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 Hungary which took place from 7 to 16 May 2019 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 primary production, frozen products, 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 (DG SANTE 2016/8727) have been implemented and their effectiveness in addressing the identified shortcomings.

Overall, there is a system for registering producers and processor of food of non-animal origin and for the registration and approval of sprout-producing establishments. Official controls are supported by official samples taken at the level of production, processing and retail. Regarding official samples, the appropriate laboratory capability and capacity is available.

However, the risk based planning showed major deficiencies concerning the prioritisation of official controls of food of non-animal origin and the organisation of such controls, including the lack of supervision. In addition, the system does not allow inspectors to gain and maintain sufficient experience in this field in order to perform effective controls.

This has a considerable impact on both the implementation of official controls and their effectiveness. As a consequence non-compliances are rarely detected and enforcement of the relevant requirements is seriously affected.

Despite a major Listeria monocytogenes outbreak linked to frozen corn processed in Hungary, the competent authorities have not taken measures to improve the system of official controls regarding food business operators' obligations. The system currently in place is not sufficiently capable to verify that food of non-animal origin is produced under conditions which comply with Regulation (EC) No 852/2004 to prevent contamination with pathogens.

As a result, official controls and enforcement would not be able to contribute to the prevention of further possible Listeria monocytogenes contaminations in frozen food of non-animal origin, or to limiting the risk of non-compliant products being placed on the market.

Nevertheless, and in respect of the follow-up to the previous audit, actions taken have been effective in addressing the shortcomings identified at the time in particular in relation to seeds for sprouting.

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

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<td>E. coli</td>
<td><em>Escherichia coli</em></td>
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<td><strong>DG Health and Food Safety</strong></td>
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<td>DFCSAHU</td>
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<td>DFCSLR</td>
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<td>DPHFCS</td>
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<td>DPPSCA</td>
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<td>EFSA</td>
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<td>EU</td>
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<td>Food Business Operator</td>
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<td>Food of Non-Animal Origin</td>
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<td>GAP</td>
<td>Good Agricultural Practices</td>
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<td>ISO</td>
<td>International Organisation for Standardization</td>
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<td>Lm</td>
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<td>MANCP</td>
<td>Multi-Annual National Control Plan</td>
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<td>MoA</td>
<td>Ministry of Agriculture</td>
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<td>MS</td>
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<td>NFCSO</td>
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<td>Food Microbiological National Reference Laboratory</td>
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<td>PT</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>STEC</td>
<td>Shiga toxin-producing <em>Escherichia coli</em></td>
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1 INTRODUCTION
The audit took place in Hungary from 7 to 16 May 2019 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.

An opening meeting was held on 7 May 2019 with representatives from the Ministry of Agriculture (MoA) as well as representatives from the central and local competent authorities (CCA and CAs) responsible for official controls related to the objective and scope of the audit. 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. A representative of the MoA accompanied the audit team 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);
- Evaluate the system of official controls in the area of traceability of sprouts\(^1\) and seeds intended for sprouting, including applicable microbiological criteria and the approval of sprout-producing establishments;
- 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 2016\(^2\) 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 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 food business operators (FBOs) obligations included: cultivation of fruit and vegetables (consumed raw), frozen vegetables, cultivation of seeds for sprouting, sprout-producing establishments, internet sales of sprouts and seeds for sprouting, retailers and the handling of non-conforming products.

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

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\(^1\) ‘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.

### Table 1: Audit visits and meetings

<table>
<thead>
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<th>Visits / meetings</th>
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<td><strong>Competent Authorities</strong></td>
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<td>Opening and Closing Meeting with Representatives of:</td>
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<tr>
<td>• MoA – Food Chain Control Department</td>
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<tr>
<td>• National Food Chain Safety Office (NFCSO)</td>
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<td>✓ System Management and Supervision Directorate</td>
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<td>✓ Risk Management Directorate</td>
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<td>✓ Food Chain Safety Laboratory Directorate (FCSLD)</td>
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<td>✓ Food and Feed Safety Directorate (FFSD)</td>
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<td>✓ Directorate of Plant Protection and Soil Conservation and Agri-environment (DPPSCA)</td>
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<tr>
<td>• Deputy State-secretariat responsible for the Operation of Territorial Public Administration of the Prime Minister's Office</td>
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<td><strong>Regional/Local level</strong></td>
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<td>County Offices</td>
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<td>• Csongrăd County</td>
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<td><strong>Laboratories</strong></td>
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<td>Official Laboratory</td>
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<td>National Reference Laboratory (NRL)</td>
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<td><strong>Food Business Operators (FBOs)</strong></td>
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<td>Farm producing strawberries</td>
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<td>Green leafy vegetables</td>
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<td>Farm producing green leafy vegetables</td>
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<td>Frozen green vegetables processor</td>
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<td>Packer and Retailers of Seeds for Sprouting</td>
<td>1</td>
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<tr>
<td>FBO packer and seller of seeds for sprouting (including selling via the internet)</td>
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<tr>
<td>Sprout-producing establishments</td>
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<tr>
<td>Approved sprout-producing establishments</td>
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3 LEGAL BASIS

The audit was carried out under the general provisions of the European Union (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 outbreak. 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 \textit{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:


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 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 Hungary on this topic.

5. FINDINGS AND CONCLUSIONS

5.1 RELEVANT NATIONAL LEGISLATION AND GUIDELINES

Legal requirements

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

Findings

1. The directly applicable EU legislation is supplemented by national provisions.

2. All relevant legislation has been brought within a single framework, Act XLVI of September 2008. According to this act the main priority of the food chain official control is the protection of human health, plant and animal health and national economy.

3. The development of a Guide on GAP for fruit and vegetable production, including information to prevent microbiological contamination for primary producers, is still under development as was the case during the previous audit.

Conclusion on Relevant National Legislation and Guidelines

4. There is national legislation in place complementing the directly applicable EU legislation. No progress was observed since the last audit regarding the development of a Guide of GAP for fruit and vegetable.

5.2 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS

5.2.1 Designation of Competent Authorities and Resources for Official Controls

Legal requirements

Findings

Designation of CAs

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

6. Official laboratories are designated according to the Act XLVI of September 2008. They are part of the CCA and perform analyses of official samples.

7. The NFCSO is the CCA within the scope of this audit. NFCSO is responsible for supporting the decision-making of the MoA and providing control plans, procedures and guidelines to local level.

8. At central level coordinating tasks are shared between two directorates of NFCSO:
   - NFCSO DPPSCA, responsible for coordination of inspection tasks in the field of primary production (except sprout establishments and establishments packing seeds for sprouting);
   - NFCSO FFSD, responsible for coordination of inspection tasks in the field of sprouts-producing establishments, establishments of packing seeds for sprouting, FNAO processing establishments (including freezing, pre-cut and canned plants).

9. There are 19 County Government Offices CGOs, one in each county; at local level, the administration consists of 174 District Government Offices (DGOs). Staff professional management and funding are under the responsibility of the Prime Minister's Office.

10. CGO Department of Food Chain Safety and Land-Registry / Department of Public Health and Food Chain Safety (DFCSLR/DPHFCS) are the local CAs in charge of approval of sprout-producing establishments.

11. DGO of Plant Protection and Soil Conservation Unit (PPSCU) are the local CAs in charge of implementing official control at primary production excluding sprout-producing establishments (farmers, facilities producing/growing vegetables, fruit, seeds for sprouting and importers of seeds for sprouting). The inspectors are generally plant protection specialists.

12. Within the DGOs there are 82 District Food Chain Safety and Animal Health Units (DFCSAHU). On average each DFCSAHU is responsible for 2-3 DGOs. DGO DFCSAHU are the local CAs in charge of implementing official control plan at FNAO processing establishments, sprout-producing establishments and establishments packing seeds for sprouting. The inspectors are generally food technologist or veterinarians.

Training

13. Guidelines and checklists for official controls are produced at central level, are used all over Hungary and their use is part of annual training. The CCA informed the audit team that such training is compulsory for all the inspectors involved in official controls.

14. The CCA presented, to the audit team, staff training files concerning EU legislation for sprouts and seeds for sprouting, microbiological safety in primary production,
microbiological sampling, *Listeria monocytogenes (Lm)* risk in FNAO production. These trainings are provided regularly and are attended by local staff.

**Resources**

15. The CAs informed the audit team that due to shortages in resources the official control plan cannot be fully implemented and official inspection reports are not systematically uploaded in the central IT system (see points 34, 45, 51, 52 and 117). This limits the availability of information that would be relevant for future control planning and supervision purposes.

16. Although the CAs suggested shortages in staff, the CCA informed the audit team that the official controls in FNAO processing plants are also performed by the CCA in addition to those of the DGOs (see points 50, 51, 52, 89, 93 and 95) and in most cases without notification to the local authorities (DGO). Similarly, DGOs at local level, as required by official procedures and work instructions, carry out their official controls and upload their data to the central IT system but to which the CCA has no access.

17. In addition, the inspectors involved in official controls on FNAO perform a low number of inspections per year in this sector and this makes it hard for them to gain and maintain the required expertise. Moreover, moving the implementation of controls for FNAO processing establishments from CGO to DGO results in further lowering the number of inspections in such establishments (processing and sprout-producing establishments) for every individual inspector. This further limits the possibility to gain practical experience in controlling this type of establishments.

**Conclusions on Designation of CAs and Resources for Official Controls**

18. The CAs are designated for all stages of FNAO production and this gives a good basis for the implementation of official controls. However, contrary to the requirements of Article 4(5) of Regulation (EC) No 882/2004, limited coordination and cooperation between CAs results in inefficient use of resources and information, thus impacting on the effectiveness of the official control system.

19. Contrary to what is required by Regulation (EC) No 882/2004 Article 4(2)(c), the provision of a sufficient number of qualified staff is not ensured, thus weakening the system of official controls.

5.2.2 *Registration / Approval of Food Establishments*

**Legal requirements**

Findings

Registration of Food Establishments

Primary producers

20. They can be registered in different official databases. For the purpose of planning official controls, data about produce/producers are taken from the Hungarian State Treasury.

21. At central level, NFCSO DPPSCA has completed the list of primary producers of FNAO under official control regarding microbiological risk. The primary producers included in the list are 153 growers of leafy green vegetables and 1,066 growers of soft fruits. At the time of the audit, other primary producers in the scope of the audit were controlled at retailer level as part of the annual official microbiological monitoring plan (see paragraph 5.2.5).

FBOs involved in the “sprout chain”

22. Importers, distributors, seed retailers and internet sellers are registered. They have to submit an application for registration with the DGO. Packers are registered at the DGO. The CCA informed the audit team that at the time of the audit there were no importers of seeds for sprouting from third countries.

23. The audit team was also informed that the NFCSO has since the last audit (DG SANTE 2016/8327) a project to control e-commerce. This project is aimed at establishing a national system of official controls for such traders.

Producers of seeds for sprouting

24. At the time of the audit there were six producers of seeds for sprouting. The DGOs in charge of sprout-producing establishments and packers of seeds for sprouting informed the CCA in charge of primary production of FNAO (including seeds for sprouting) of these producers. In addition, during the audit the CCA in charge of primary production of FNAO informed the audit team and NFCSO FFSD (CCA in charge of sprout-producing establishments) that two of them ceased the production.

FNAO processing establishments

25. Registration of FNAO processing establishments is kept at local level by the DGO DFCSAHUs which are responsible for the registration of FNAO processing establishments (including freezing, pre-cut and canning plants).

Approval of Sprout-Producing Establishments

26. The procedure for approval of sprout-producing establishments starts with the application for approval by the operator followed by an official control on-the-spot. The CGO DFCSLR/DPHFCS issues approvals – according to act No XLVI of 2008, the requirements of Annex I in Regulation (EC) No 852/2004 and Regulation (EU) No 210/2013 – for sprouts producing establishments. Approvals can be withdrawn by the CGO if conditions are no longer considered satisfactory.

27. According to the information provided by the CCA, at the time of this audit there were seven registered and approved sprout-producing establishments. The audit team verified
the approval files of the sprout-producing establishments and noticed that one FBO produced as a registered establishment until 30/04/2019. However, the registration was done in consideration of the requirements of Annex I of Regulation (EC) No 852/2004 and Regulation (EU) No 210/2013 after an inspection.

**Conclusion on Registration / Approval of Food Establishments**

28. There is a system in place for registration of producers and processors of FNAO and for registration and approval of sprout-producing establishments, which enables the inspectors to identify FBOs for the purpose of official controls.

5.2.3 *Organisation and Scope of Official Controls*

**Legal requirements**


**Findings**

29. The Structure and the Organizational and Operational Rules of NFCSO had been changed on 1st January 2019, and all the procedural changes have to be reflected by the new Multi-Annual National Control Plan (MANCP), which is planned to be issued this year.

30. For the time being, the system of official controls is described in the Hungarian MANCP, the current version of which covers the period 2017 to 2020. However, the audit team was informed by the CCA that the current version of the MANCP does not include a specific description of the control system for primary production of FNAO which will be part of the new MANCP.

31. The plan for official controls (inspections and sampling) produced by NFCSO at central level is sent to the local GCO and DGO for evaluation before publication and implemented at local level. The plan covers the period April/year – March/year + 1.

**Primary Production**

32. In all counties visited, at the time of the audit, official samples at farm level were taken for lettuce and soft fruits. Samples of other products in the scope of the audit are taken at retail level (county plans) unless there is a suspicion in which case inspectors can sample individual producers as appropriate.

33. Based on the opinion of EFSA\(^3\), for official inspections at farm level, the CCA decided to focus on the two most risky crops: leafy green vegetables and soft fruits. In order to optimize the resources, with regard to the leafy green vegetables the CCA decided to include in the official controls the producers with a surface greater than 3 hectares. On that basis, the CCA allocate a number of inspections and official samples to each county following the criteria defined above. At local level, the producers to be inspected are chosen by the CAs.

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\(^3\) Scientific Opinion on the risk posed by pathogens in food of non-animal origin. Part 1 (outbreak data analysis and risk ranking of food/pathogen combinations) 1 – EFSA Journal 2013; 11 (1):3025
34. The CCA informed the audit team that during 2016, 2017 and 2018 a total of 315 out of 1,050 planned inspections have been carried out for leafy green vegetables and soft fruits, resulting in zero non-compliances. The CCA attributed the difference between planned and performed inspections to shortages in resources.

35. A centrally developed checklist is used during the official control. This detailed checklist contains 75 key questions related to microbiological risk prevention. For each question, score zero means fully compliant, score one means non-compliance or a situation of higher risk. As examples, the checklist correctly takes into account the difference in risks when using tap water (score equal zero) or well water (score equals 1).

36. In the checklist five out of the 75 questions, are "red questions", considered basic requisites by the CAs: presence of tests results for irrigation water, sufficient number of toilets and/or fields' toilets, sufficient number of hand washing facilities, workers' health conditions and traceability.

37. According to the procedures for official controls, if an inspection marks more than 37 points or if a red question marks 1, an official sample must be taken. However, if the analytical result is compliant, no corrections to the FBO are required as the inspection is deemed to be compliant. As a consequence of this approach, detected non-compliances are not documented (see point 34, "zero non-compliances") as such and are not rectified.

38. The CCA decided that in case a primary producer is certified as compliant with a relevant Private Certification Scheme the checklist can be limited to the five "red questions" without going through the entire checklist. However, presence of the Quality Certification is taken into account without verifying the effective application of this private standard (e.g. verification of the inspection report and/or the action plan required by the certification body and performance of the organisation performing the third party controls).

39. At local level a monthly report concerning number of inspections and number of samples is produced for the central level. Evaluation of analytical reports are made by local level and state of the inspection plan's implementation are performed at central level.

**Sprout-producing establishments**

40. Under the official control plan, sprout-producing establishments have to be inspected once a year. An official guideline and a checklist covering all the relevant aspects of the sprouts legislation are in place. Official sampling for sprouts are planned at producer and retailer level.

**Processing Establishments**

41. Before January 2017 official controls were implemented by CGOs. From that date the implementation moved to the DGOs (except in one CGO).

42. A risk-based planning protocol has been in use since 2012. Registered FBOs are ranked by an algorithm, therefore all assessed establishments receive a risk score according to key factors included in the calculation:
   - main activity of the establishment – max. 25 points;
• other transactional data related to its activity (i.e. production volume) – max. 25 points, if there is no data 15 points are set;
• data from previous official controls (i.e. non-compliances) – max. 40 points;
• time elapsed since the last control – 5 points/year.
If the score exceeds a threshold value, the establishment will be included in the control plan.

43. The activity of freezing and pre-cut fruits and vegetables is classified as a medium risk activity (class 2 out of four). Freezing establishments have not been moved to a high-risk class after the Lm outbreak linked to frozen corn from Hungary.

44. The preliminary plan is provided to each county with the number and the name of the establishments to be inspected as well as the samples to be taken. The CGO forwards the preliminary plan to the DGO in charge of its implementation.

45. For local inspectors in charge of FNAO establishments, at the time of the audit, it is not required to provide in the IT system more details regarding the establishments (i.e. production volume, history of compliance and consumers claim). This has an impact on the risk ranking (frequency of inspections) resulting in all the FNAO processing establishments having the same risk ranking (see point 42).

46. The CCA informed the audit team that no changes were made to controls after the Lm outbreak related to frozen corn processed in Hungary.

47. Guidelines and dedicated checklists produced at central level can be downloaded by the inspectors. Checklists have to be filled out electronically and all other supporting documentation could be uploaded in the system as well.

48. For processing establishments there are different types of inspections:
   - Planned inspections (risk based plan);
   - Compensation inspections (Discretionary, to reach the objective of number of inspections);
   - Customer complaints of public interest
   - Follow-up inspections

49. The CCA informed the audit team that during 2016, 2017 and 2018 a total of 148 inspections have been carried out in freezing and pre-cut establishments of FNAO, resulting in one non-compliance in 2016 and two non-compliances in 2018. At the time of the audit, the plan for 2019 was not available.

50. The CCA stated that due to the fact that they have no access to the IT system, the number of planned inspections could not be provided to the audit team.

51. The CCA and one county visited informed the audit team that for FNAOs, their access to the system is still very limited, resulting in inspections performed by the CCA not being uploaded in the system. The CCA does not have the possibility to verify the current state of implementation of the inspections and has no possibility to enter data relevant to the classification of the risk such as size and production volume of the FBO (see point 42).
52. On the other hand, two other counties visited informed the audit team that they have access to the system. Every inspector can see his/her establishments and all the planned inspections performed are uploaded. Other inspections, i.e. compensation inspections, citizens' complaints and follow-up inspections are not systematically uploaded in the system. The CCA explained this to be due to a lack of resources and clarity in the official work instructions.

53. The CCA informed the audit team that these above information should be evaluated at central level in order to generate the data needed for the design and implementation of the risk-based plan (establishments' relevant information, establishments' non-compliances). However, due to lack of resources this information is not available yet, resulting in all the FNAO processing establishments in the scope of the audit having the same risk ranking.

54. The CCA agreed that the lack of relevant information such as production volume and implementation of inspections with its history of compliance would affect two of the main four parameters used for the risk based plan, making the risk assessment not reliable.

55. There is an official control system in place covering primary production which includes risk based inspections at farm level. However, contrary to the requirements of Article 54(1)(2) of Regulation (EC) No 882/2004 and due to the fact that corrective actions are only required in case of non-compliant laboratory results, identified non-compliances which may impact on the microbiological safety of products, are not necessarily corrected and therefore continue to constitute a potential risk.

56. An adequate official control system for sprout-producing establishments including official guidelines supported by a checklist is in place. This allows inspectors to cover all the relevant aspects of the sprout legislation.

57. Due to the lack of availability of key parameters (i.e. production volume, outcome of inspections other than planned, history of compliance), contrary to the requirements of Article 3(1) of Regulation (EC) No 882/2004, the IT system used to categorise the establishments according to risk cannot prioritise FNAO processing establishments with higher microbiological risks for official controls. This weakens the effectiveness of the official control system.

58. Crucial data necessary for the preparation of a risk-based control plan are not available or not accessible to the relevant staff. This results in a system of official controls regarding FNAO processing establishments that is effectively not risk-based, as required by Article 3(1) of Regulation (EC) No 882/2004.

5.2.4 Implementation of Official Controls over FBO 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,

**Findings**

**Cultivation**

59. The audit team visited four growers in three different counties, two leafy green vegetable and two strawberry producers. All these growers use well water for irrigation (drip and sprinkler system) and they stated that they had no microbiological problems with irrigation water until now. Their workers have been trained in personal hygiene and are obliged to report when suffering from transmissible diseases. When temporary workers are employed, the same rules apply.

60. Three out of the four FBOs visited informed the audit team that they had already been inspected by the CAs in relation to microbiological risks of FNAO.

61. One of the two strawberry producers was inspected for the first time in the scope of microbiological risks. He was not under a private certification scheme; therefore all 75 questions of the checklist were addressed by the inspector.

62. 29 (included also 4 out of the five “red questions”) out of the 75 questions scored 1 with a total score of 29. As a consequence of the score, an official sampling had to be performed and based on the results of such sample the inspection will be assessed as compliant or non-compliant.

63. A number of deficiencies were identified such a poor hygienic condition of the trays used for the picking, insufficient hand washing facilities, missing instructions for workers and unclear traceability procedures. Nevertheless, in the case that the sample taken would render a compliant test result, the inspection outcome would be compliant and therefore no corrective actions to remedy the non-compliances identified will be required.

64. The inspector explained that he will ask for corrective measures regardless of the outcome of the laboratory test result. However, no evidence was provided that this ever happened in the county. The CCA confirmed that in this case, and according to the procedures in place, corrective action by the FBO should not be requested, unless the sample renders a non-compliant result.

65. The audit team observed a second inspection to another strawberry grower where it was confirmed that the control system applies as described in the first grower visited. In this case the inspector required the water analyses reports for irrigation water but he had no knowledge on how to assess them.

66. Two large lettuce producers with pack houses were visited in two different counties.

67. As these FBOs held certification under a private certification scheme the official inspections were limited to the five checklist "red questions"
68. These two FBOs performed several microbiological tests per year on irrigation water (from 2 to 6/year) and, so far, no non-compliances had been detected. One of the producers informed the audit team that he takes one microbiological sample for each crop and for each harvest season (late spring and autumn) amounting to 18 samples/year. In addition, his customers carry out microbiological tests for each batch consigned and the results are made available to the FBO.

69. One farm was already inspected for microbiological risks in 2017. For the inspector performing the official control in the presence of the audit team it was the first time inspecting this farm. The audit team noted that the inspector was not aware of the outcome of the previous inspection, and was not familiar with the requirements from the private standard certification, in particular:

- the inspector accepted that field toilets and field washing hands facilities were not in place, despite the fact that the toilets are at 800/900 meters from the fields;
- the inspector overlook of the fact that the fields were not protected against wild animals;
- microbiological tests of the finished products were not verified by the inspector;
- the private certificate and/or report or action plan from last inspection of the private certification body was not verified by the inspector.

70. The official control to the second leafy green vegetables took place with the inspector who usually performs official controls of this producer.

71. The inspector failed to look for evidence in particular for the water analysis. However, water analyses for 2017 and 2018, were provided upon request of the audit team, and they were compliant.

72. The outcome of the two inspections at leafy green producers ended with full compliant reports from the CAs. An official sample in each farm was taken regardless of the risk obtained because they were part of the official control plan.

73. The CCA confirmed that the same approach for inspection and sampling is used throughout Hungary.

**Freezing establishments**

74. There are 35 FNAO freezing establishments. In 2016 and 2017, 27 official inspections were carried out with one non-compliance detected (hygiene and HACCP). In 2018, after the \( Lm \) outbreak related to frozen corn, 56 official inspections were carried-out with two non-compliances detected (water quality and hygiene).

75. Nine out of these 56 inspections have been carried out by a special taskforce from the CCA without informing the local CAs responsible for the control of the establishment. These last inspections highlighted:

- that hygiene, maintenance and technology conditions were not good enough to avoid cross-contamination;
- that labelling was not clear enough and companies believe that consumers are aware of the correct use of these frozen products;
- poor traceability;
that no environmental sampling was performed by the FBOs.

76. None of these non-conformities had been documented during the previous official inspections performed by the local CAs.

77. There is no system in place including elements such as audits or supervisions to verify the effectiveness of official controls carried out by the local CAs.

78. Until January 2017 the CGOs were responsible for the official controls while after this date such this responsibility rests with the DGOs which informed the audit team that no data concerning the history of the establishments have been provided to them.

79. Official samples taken by the local CAs during these inspections tested negative for Lm.

80. The audit team visited two freezing establishments in two different counties. The FBOs visited informed the audit team that they had already been inspected by the CCA and local CAs concerning microbiological contamination of FNAO.

First freezing establishment

81. The last comprehensive inspection performed by the CGO was carried out on 17 November 2015 followed by its follow-up on 15 September 2016 to verify the implementation of corrective measures mainly concerning structural and maintenance aspects. This establishment's production amounted to significant volumes. This information was not available for the design of the risk based control frequency (see point 42).

82. Although the follow-up ended in an unsatisfactory manner, identifying further non-conformities always linked to structural/maintenance aspects, no further inspections were planned by the CGO. The audit team was informed by the CAs that the following points were part of their official controls:

- HACCP risk analysis
- pest and rodent control
- traceability
- microbiological tests carried out by the in house-laboratory of the company and an external accredited laboratory

No non-compliances have been documented.

83. On February 2018 the FBO received from his Polish partner company information concerning the presence of Lm in its produce. Nevertheless he did not inform the CA about this situation. On 7 February 2018, the DGO in charge of official control since January 2017 carried out its first inspection to this FBO in the context of a RASFF notification.

84. Within the inspection, the DGO noticed that the in house-laboratory of the company which performed also the tests for Lm and Salmonella spp. was not registered, as required by national provisions, but no measures were taken to stop the activities of the laboratory. Within the inspection also official sampling (counter sample of the company from the same batch mentioned in the RASFF alert 2018.0216) was performed.
85. On February 2018 the NRL informed the DGO, that the sample was Lm positive (1,400 cfu/g). Due to the fact that the batch was already recalled from the market no further measures were taken by the CA or requested from the FBO (such as environmental testing), regardless of the high plate count.

86. On March 2018, the CCA decided to carry out a joint inspection with the DGO which identified:
   - Structure and maintenance non compliances
   - Specific microbiological hazard (i.e. Lm) not addressed in the HACCP plan's risk analysis;
   - Laboratory methods used by the company’s own laboratory not in line with Regulation (EC) 2073/2005 (methods and number of sample units taken were not fit for purpose);
   - Cross contamination risks and absence of a high care zone;
   - Labels of products could mislead the consumers.

87. The DGO, asides from the structure and maintenance non compliances, did not notice other non-compliances during the previous official controls.

88. The CAs considered that the deep frozen corn was an “unsafe product”, stopped the production and ordered the FBO to recall all batches of corn produced after 13/08/2016. From this point:
   - the CCA took over the responsibility for this establishment;
   - the FBO started to take measures to remedy the non-compliances.

89. After this joint inspection a number of different on the spot controls were carried out by the CCA to search for the cause of the Lm contamination of the products. The local CAs were not involved in these inspections. The results of environmental samples taken on the production lines revealed as the possible source a contaminated chopper plate after the blanching step.

90. As the CCA found Lm serotype IVb in a surface sample after cleaning and disinfection on the production lines, on 29/06/2018 the recall was expanded to the whole production between 13/08/2016 and 20/06/2018. In addition, the remaining production lines of the plant were stopped. Only pilot scale productions for testing purposes were allowed.

91. Company’s own check and official sampling on new production trials showed again a contamination with Lm. Therefore the FBO stopped the production tests on 01/08/2018 and established a team with internal and external experts in order to identify the source and solve the problem. After reviewing the new hygienic design of the plant and the upgraded sampling plan the CCA allowed production restart at the 14/08/2018. The CCA carried out on the spot controls and sampling (environmental samples) rendering negative results in the production area. Nonetheless, Lm was identified in the packaging area.

92. The CCA and the FBO were not able to explain this contamination in the packaging area. However, in the last two inspections carried out by the CCA on January 2019 and May 2019, no non-compliances were detected.
93. At the closing meeting the audit team was informed by the IT system manager that in March 2019 contrary to the information received previously by the DGO, an inspection performed by local CAs to this establishment was uploaded into the system. The CCA that took over official control to this establishment stated that it was not aware of this inspection.

Second freezing establishment

94. In the second freezing establishment the DGO carried out four inspections between 2017 and 2019 with the last inspection performed on March 2019. This inspection was initiated on foot of a consumer complaint concerning the presence of packaging inside the product. The inspection included the follow-up of non-compliances identified in previous controls. This inspection did not identify non-compliances. The inspections were carried out by a DGO inspector always accompanied by a CGO inspector with experience in the FNAO field.

95. On June 2018 the company was inspected by the CCA in the framework of a targeted campaign in the frozen fruit and vegetables sector. In the context of this campaign, samples of frozen fruits and vegetables were taken at retail level and investigated for the presence of *Lm*. The frozen sweet corn samples from this establishment taken during this campaign at retail level were positive for *Lm* (four samples out of five positive). Within the scope of the official control, the CCA assessed traceability and took product and environmental samples. No non-compliances were detected.

96. The audit team was informed by the DGO that, since 2013, this FBO takes environmental samples for microbiological contamination within the framework of the company’s own checks. Since November 2018 also surface sampling is carried out using a quick test for the presence of *Listeria* spp. The sampling takes place during production and after cleaning. So far, in 2019 seven positive results were obtained, e.g. from drains, brooms, but not from product contact surfaces.

97. The FBO informed the audit team that intensified cleaning of these areas was carried out which was deemed satisfactory by the CAs. No other measures were undertaken by the FBO and / or required by the CA.

98. The CA informed the audit team that with the help of external expertise the FBO is reconstructing the production lines, introducing high, middle and low care zones.

99. During the inspection the audit team noted poor hygiene, poor maintenance conditions (i.e. rust and cracks) of the structures, and two situations of possible direct contamination of food (beans):
   - beans packages stored in a box leaning directly on the floor;
   - dirty outer part of a big bag containing frozen beans in bulk directly in contact with a surface intended for contact with food.

100. The CA requested corrective actions for hygiene and maintenance problems. Concerning the two situations of potential food contamination, the CA indicated the first situation as non-compliant but did not request immediate action from the FBO.
101. The second situation was deemed compliant by the CA as the outside of the bag did not touch the food (frozen beans). The fact that it touched a surface intended for contact with food (conveyor belt for packing machine), was deemed compliant by the inspectors contrary to the requirements of Annex II, Chapter V and Chapter X of Regulation (EC) No 852/2004. In addition, such types of bags are stored in a refrigerated cell with other products, pass through an open courtyard to enter the packing room and could have been in contact with other unclean or contaminated surfaces. This was not considered by the inspector.

102. The CCA representatives present at this visit did not agree with the assessment of the CA because the big bag could represent a source of direct contamination of food. However, no action was taken by the CAs or requested from the FBO.

**Producers of Seeds for Sprouting**

103. Producers of seeds for sprouting are listed at central level and since 2019 they are under official control. Due to their low number (six), the CCA decided to carry out the official controls itself, in order to maintain inspector knowledge at the required level.

104. Four out of six seed for sprouting producers were first inspected in March 2019 using the primary production checklist. The CCA informed the audit team that there was no production of seeds for sprouting and no product in store. The official controls did not identify non-compliances. The CCA informed the audit team that two out of the six producers stopped the activity.

**Sprout-Producing Establishments**

105. Until 31 December 2016 sprout producing establishments' inspections were performed by the county CA inspectors. Since this date this responsibility has been transferred to the DGOs. Checklists used were attached to the reports.

106. The risk based plan of official controls prescribes yearly inspections. However, the CCA and the CAs informed the audit team that due to resource constrains they are not able to meet that frequency (see points 40, 112, 116 and 117).

107. The audit team observed two inspections, each one in a different county. One of the establishments was first approved in April 2015 and the other one in April 2019. In both establishments only minor hygienic deficiencies were noticed by the CA.

108. In the first sprout producing establishment visited the seeds for the different varieties are obtained from two Italian and five Hungarian suppliers. During inspection, it was noted by the audit team that one of the Italian suppliers was selling mung bean seeds labelled as Organic – Italian origin. The CA detained the seeds until obtaining a clarification by the Italian supplier. In parallel, the CCA informed the Italian CAs and asked for clarification.

109. This sprout-producing establishment was granted a derogation for preliminary testing for seeds for sprouting after six consecutive month of testing with satisfactory results. The tests of final product were carried out according to the requirements of Regulation (EC)
No. 2073/2005. Every month five samples are tested for the presence of *Salmonella* spp. and STEC, twice a year tests for the presence of *Lm* were performed.

110. Environmental checks of production surfaces for the presence of *Lm* were also performed twice a year. Furthermore the FBO implemented own microbiological checks for the drinking water used for soaking and washing seeds for sprouting and sprouts.

111. The fact that contrary to the EURL guidelines the environmental checks were carried out after cleaning and disinfection before starting the new production, was not noticed by the CA.

112. Inspections in the sprout producing establishment were carried out in the framework of approval in 2015 and in 2019. For the inspection periods 2016/2017 and 2017/2018 there was no evidence of an official inspection. The inspectors informed the audit team that all these inspections were uploaded into the system.

113. In the second sprout producing establishment visited by the audit team the seeds for sprouting are obtained from two Italian, one German and one Polish supplier and also from three small producers in Hungary. During inspection the CA noted in the seed storage room two different kinds of mung beans, one from an Italian supplier from 2018 and one from a German supplier from 2017. Traceability checks showed that both consignments were not accompanied by an import certificate, in accordance with Regulation (EU) No 208/2013. On the documents (receipt, organic certificate and invoice) of the German supplier the origin of the mung beans was unclear, but on the receipt a second consignment of fenugreek seeds from India was listed also without a correct import certificate.

114. The CA requested the FBO to act immediately in order to provide the certificate, which was obtained from the Italian supplier. In parallel, the CCA informed the German CAs and asked for clarification relating to the documents of the German supplier.

115. At the time of the audit team visit, this sprout-producing establishment has not received a derogation for preliminary testing of seeds for sprouting because the DGO did not interpret correctly Annex I, Chapter 3, Section B of the Regulation (EC) No 2073/2005. Therefore all new batches were tested according to the requirements of Regulation (EC) No 2073/2005. Also the monthly tests of the finished product as required by Regulation (EC) No 2073/2005 and the tests for *Lm* (product and environmental samples) were carried out correctly.

116. Inspections in this sprout producing establishment were carried out in 2016 and in 2019. For the inspection period of 2017/2018 there were no inspection documents (checklists or reports) available and due to personnel changes the CA could not provide evidence of official controls performed in this period.

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4 EURL *Lm* – European Union Reference Laboratory for Listeria monocytogenes Guidelines on sampling the food processing area and equipment for the detection of Listeria monocytogenes - Version 3 – 20/08/2012, Maisons Alfort, Laboratory for Food Safety, ANSES, France.
117. Despite the fact that inspections should be uploaded in the IT system the CAs informed the audit team that the system is not reliable, as the limited CA resources cannot ensure the regular up-date of the system.

118. In 2019 in particular, a joint inspection by the CCA and DGO, its follow-up and a joint inspection with CGO and DGO for approval were carried out. However, in none of these inspections the fact that batches of organic mung beans were sourced without import certificates, as required by Regulation (EU) No 211/2013, was noticed. It is worth to mention that organic mung beans were clearly labelled as "Origin: Agriculture non EU".

119. The CCA confirmed that the same approach is used for inspection of sprout-producing establishments throughout Hungary.

Packers and Retailers of Seeds for Sprouting

120. The audit team visited one packer, wholesaler and retailer of seeds for sprouting (alfalfa and radish) who was also an internet seller. The inspector who is responsible for official controls in the establishment gave a short overview over the normal content of such a control. Normally the main point for official controls is whether all distributers in the seed chain kept seed traceability records as required under Article 3 of Regulation (EU) No 208/2013. No seeds from non-EU countries were present. The audit team checked the last three consignments, which all were delivered from an Italian supplier; the origin was in all cases Italy.

121. The reports of the previous inspection were available and did not document non-compliances related to seeds for sprouting. The CA informed the audit team that a report would be always completed following the inspection and a copy given to the FBO.

122. The CCA confirmed that the same approach is used for inspection of packers and retailers throughout Hungary.

Other Control Systems

123. According to data provided by FBOs, major growers that supply to supermarkets are certified under private quality control schemes.

124. The CCA informed the audit team that these private schemes, so far, have not been taken into account in the planning of official controls. However, private certification schemes are included as a question in the checklist used for official controls at primary production. Being certified results in less questions to be addressed by the inspector to the FBO during official controls. This results in less time needed for inspections.

Non-Compliant Products

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

126. Legal powers to take measures or to impose sanctions are in place all 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.
Conclusions on implementation of official controls over FBO obligations

127. During official controls of FNAO the national checklist is used. This allows a uniform way of official controls in this sector. However, without sufficiently comprehensive background knowledge, inspectors can easily overlook aspects relevant for the prevention of microbiological risks.

128. Contrary to what is required by Article 54(1)(2) of Regulation (EC) No 882/2004, at primary production, the inspection / reporting system in place does not ensure that identified shortcomings are systematically followed-up.

129. The documentation regarding primary producers and processors official controls showed that non-compliances were rarely detected and, when detected, rarely followed up. This indicates that the official control system is not sufficiently able to identify and rectify shortcomings.

130. Due to the fact that each inspector controls only a few FNAO processing establishments, a lack of theoretical and especially practical knowledge was observed (i.e. shortcoming identified by CCA and no evidence that such shortcomings have been identified previously during DGO official controls). In addition, the fact that more experienced inspectors of CCA perform controls in such establishments without involving DGO or CGO does not help the local inspectors to gain experience in such controls. This weakens the effectiveness of official controls in the field of FNAO.

131. Also due to the inspector's lack of experience, the verification that the requirement concerning certification of seeds for sprouting imported from third countries into the EU is met was overlooked during official controls and therefore could lead to the use of imported seeds not complying with EU hygiene rules not being identified.

5.2.5 Official Sampling Procedures

Legal requirements


Findings

132. The CA informed the audit team that there is a national annual monitoring programme in place, which covers also microbiological hazards in FNAO. Additionally, samples for microbiological investigations are taken in case of suspicion or outbreak situations.

133. At primary production stage the official plan for 2017 and 2018 included 50 lettuce samples and 40 strawberry samples each for the detection of Salmonella spp. and/or Lm. However, 20 and 22 lettuce samples and 25 and 36 for strawberries were taken respectively with no non-compliances detected.

134. At the stage of processing, data related to the number of planned samples were not available. For 2016 zero samples were taken for frozen vegetables or frozen berries. In 2017, 3 samples for frozen vegetables and one for frozen berries were taken with no non-
compliances detected. In 2018, after the \textit{Lm} outbreak related to domestic production of frozen corn, the number of official samples for frozen vegetables increased significantly. Out of 458 official samples taken in frozen vegetables, 48 were positive to \textit{Lm}.

135. At retail level sampling of pre-cut vegetables, sprouts and vegetables intended to be eaten raw (for \textit{Salmonella spp.}, \textit{Lm} and STEC detection) and soft fruits (for the detection of virus) is in place. In 2018, frozen fruits and vegetables were included in the official plan for the detection of \textit{Lm} (see point 150).

136. In three counties, the audit team observed sampling at production sites, two for lettuce and one for strawberries. All inspectors demonstrated satisfactory knowledge of general sampling requirements (number of samples/sample size, stratified sampling) but shortcomings on microbiological knowledge. In two cases sample packaging and transportation procedure showed deficiencies, \textit{inter alia} regarding the handling of sterile bags and the handling of the batch from which the sample was taken. In two cases the sampling was not done in a way that prevents cross-contamination of the sample and the rest of the batch.

<table>
<thead>
<tr>
<th>Conclusions on Official Sampling Procedures</th>
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<tbody>
<tr>
<td>137. There is a national monitoring system in place, which covers microbiological hazards in FNAO on primary production, processing stage and retail level. However, sampling of frozen vegetables and fruits only started significantly after the 2018 \textit{Lm} outbreak linked to frozen corn and showed a large percentage of contaminated samples.</td>
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<td>138. The sampling procedure showed some deficiencies in practical implementation; therefore the official sampling procedure could not ensure the integrity of the samples for microbiological analysis in all cases investigated.</td>
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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

139. Microbiological laboratory investigations in FNAO are carried out by the NRL as part of the Food Chain Safety Laboratory (FCSLD), and four regional Food Chain laboratories. The FCSLD is designated as microbiological NRL \textit{inter alia} for \textit{Salmonella spp.}, STEC, \textit{Lm} and food-borne viruses. Additionally the FCSLD acts as regional laboratory for Budapest and the connected county. Furthermore, all investigations for STEC and foodborne viruses and the (molecular) serotyping of \textit{Salmonella}- and \textit{Lm}-isolates are carried out in the FCSLD.

140. The laboratory has a comprehensive quality management system and is accredited according to International Organisation for Standardization (ISO), EN ISO 17025:2005

141. The FCSLD is to coordinate and to supervise the four regional laboratories. This is done *inter alia* within a working group meeting twice a year and also with on-site-trainings for new colleagues. In this function, the FCSLD also organises proficiency tests (PT) for the regional laboratories and for private laboratories. The PTs covered since 2016 different matrices of FAO and FNAO, in 2016 *inter alia* pre-cut vegetable and in 2018 vegetable with mayonnaise.

142. *Salmonella*- and *Lm*-isolates from official controls are always sent to the NRL for further differentiation (molecular based serotyping). In outbreak situations the NRL will also request the strains isolated in private laboratories.

**Technical equipment and staffing situation**

143. The laboratory building is properly designed. In general, the technical layout follows the forward flow principle as required for cultural and molecular analysis.

144. The technical equipment includes besides the whole equipment for classical cultural microbiological methods also polymerase chain reaction (PCR) and real-time machines, meeting the current standards.

145. Culture media are mainly prepared from dehydrated media in one separated part of the laboratory. Performance testing of culture media is done in accordance to the current version of EN ISO 11133.

146. Tracking through the laboratory process is mostly based on written documentation in laboratory books. The audit team checked the traceability of the different steps of laboratory work on a random basis and found no non-compliances. The communication between the CA and the laboratory (sampling report, final results of the investigations, and report of the results) is done electronically via a national system also in place at the regional laboratories. The NRL has the possibility to check also the samples and the results of the investigations of the regional laboratory through the system.

147. The resources are 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**

148. Sample handling and sample processing follows clear structures with designated areas for every step in which the responsibilities are clearly designated.

149. The audit team focussed on classical cultural detection of *Salmonella spp.* and *Lm* and the molecular analysis of FNAO for food-borne viruses and STEC. All checked methods followed international standards or methods of the different EU-RLs. Every year the laboratory takes part on the different PTs organised by the EU-RLs always with satisfactory results. These points are the basis for highly reliable analytical results.
150. At present, for FNAO planned samples and samples of supposed foodborne outbreaks are analysed. In the sample period 2018/2019 overall 1,064 samples of FNAO were analysed for microbiological parameters, there were 65 non-compliances for \( Lm \) and one non-compliance for \( Norovirus \) (quick-frozen raspberries).

**Conclusion on Laboratory Performance**

151. The laboratory has the capacity in terms of staff, equipment and procedures to fulfil its role as microbiological NRL for *Salmonella spp.*, \( Lm \), STEC and food-borne viruses and its role as regional Food Chain Laboratory.

**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**

152. The CCA informed the audit team that following every inspection, a report is drawn up in line with Articles 8 and 9 of Regulation (EC) No 882/2004. A copy is signed and given to the FBO and one retained by the CA. A number of inspection reports were reviewed by the audit team and all were considered satisfactory.

153. Checklists, which are prepared at central level, are used for performing the inspection. Standard Operation Procedures guide setting out the actions to be taken in case of infringements, are in place.

154. The CCA informed the audit team that an audit system is in place and independent audits for all activities of the food chain inspection are performed. However, at the time of this audit evidence of audits or other mean of on-the-spot supervision over controls of FNAO were not provided.

**Conclusions on Procedures for Performance and Reporting of Control Activities**

155. The CA has procedures, instructions and checklists that enable the CAs to perform official controls of FNAO establishments and for establishments seeking approval, in a uniform fashion.

156. In accordance with Article 4(6) and Article 8(3) of Regulation (EC) No 882/2004, the CCA has procedures in place to carry out audits and/or otherwise verify the effectiveness of official controls. However, no evidence could be provided that in respect of FNAO within the scope of this audit, these procedures had been applied to date, thus precluding the identification of any shortcomings in the performance of official controls and the implementation of any corrective measures.

**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
Findings

157. The NFCSO Directorate for Food Safety Risk Assessment is the national contact point for RASFF notifications. Alerts are communicated to directory and local level, where applicable, and results of investigations are reported back. The audit team evaluated one RASFF notification from a Hungarian company. This notification was handled in a correct way, but the recall procedure was launched six days after receiving the RASFF. The audit team was informed that deadlines for launching actions are not indicated in the procedures.

Conclusion on RASFF

158. There is a system to manage RASFF notifications. The absence of deadlines for launching actions could lead to unsafe products remaining on the market longer than necessary, increasing the risk for citizens.

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

159. The table below summarises the follow-up to the relevant recommendations made in report DG SANTE 2016/8727-MR Final.

<table>
<thead>
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<th>No</th>
<th>Previous</th>
<th>Assessment</th>
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| 1. | Ensure better coordination and cooperation within the CCA, as required by Article 4(5) of Regulation (EC) No 882/2004, with a view to including producers of seed for sprouting in the scope of official controls. | Addressed  
Implemented  
See findings: 24, 103 and 104. |
| 2. | Ensure, as required by Article 1 of Regulation (EC) No 2073/2005, that official controls consistently enforce the requirements laid down by Annex I, Chapter 3.3, Part A.1 and Part A.2 of the said Regulation (as regards preliminary testing of seeds intended for sprouting and sprouts). | Addressed  
Implemented  
See findings: 40, 109, 110 and 115. |

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

160. The two recommendations made in the previous report on this topic, in respect of seeds for sprouting, have been fully implemented. As a result, progress was noted in respect of the implementation of a control system on primary production since the previous audit.

6 OVERALL CONCLUSIONS
There is a system for registering producers and processor of FNAO and for the registration and approval of sprout-producing establishments. Official controls are supported by official samples taken at the level of production, processing and retail. Regarding official samples, the appropriate laboratory capability and capacity is available.

However, the risk based planning showed major deficiencies concerning the prioritisation of official controls of FNAO and the organisation of such controls, including the lack of supervision. In addition, the system does not allow inspectors to gain and maintain sufficient experience in this field in order to perform effective controls.

This has a considerable impact on both the implementation of official controls, and their effectiveness. As a consequence non-compliances are rarely detected and enforcement of the relevant requirements is seriously affected.

Despite a major *Lm* outbreak linked to frozen corn processed in Hungary, the competent authorities have not taken measures to improve the system of official controls regarding FBOs' obligations. The system currently in place is not sufficiently capable to verify that FNAO is produced under conditions which comply with Regulation (EC) No 852/2004 to prevent contamination with pathogens.

As a result, official controls and enforcement would not be able to contribute to the prevention of further possible *Lm* contaminations in frozen FNAO, or to limiting the risk of non-compliant products being placed on the market.

Nevertheless, and in respect of the follow-up to the previous audit, actions taken have been effective in addressing the shortcomings identified at the time in particular in relation to seeds for sprouting.

7 CLOSING MEETING

A closing meeting was held on 16 May 2019 with representatives of the CCA and other CAs concerned. 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.
8 RECOMMENDATIONS

The CA are invited to provide details of any actions taken and planned, aimed at addressing the recommendation set out below, including deadlines for the completion ("action plan"), within 25 working days of receipt of the translated draft audit report.

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| 1   | Ensure coordination and cooperation within the CAs, as required by Article 4(5) of Regulation (EC) No 882/2004, specifically:  
• Coordination between CAs and CCA to exchange information in order to optimise resources and to help CA at local level to gain experience;  
• Access to the IT system to all actors involved in official control in order to have a more efficient use of the available information.  
*Recommendation based on conclusions: 18 and 130.*  
*Associated findings: 16, 51, 52, 78, 89 and 93.* |
| 2   | As required by Article 4(2)(c) and Article 6 of Regulation (EC) No. 882/2004, CAs should ensure sufficient number of qualified and experienced staff for official controls. In addition, it should increase the qualification of the inspectors involved in official controls by providing them with the relevant tools (i.e. training and expertise) in order to ensure effective and appropriate official controls.  
*Recommendation based on conclusions: 19, 127, 130, 131 and 138.*  
*Associated findings: 15, 17, 34, 45, 51, 52, 53, 64, 65, 75, 76, 84, 100, 101, 115, 117, 118 and 136.* |
| 3   | Ensure that when the CAs identify non-compliances at primary producers and processors, actions are taken to ensure that the FBOs remedies the situation as required by Article 54(1) of Regulation (EC) No 882/2004 in order to improve the effectiveness of the system.  
*Recommendation based on conclusions: 55, 128 and 129.*  
*Associated findings: 34, 37, 49, 63, 64, 65, 69, 74, 76, 82, 84, 86, 87, 99, 101 and 102.* |
| 4   | Ensure that the system of official control is risk based as required by Article 3(1) of Regulation (EC) No 882/2004 in order to prioritise for official controls FBOs with higher microbiological risks.  
*Recommendation based on conclusions: 57 and 58.*  
*Associated findings: 15, 42, 43, 45, 51, 53 and 54.* |
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| 5   | Ensure that CAs have procedures in place to verify the effectiveness of official controls in FNAO and to ensure that corrective measures are taken when shortcomings are identified as required by Article 8(3)(a) and (b) of Regulation (EC) 882/2004.  
*Recommendation based on conclusion: 156.*  
*Associated findings: 77 and 154.* |
| 6   | Define deadlines to take actions in case of RASFF alert notification to ensure that actions are taken without any delay as required by Article 50(3) of Regulation (EC) No 178/2002 in order to minimize the likelihood that unsafe products could remain on the market for longer times thus, increasing the risk for citizens.  
*Recommendation based on conclusion: 158.*  
*Associated finding: 157.* |

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

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
<th>Title</th>
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