the implementation of the 2014 action plan.

142. The NFA requested an action plan to be received by September 2018. The action plan proposed by the CAB was received by the NFA in August 2018. Corrective actions and deadlines were assessed by NFA as satisfactory.

Conclusions on Procedures for Performance and Reporting of Control Activities

143. Procedures for reporting of control activities were in place. The internal audits in place for FNAO identified a number of weaknesses which were also identified during this audit, including a lack of correction of identified shortcomings. This results in a system that is not effective in rectifying deficiencies.

5.3 RAPID ALERT SYSTEM FOR FOOD AND FEED

Legal requirements

Article 50 of Regulation (EC) No 178/2002 and Article 19(3) of Regulation (EC) No 882/2004

Findings

144. The NFA is the national contact point for RASFF in relation to food. NFA supports the other control authorities in Sweden in the management of RASFF-notifications. The Commission and Sweden exchange RASSF notification *via* Commission web-based platform iRASFF. In Sweden the exchange of information is done through forms available at Livsteck.net and e-mail. FNAO that are associated with a risk that is caused by primary products is notified in the RASFF-system just like all other foods where there is a risk to human health.

145. In the last three years, one RASFF notifications related to microbiological contamination of FNAO originating from Sweden was notified.

146. Three examples of RASFF notifications were followed-up by the audit team and the measures taken by the CAs were satisfactory.

- RASFF 2018.1813 foodborne outbreak caused by hepatitis A virus (1B) in frozen strawberries from Poland;
- RASFF 2017.2173 norovirus (presence /25g) in frozen raspberries from Serbia;

- RASFF 2017.0898 *Listeria m.* (<10cfu/g) in chilled mixed cut salad from Sweden.

Conclusions on Rapid Alert System for Food and Feed

147. There is an effective system in place for dealing with RASFF notifications that enables the CA to take appropriate action in response to RASFF notifications.

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

148. The table below summarizes the follow-up to the relevant recommendations made in report DG SANTE 2015/7459-MR Final

No	*Previous*	*Assessment*
1.	Ensure that all FBOs are registered as required by Article 6 of Regulation (EC) No 852/2004.	Addressed Implementation on-going *See findings: 17 and 19.*
2.	Ensure that all sprouting establishments are approved, as required by Article 2 of Commission Regulation (EU) No 210/2013.	Addressed Partially Implemented *See findings: 20, 21, 23, 68, 69, 70, 71 and 72.*
3	Ensure that official controls include the traceability and certification requirements for imports into the EU of sprouts and seeds intended for the production of sprouts as required by Regulation (EU) No 211/2013 and Regulation (EU) No 208/2013.	Addressed Not implemented *See findings: 81, 82, 83, 84 and 107.*
4.	Ensure CAs are fully aware of the requirements for the own control systems to be implemented by the FBOs for monitoring of food safety criteria for seeds for sprouting as required by Regulation (EC) No 2073/2005. Annex 1, Chapter 3.3.	Addressed Not implemented *See findings: 87, 88, 90, 91, 96, 97 and 99.*
5.	Ensure that the NRL undertakes all the relevant duties of an NRL as described in Article 33 of Regulation (EC) No 882/2004.	Addressed Implemented *See findings: from 127 to 135.*

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

149. Out of five recommendations the CA has fully implemented one recommendation and

partly implemented two recommendations made in the previous report on this topic. No major progress was observed in implementing and improving the control system for the reduction of microbiological contamination of food of non-animal origin since the previous audit.

7 OVERALL CONCLUSIONS

A risk-based control system for official controls on FNAO is in place. There is a system for registering primary producers and for the approval of sprout-producing establishments. This facilitates the implementation of a risk-based approach to official controls including microbial risks associated with FNAO.

Regarding official samples, the appropriate laboratory capability and capacity is available.

Significant shortcomings were identified in relation to the registration of FBOs and approval of sprout-producing establishments. The approval system does not ensure that non-compliances have been rectified before that approval is granted. In addition, the official control system presents a number of gaps, notably related to provision of specific instructions, technical support and staff training. As a result, official controls cannot be implemented correctly and effectively, resulting in poor controls. This impacts on the enforcement, where non-compliances are hardly detected and when detected are rarely followed-up. Thus, non-compliant products might be undetected and the correct application of the relevant legislation might not be enforced, resulting in placing on the market of non-compliant products which may present a health risk. A number of these shortcomings were equally reflected in the outcome of an internal audit performed by the Central Competent Authority in June 2018, and which found little corrective action since the previous internal audit, in 2014.

In respect of the follow-up to the previous audit, certain actions have not been effective in addressing the identified shortcomings. Overall, the audit had to conclude that there has been limited improvement compared to what was found previously.

8 CLOSING MEETING

A closing meeting was held on 27 September 2018 with representatives of the CCA and other CAs concerned. At this meeting the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement on the findings presented.

9 RECOMMENDATIONS

No.	Recommendation
1	Ensure that all FBOs are registered as required by Article 6 of Regulation (EC) No 852/2004. *Recommendation based on conclusion: 24.* *Associated findings: 17 and 19.*
2	Ensure that approval of sprout-producing establishments is granted following the resolution of all non-conformities regarding infrastructure, equipment and the other relevant requirements of food law, as specified by Regulation (EC) 882/2004 Article 31(c), (d) and (e). *Recommendation based on conclusion: 25.* *Associated findings: 21, 22, 23, 68.*
3	Ensure that official controls include the certification requirements for imports into the EU of sprouts and seeds intended for the production of sprouts as required by Regulation (EU) No 211/2013 and Regulation (EU) No 208/2013. *Recommendation based on conclusion: 118.* *Associated findings: 81, 82, 83, 84 and 107.*
4	Ensure that CAs verify compliance with the rules and criteria laid down in Regulation (EC) No 2073/2005, Annex 1, Chapter 1 and Chapter 3.3 in accordance with Regulation (EC) No 882/2004. *Recommendation based on conclusions: 119 and 120.* *Associated findings: 87, 88, 90, 91, 96, 97 and 99.*
5	Ensure that NFA guidelines regarding microbiological parameter for sprouts are in compliance with EU legislation, in particular with Regulation (EC) No 2073/2005. *Recommendation based on conclusion: 120.* *Associated findings: 88, 89, 90, 91 and 96.*
6	CAs should increase the qualification of the inspectors involved in official controls by providing them with the relevant tools (i.e. training and technical support including sufficiently detailed checklists) in order to ensure effective and appropriate official controls as required by Article 4 and Article 6 of Regulation (EC) No. 882/2004. *Recommendation based on conclusions: 13, 117, 118, 119, 120 and 121.* *Associated findings: 9, 59, 74, 79, 80, 82, 84, 96, 109, 110, 111 and 112.*

No.	Recommendation
7	CAs should implement enforcement measures in order to give effect to the requirement set out in Article 54 of Regulation (EC) No 882/2004 and thus, to allow official controls to be effective in raising/maintaining the level of compliance. *Recommendation based on conclusions: 25, 42, 117 and 143.* *Associated findings: 23, 37, 68, 77, 78, 80, 83, 96, 98, 110, 115, 139, 140, 141 and 142.*

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=2018-6383

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
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-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
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
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. 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. 211/2013	OJ L 68, 12.3.2013, p. 26-29	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