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**Final report**

**EFTA Surveillance Authority's audit to**

**Iceland from 8 to 17 September 2025**

**to evaluate the system of official controls relating to microbial safety of food**

**of non-animal origin**

*In response to information provided by Iceland, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote. Comments to the draft report and information on the corrective actions already taken and planned by the Icelandic competent authorities are included in Annex 3 and 4 to the report.*

### **Executive Summary**

*This report describes the outcome of an audit carried out by the EFTA Surveillance Authority (ESA) in Iceland from 8 to 17 September 2025.*

*The primary objective of the audit was to verify compliance with European Economic Area (EEA) food safety legislation governing the production of food of non-animal origin (FNAO) and to evaluate the effectiveness of the official control systems in place.*

*The audit focused on official control systems in place for primary producers of leafy greens and soft berries, producers of cut fruits and vegetables and sprout producing establishments.*

*The audit found that Iceland has established an official control system for FNAOs which is generally functioning. Approved establishments are subject to sufficiently frequent official controls, and the competent authorities have clearly designated roles and responsibilities. They have developed some procedures and guidelines to support the implementation of controls, and there is a system in place for managing the Rapid Alert System for Food and Feed (RASFF) notifications.*

*However, the audit identified several weaknesses that undermine the effectiveness of the control system, so increasing the risk of unsafe products entering the market.*

*These include insufficient enforcement of corrective actions for non-compliances, inconsistent approaches to risk assessment and approval of food business operators and a lack of coordination and oversight between central and local authorities.*

*In addition, sampling and analysis procedures for microbial safety were found to be inadequate in several respects. Pooling of samples, lack of verification of the equivalence of alternative analytical methods and incorrect sampling practices for sprouts and ready-to-eat vegetables risk compromising the reliability of microbiological testing.*

*The report includes four recommendations addressed to the Icelandic competent authorities aimed at rectifying the identified shortcomings and enhancing the control system in place.*

## Table of Contents

<b>1</b>	<b>INTRODUCTION</b> .....	<b>4</b>
<b>2</b>	<b>OBJECTIVES AND SCOPE OF THE AUDIT</b> .....	<b>4</b>
<b>3</b>	<b>LEGAL BASIS FOR THE AUDIT</b> .....	<b>5</b>
<b>4</b>	<b>BACKGROUND - PREVIOUS AUDITS</b> .....	<b>5</b>
4.1	Background information .....	5
4.2	Previous audits .....	6
<b>5</b>	<b>FINDINGS AND CONCLUSIONS</b> .....	<b>6</b>
5.1	Legislative and implementing measures .....	6
5.1.1	<i>National legislation</i> .....	6
5.1.2	<i>National guides to good hygiene practice</i> .....	7
5.2	Competent authorities .....	7
5.2.1	<i>Competent authorities involved</i> .....	7
5.2.2	<i>Training of staff</i> .....	8
5.2.3	<i>Documented procedures and arrangements in place</i> .....	8
5.2.4	<i>Audits of competent authorities and control verification procedures</i> .....	9
5.3	Organisation of official controls .....	10
5.3.1	<i>Planning of official control</i> .....	10
5.3.2	<i>Approval and registration of food business operators</i> .....	11
5.4	Implementation of official control.....	12
5.4.1	<i>Primary producers of leafy greens and soft berries</i> .....	12
5.4.2	<i>Sprout producing establishments</i> .....	13
5.4.3	<i>Processors of cut fruits and vegetables</i> .....	14
5.5	Official sampling procedures and laboratories .....	15
5.6	Rapid Alert System for Food and Feed .....	16
<b>6</b>	<b>OVERALL CONCLUSION</b> .....	<b>17</b>
<b>7</b>	<b>FINAL MEETING</b> .....	<b>17</b>
<b>8</b>	<b>RECOMMENDATIONS</b> .....	<b>18</b>
	<b>ANNEX 1 - LIST OF ABBREVIATIONS AND TERMS USED IN THE REPORT</b> .....	<b>19</b>
	<b>ANNEX 2 - RELEVANT LEGISLATION</b> .....	<b>20</b>
	<b>ANNEX 3 - ICELAND'S COMMENTS TO THE DRAFT REPORT</b> .....	<b>22</b>
	<b>ANNEX 4 - ICELAND'S ACTION PLAN FOR CORRECTIVE MEASURES</b> .....	<b>23</b>

## 1 Introduction

The audit took place in Iceland from 8 to 17 September 2025. The audit team comprised two auditors from the EFTA Surveillance Authority (ESA).

ESA sent a pre-audit questionnaire to the Icelandic Ministry of Industries on 19 May 2025. ESA received the reply ('the pre-audit document') on 15 August 2025.

On 8 September 2025, an opening meeting was held at the Head Office of the Icelandic Food and Veterinary Authority (MAST) in Selfoss. The meeting included representatives from the Ministry of Industries, MAST and eight out of the nine Municipal Environmental and Public Health Offices (local competent authorities – LCAs). During the meeting, the audit team outlined the objective, scope, and itinerary of the audit. The Icelandic representatives supplemented the information provided in the pre-audit document with additional details.

Throughout the audit, representatives from MAST and the LCAs accompanied the audit team.

A final meeting was held at the MAST's Office in Reykjavík on 17 September, at which, the audit team presented its main findings and preliminary conclusions from the audit.

The abbreviations used in the report are listed in Annex 1.

## 2 Objectives and scope of the audit

The main objective of the audit was to verify compliance with applicable European Economic Area (EEA) food safety legislation governing the production of food of non-animal origin (FNAO) and to evaluate:

- The system of official controls in food hygiene to prevent microbiological contamination in FNAO.
- The system of official control in traceability of sprouts and seeds intended for sprouting, including applicable microbiological criteria and the approval of sprout-producing establishments.

In terms of scope, the audit focused on the planning and implementation of official controls, control procedures and sampling. The audit also focused on the production of sprouts, the cultivation of fruits and vegetables consumed raw (soft berries and leafy greens) and producers of cut fruits and vegetables.

The audit focussed on official controls performed in 2022-2024.

The findings and conclusions of the audit are based on the information provided in the reply to the pre-audit questionnaire, documents provided by the competent authorities during the audit and complemented by interviews with authorities' staff. In addition, review of food business operators (FBOs) documentation, interviews with FBOs staff as well as on-the-spot visits at the operators' sites were also the basis for the findings and conclusions.

The meetings with the competent authorities and visits to FBOs during the audit are listed in Table 1.

Table 1. Competent authorities and establishments/sites visited during the audit

Visits/meetings	Number	Comments
Competent authorities – central level	3	An initial meeting, clarification meeting and a final meeting between the audit team, MAST and LCAs.
Local Competent Authorities (LCAs)	5	There are nine LCAs in Iceland
Primary producers of leafy greens	3	Two were hydroponic growers
Primary producers of soft berries	2	Greenhouse growers
Sprout producing establishments	2	One of two sprout producers originally included in the itinerary was only producing microgreens
Producers of cut fruits and vegetables	2	

### 3 Legal basis for the audit

The audit was carried out under the general provisions of the EEA Agreement and relevant legislation, in particular Articles 116, 117 and 119 of Regulation (EU) No 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, as amended and as adapted to the EEA Agreement by Protocol I and Annex I thereto.

EEA legislation relevant to this audit is listed in Annex 2.

## 4 Background - Previous audits

### 4.1 Background information

FNAO is consumed in a variety of forms and is a major component of most meals. These food types have been associated with large disease outbreaks in the EEA:

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

The European Food Safety Authority (EFSA) concluded in a scientific opinion on the risk posed by pathogens in food of non-animal origin<sup>1</sup> that the top-ranking food/pathogen combination was leafy greens eaten raw and *Salmonella spp.*, followed by (in equal rank)

<sup>1</sup> [EFSA Opinion on the risk posed by pathogens in food of non-animal origin](#)

bulb and stem vegetables and *Salmonella spp.*, tomatoes and *Salmonella spp.*, melons and *Salmonella spp.*, and fresh pods, legumes or grain and pathogenic *Escherichia coli*.

In view of the number of large outbreaks, the high number of Rapid Alert System for Food and Feed (RASFF) notifications concerning products of non-animal origin and the time since the last audit carried out by ESA on the subject, it was decided to undertake an audit to Iceland on FNAO.

Information about the annual domestic production of leafy greens, soft berries and sprouts in Iceland was not provided. There is no export of leafy greens and soft berries from Iceland and trade is mainly with producers from within the EEA.

## 4.2 Previous audits

The last ESA audit relating to primary production on food of non-animal origin took place in September 2014<sup>2</sup>. The recommendations issued following that audit are closed and were not reviewed during this audit.

## 5 Findings and conclusions

### 5.1 Legislative and implementing measures

#### 5.1.1 National legislation

##### Legal Requirements

Article 7 of the EEA Agreement requires acts referred to or contained in the Annexes to the Agreement to be made part of the Icelandic internal legal order.

##### Findings

1. Iceland provided information in the pre-audit document about legislative and implementing measures. Information on current laws, regulations, and administrative provisions applicable to the control of food of non-animal origin was provided to the audit team.
2. Article 6 of Regulation (EU) No 2017/625 requires competent authorities to ensure their compliance with the requirements of that regulation by carrying out internal audits or have audits carried out on themselves and to take appropriate measures in light of those audits. This requirement is made part of the Icelandic internal legal order in Article 27.e. of the Icelandic Food Act No 93/1995<sup>3</sup> (*Lög um matvæli nr. 93/1995*).
3. Article 9(1) of Regulation (EU) No 2017/625 sets out that the frequency of official controls shall be based on the risk associated with the FBOs activities and their performance during past official controls. The requirement is made part of the Icelandic internal legal order in Article 22(7) of the Icelandic Food Act No 93/1995. The Icelandic Food Act also sets out the legal basis for the relevant minister to adopt a regulation on the publication of the results of official controls and the performance classification of FBOs.
4. The requirements of Article 148 of Regulation (EU) No 2017/625 and Article 6 of Regulation (EC) No 852/2004 are reflected in Article 9 of the Icelandic Food Act which sets out which FBOs require approval from the competent authorities, and which require registration. Primary producers of fruits and vegetables do not require an

<sup>2</sup> [ESA's audit report 2014 – food of non-animal origin](#)

<sup>3</sup> [The Icelandic Food Act No 93/1995](#)

approval but are obliged to register its operations with the relevant LCA. All other FBOs within the scope of the audit require an approval.

5. The national rules for the direct supply of small quantities of primary products to the consumer are provided in the Icelandic regulation on small quantities and primary producers (*Reglugerð nr. 580/2012 um framleiðslu og markaðssetningu aðila undir smáræðismörkum á matvælum og afhendingu frumframleiðanda á litlu magni matvæla beint til neytenda og staðbundinna smásölufyrirtækja*)<sup>4</sup>. The regulation defines the quantities for various products and distribution that classifies as small quantities of primary products.

### 5.1.2 National guides to good hygiene practice

#### Legal Requirements

Articles 7 and 8 of Regulation (EC) No 852/2004

#### Findings

6. Currently, Iceland does not have national guides to good practice for primary producers of leafy greens, soft berries, sprouts, or processors of cut fruits and vegetables.

#### Conclusions

7. Relevant EEA legislation concerning official controls, hygiene and microbial safety of food of non-animal origin and the traceability of sprouts and seeds has been made part of Iceland's internal legal order in accordance with Article 7 of the EEA agreement. This enables the competent authority to carry out official controls on food hygiene to ensure production of food of non-animal origin meets hygiene requirements and prevents microbiological contamination.

## 5.2 Competent authorities

### 5.2.1 Competent authorities involved

#### Legal Requirements

Articles 4(1) of Regulation (EU) No 2017/625

#### Findings

8. The Ministry of Industries is the lead Ministry for policy, co-ordination and transposition of legislation concerning food and feed, veterinary and phytosanitary matters.
9. The Icelandic Food and Veterinary Authority (MAST) is the central competent authority for food and feed safety, animal health and animal welfare.
10. There are nine municipal environmental and public health offices (local competent authorities, LCAs) in Iceland. Each LCA operates under the jurisdiction of a local public health committee, comprising district control staff, five politically appointed members, one member appointed by the local nature preserve committees, and one member representing the confederation of Icelandic enterprises.

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<sup>4</sup> [Icelandic regulation of small quantities and primary producers](#)

11. MAST has a supervisory role of all official controls of FBOs being carried out in Iceland, which includes ensuring that the implementation of the official controls is harmonised throughout the country.
12. Within the scope of this audit, official controls were exercised primarily by the various LCAs. All establishments visited were under the official control of the LCAs.

### 5.2.2 *Training of staff*

#### Legal Requirements

Articles 5(4) and 130(4) of and Chapter I of Annex II to Regulation (EU) No 2017/625

#### Findings

13. MAST documents its staff training program in its quality manual. New employees are introduced to MAST's structure, roles, responsibilities, and key procedures. Staff responsible for official controls must complete specialized training before acting independently.
14. The audit team was informed that all employees of the LCAs have a university degree relevant for the work being carried out. All new LCA inspectors are required to attend a course for health inspectors. The course duration is 5 weeks and covers e.g. food, environment and occupational issues.
15. BTSF training is available for employees, both from MAST and from the LCAs. The audit team met two inspectors from two different LCAs that had participated in a Better Training for Safer Food (BTSF) course on food hygiene at primary production.
16. No central procedures are in place for disseminating the training that competent authorities' staff participate in. Dissemination of knowledge from training courses, such as BTSF that the audit team examined, was limited to the competent authority the inspector worked for. This is not in line with Article 130(4) of Regulation (EU) No 2017/625. There it states that competent authorities shall ensure that the knowledge acquired through training activities, such as BTSF, is disseminated appropriately.
17. The audit team observed training procedures in the competent authorities visited. The use of mentor training and joint inspections is often used to transfer knowledge to new inspectors. It varies between LCAs how long the training takes before an inspector can carry out inspections unsupported.
18. Not all LCAs had written records of training of staff to provide overview of the competence and training.

### 5.2.3 *Documented procedures and arrangements in place*

#### Legal Requirements

Articles 2(1), 5(1)(a-c), 9(1) and 12(1) of Regulation (EU) No 2017/625

#### Findings

19. MAST has a documented quality management system in place. Several of the procedures, guidelines and work instructions are relevant to the scope of the audit. An inspection manual<sup>5</sup> has been developed to assist the LCAs in their official controls. The editorial board consist of one representative from MAST and three from the LCAs.

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<sup>5</sup> [Inspection manual for official control by the LCAs](#)

20. The inspection manual is used for official control of all FBOs that fall under the supervision of the LCAs. That includes the primary producers of leafy greens and soft berries. However, the inspection manual does not cover all the requirements for primary producers as listed in Annex I to Regulation (EU) 852/2004. This is not in line with the requirements of Articles 2(1) and 5(1)(a) of Regulation (EU) No 2017/625 that competent authorities carry out controls to verify the compliance with the relevant EEA rules and ensure the effectiveness and appropriateness of those controls.
21. MAST and the LCAs have published a guidance document describing the method of risk categorisation and performance evaluation<sup>6</sup> to be used by the LCAs to determine the frequency of official controls of the FBOs under their control.

#### 5.2.4 Audits of competent authorities and control verification procedures

##### Legal Requirements

Articles 6 and 12(2) and (3) of Regulation (EU) No 2017/625

##### Findings

22. MAST has a system in place for carrying out internal audits on different control areas, including operations of the LCAs. The procedures are part of MAST's quality control system and describe the objectives and scope of the internal audits.
23. The country profile Part I<sup>7</sup> for Iceland describes that the internal audit system of the competent authorities. It has been developed and approved by the Ministry of Industries. The quality manager at MAST is responsible for the internal audit process. A five-year plan, multi-annual national internal audit plan (MANIAP) is issued and approved by the audit steering committee.
24. The MANIAP covers the responsibilities based on Regulation (EU) No 2017/625 and the competent authorities involved in official control in Iceland, MAST and the LCAs.
25. The audit team noted that no internal audits have been carried out on the official control system regarding primary production and processing of FNAO in the last five years. The last internal audit on controls carried out by the LCAs was conducted in 2022. In total, seven out of the nine LCAs have been subject to an internal audit since 2016. The two remaining LCAs had never been audited. Furthermore, the audit team noted that the MANIAP for 2024-2028 did not include any internal audits for the controls carried out by the LCAs until 2028. This is not in line with Article 6(1) of Regulation (EU) No 2017/625. Every competent authority must carry out internal audits or have audits carried out on themselves.
26. The audit team further noted that the LCAs did not take corrective actions in all cases where the internal audits had identified shortcomings. This is not in line with the requirements of Articles 6(1) and 12(3) of Regulation (EU) No 2017/625 that competent authorities shall take appropriate measures and corrective actions in light of the results of internal audits and where control verification procedures have identified shortcomings.

##### Conclusions

27. The competent authorities for primary producers of leafy greens and soft berries, sprout producing establishments and processors of cut and washed fruits and vegetables have been clearly designated. This provides a good basis for the implementation of the official control system.

<sup>6</sup> [Risk and performance categorisation](#)

<sup>7</sup> [Country Profile Part 1 Iceland July 2024.pdf](#)

28. The effectiveness of some of the training is reduced due to a lack of dissemination to all relevant staff. This may lead to inconsistency in the official controls.
29. The lack of documented procedures encompassing all relevant criteria, combined with unclear instructions for inspectors conducting inspections on primary producers of food of non-animal origin, undermines the effectiveness and appropriateness of the official controls.
30. The competent authorities have not carried out internal audits or had audits carried out on themselves in relation to the official control system for microbiological safety of food of non-animal origin. The absence of verification of the official controls in this sector hinders the competent authorities from ensuring their compliance with the relevant legislative requirements and identifying any weaknesses or gaps in the official control system.

### 5.3 Organisation of official controls

#### 5.3.1 Planning of official control

##### Legal Requirements

Articles 9 and 10 of Regulation (EU) No 2017/625

##### Findings

31. The LCAs plan their controls on a yearly basis. Fees for the controls are based on the total hours that the controls are expected to take. The total fee is the sum of four factors: Preparation + travel time + actual inspection + report writing = total time.
32. Each LCA sets up its control plan in Excel, which allows the LCAs to monitor the status of the planned inspections. The system also permits an overview of inspections that had not been carried out in the previous year. Those will be highlighted and prioritised in the coming year. The FBOs are divided between the available inspectors. However, MAST does not have access to or oversight over these control plans.
33. The LCAs create their individual control plans based on different approaches. Some LCAs use the system for risk categorisation that was developed by MAST and the LCAs to determine their control frequency. The audit team was informed that other LCAs use an older system which is based on guidelines set out for the system to calculate control fees for the LCAs and an expert panel of experienced inspectors. Using different system for risk categorisation is not in line with the requirements of Article 4(2) of Regulation (EU) No 2017/625 to ensure efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls across the territory of the EEA State.
34. None of the LCAs consider the outcome of previous controls nor the FBOs past record of compliance with relevant EEA legislation when determining the frequency of the official controls. This is not in line with Article 9(1)(c) of Regulation (EU) No 2017/625.
35. The audit team noted, in two different LCAs, that the control plan was not always followed. The team found two primary producers of vegetables that had no records of inspections being conducted. One of these producers had a planned frequency of annual controls and the other a planned frequency of biennial controls. This had not been noted or followed up by LCA management.
36. In one LCA the head office did not have access to the inspection reports, nor an overview of the inspections carried out in one part of the LCA's district. The inspector in that area did not use the same system for registering the inspections as the rest of the inspectors in that LCA.

### 5.3.2 Approval and registration of food business operators

#### Legal Requirements

Article 148 of Regulation (EU) No 2017/625

Article 6 of Regulation (EC) No 852/2004

Article 2 of Regulation (EU) No 210/2013

#### Findings

37. For the scope of this audit, processors of cut fruits and vegetables and producers of sprouts must be approved, and primary producers of fruits and vegetables are obliged to register with the relevant LCA (see paragraph 2). The audit team noted that, all the producers of leafy greens and soft berries visited during the audit were approved, and that it is an established administrative practice to require primary producer that packs the products in consumer packaging, to be approved.
38. The competent authorities require most FBOs covered by this audit to be approved. The FBOs that are only required to meet the requirements of Regulation (EC) No 852/2004 are subject to approval by the LCAs. Iceland has not informed ESA and other EEA States that the LCAs require FBOs that must meet the requirements of Regulation (EC) No 852/2004 to be approved, as required by Article 6 of that regulation.
39. The LCA's inspection manual includes guidelines for approval of establishments and how registration of primary producer should be organised. The LCAs have a registration form on their website for FBOs applying for approval. The responsible person can fill out the basic information about the production, etc. However, there was not in all cases the possibility to register online an establishment that only requires a registration.
40. The inspection manual for the LCAs outlines an approval process that the LCAs can adopt and use for their approvals. This process includes issuing an initial conditional approval for no more than three months. Before the end of that period a final audit must take place before a full approval is granted. However, there is an inconsistency in how the guidelines are applied between the LCAs. The audit team saw examples of FBOs that got conditional approval for three months but also examples of FBOs that got approval directly.
41. The audit team noted that in one case an FBO had extended their operation to include the production of strawberries. According to the guidelines in the inspection manual all FBOs activities that require approval must be inspected before operations can start. In this case, the operations started in January 2025, but the LCA was not aware of the change until the audit team visited the FBO in September 2025. Subsequently, the LCA took actions to inspect and issue a new approval incorporating the new production.
42. Some LCAs confirmed to the audit team that their understanding was that FBOs that do not require an approval are not part of the official control plan and are therefore not inspected regularly with appropriate frequency. This is not in line with Article 9(1) of Regulation (EU) No 2017/625.

#### Conclusions

43. The risk categorisation of operators in Iceland is inconsistent. In addition, operators past record are not considered when official controls are being planned. Some local competent authorities plan their risk-based control based on guidelines published by MAST, while others use their own system. This weakens the consistency and effectiveness of the official controls.

44. There is an inconsistent approach for the approvals of food business operators both between and within the competent authorities. The guidelines for approvals of operators are not always followed which may affect the quality and consistency of approvals.
45. There is a lack of oversight of the official control plans on a national and local level. MAST does not have an efficient and effective means of coordinating official controls between the different authorities. This weakens the consistency and effectiveness of the official controls.

## 5.4 Implementation of official control

### 5.4.1 Primary producers of leafy greens and soft berries

#### Legal Requirements

Articles 9(1), 14 and 138 of Regulation (EU) No 2017/625

Article 18 of Regulation (EC) No 178/2002

Articles 4 and 5 of and Annex I to Regulation (EC) No 852/2004

Regulation (EC) No 2073/2005

#### Findings

46. Iceland requires primary producers of leafy greens and soft berries that handle and pack their products in consumer packaging to be approved. In addition, these producers are required to fulfil the requirements of Chapter I of Annex II to Regulation (EC) No 852/2004.
47. The audit team visited five primary producers: three producers of leafy greens and two soft berry growers. Two of the leafy green producers used hydroponic cultivation in a greenhouse and one was an open-field cultivation. Both berry producers produced mainly strawberries in a greenhouse.
48. There is no checklist available to inspectors to facilitate the inspections of producers of leafy greens or soft berries.
49. All the producers of leafy greens had been inspected on a regular basis. On average, these producers were visited every other year. One grower of leafy greens in fields had not been recently inspected during the main harvesting season. The producers visited had all been inspected according to the requirements of Annex II to Regulation (EC) No 852/2004.
50. The audit team visited two producers of soft berries. One had been inspected on a regular basis, on average every other year. The last report was from early September 2025. This producer had been inspected according to the requirements of Annex II to Regulation (EC) No 852/2004. The other producer took over an existing producer of strawberries in January 2025 and had not been inspected and approved as is required by the approval procedure before operations can start (see para 40).
51. Two operators used hydroponic system for growing leafy greens. The incoming water was from the municipality, and the audit team was presented with the most recent microbiological results from the water supply/water plant. There was no treatment of the water. At one hydroponic leafy greens producer, neither the FBO nor the LCA sampled the recirculated water used for production.
52. The audit team noted non-compliances in the FBOs visited which included:

- a. Some of the crates used for harvested products had not been cleaned appropriately before use as is required by point 4(b), Part A of Annex I of Regulation (EC) 852/2004.
  - b. Declaration of compliance for plastic packaging materials was not available in all cases as is required by Article 16(1) of Regulation (EC) 1935/2004 – this had not been previously checked by the LCA.
53. The enforcement procedure described in the inspection manual states that non-compliances must be corrected as soon as possible, and no later than three months after an inspection took place. The corrective actions aimed to rectify the non-compliances shall be evaluated in next inspection. If the corrective actions have not been carried out or are insufficient, the non-compliance will be classified as a serious non-compliance.
54. One FBO had non-compliances in a report from 2021, and the next scheduled audit was in 2025. The LCA had not followed up the non-compliances after the inspection in 2021 as required by Article 138(1)(b) of Regulation (EU) No 2017/625.
55. The audit team noted that the handling of non-compliances was not in line with the procedure in the inspection manual. One FBO had the same non-compliance in three control visits, 2021, 2023 and 2025 without it being elevated to a serious non-compliance and taking necessary enforcement actions. Another FBO had the same recurring non-compliances in inspections from 2022, 2024 and 2025. This is not in line with Article 138(1)(b) of Regulation (EU) No 2017/625.
56. The audit team noted that for the cases mentioned in paragraph 55, one of the outstanding non-compliances had been rectified at the time of the audit visit. For the other case the LCA had started enforcement actions against the FBO.
57. The audit team further noted that, the primary producers of leafy greens and soft berries visited during the audit all met the general hygiene requirements of part A of Annex I to Regulation (EC) No 852/2004. However, four out of five did not fulfil the requirements of Annex II to Regulation (EC) No 852/2004 as required by Icelandic administrative practice.

#### 5.4.2 *Sprout producing establishments*

##### Legal Requirements

Articles 9(1), 14 and 148 of Regulation (EU) No 2017/625

Article 18 of Regulation (EC) No 178/2002

Articles 4 and 5 and Annex I of Regulation (EC) No 852/2004

Regulation (EU) No 208/2013

Regulation (EU) No 210/2013

Regulation (EC) No 2073/2005

Regulation (EU) No 2020/2235

##### Findings

58. The audit team visited one sprout producing establishment and one producer of microgreens. During the visit to one of two sprout producers included in the itinerary it became evident that it produced only microgreens, and the production was therefore outside the scope of the regulations applying to sprout producers.

59. The sprout producer visited had been approved in accordance with Article 148 of Regulation (EU) No 2017/625 and Article 2 of Regulation (EU) No 210/2013. Evidence was seen of the initial application, on site visits, document control, conditional approval, and final approval.
60. The sprout producing facilities and equipment were clean and in good condition.
61. The sprout producer presented an import certificate for the batch of seeds, which was currently used to produce sprouts. However, the audit team observed missing labels on some of the bags of seeds, compromising the traceability link between the bags and the certificate.
62. The audit team noted that in some cases, there was a lack of traceability between the analysis conducted by the laboratory and the batch or product being tested.
63. The FBO did not have procedures in place to conduct preliminary testing of the batches of seed in accordance with the requirements of point A.1 of Section 3.3 of Chapter 3 of Annex I to Regulation (EC) No 2073/2005. This had not been identified by the LCA in the approval process of the establishment or in subsequent inspections.
64. The batch of seeds that was used to grow sprouts was not tested when it was received in May 2024. The first sample was not taken until the summer of 2025. By that time, the batch was almost finished.
65. The sampling that was done in 2025 of the seeds was not carried out in accordance with the requirements of point A.1 of Section 3.3 (Sampling rules for sprouts) of Chapter 3 of Annex I to Regulation (EC) No 2073/2005. A representative sample of 0,5% of the weight of the batch was not taken.
66. Monthly sampling of sprouts was not done correctly. The sampling should take place at the stage when there is the highest probability of finding Shiga toxin producing *E. Coli* (STEC) and *Salmonella* spp. The minimum is 48 hours after the start of the sprouting process, the audit team saw laboratory reports for monthly testing where samples were taken after 24 hours.
67. The LCA has taken random samples of sprouts for verification FBOs sampling for the microbial safety of the products.

#### 5.4.3 Processors of cut fruits and vegetables

##### Legal Requirements

Articles 9(1) and 14 of Regulation (EU) No 2017/625

Article 18 of Regulation (EC) No 178/2002

Articles 4 and 5 and Annexe II to Regulation (EC) No 852/2004

Regulation (EC) No 2073/2005.

##### Findings

68. The audit team visited two processors of cut and washed fruits and vegetables. Both were small, with between 7-10 employees. The relevant LCAs inspect the establishment on a regular basis, at minimum yearly.
69. One of the establishments has been certified in accordance with a recognised Global Food Safety Initiative (GFSI) standard. The other was in the process of attaining the same certification.

70. The audit team observed partial inspections by the LCA inspectors and concluded that that they were carried out in a professional manner. Previous inspection reports were thorough and comprehensive.
71. The processing facilities were mostly in good condition. The audit team noted in one FBO dirty equipment left behind by maintenance staff and some of the doors to the outside in another did not close properly. The LCA inspectors did identify these non-compliances in the audit.
72. One FBO had taken samples of ready to eat vegetables for *Salmonella* and *Listeria monocytogenes* testing. However, the sample consisted of five different types of vegetables. Instead of five units of the same type, the FBO took five units of different vegetables to make up the sample. This had not been identified by the LCA and is not in line with the requirements set out in Chapter 1 of Annex I to Regulation (EC) No 2073/2005.
73. Environmental sampling for *Listeria monocytogenes* is carried out by the FBOs. However, one FBO took the samples after cleaning and disinfection. The MAST guidance<sup>8</sup> on Regulation (EC) No 2073/2005 highlights the importance of taking environmental samples for *Listeria monocytogenes* from food contact surfaces during production.

### Conclusions

74. Icelandic administrative practice requires primary producers that pack their products in consumer packaging to be approved and fulfil the requirements of Chapter 1, Annex II of Regulation (EC) 852/2004. However, the official controls do not ensure that the FBOs comply with these requirements. This weakens the consistency and effectiveness of the official control system.
75. Enforcement was insufficient to ensure that operators address non-compliances and prevent further occurrences of non-compliances, risking unresolved issues and potentially compromising product safety by failing to meet legal requirements. This may result in unsafe products being placed on the market.
76. The approval process for sprout establishments was thorough. However, the official controls do not ensure that sampling and testing rules for sprouts are correctly implemented by the FBOs. This may result in unsafe sprouts being placed on the market.
77. Sampling of food of non-animal origin was not always in line with the legal requirements. This may lead to unreliable investigation and verification of microbiological safety of food of non-animal origin.

## **5.5 Official sampling procedures and laboratories**

### Legal Requirements

Articles 34 and 35 of Regulation (EU) No 2017/625

Chapter 1 of Annex I to Regulation (EC) No 2073/2005

### Findings

78. MAST has guidelines for official sampling of food, including food of non-animal origin. The LCAs use these guidelines when carrying out their official sampling for microbial safety of food of non-animal origin.

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<sup>8</sup> [MAST guidance on microbiological criteria](#)

79. The audit team saw examples where the LCAs had taken official samples for verification purposes of FBOs sampling and analysis.
80. The FBO producing microgreens did not sample products to verify compliance with the *Listeria monocytogenes* standards set out in Chapter 1 of Annex I to Regulation (EC) No 2073/2005. This had not been identified by the LCA controlling this FBO.
81. Sampling of cut fruits and vegetables (ready-to-eat) was reviewed in two establishments. One had sampled five different types of vegetables to constitute a single sample (see also para 71). Samples from both establishments had been pooled by the laboratory and the results were presented as one result in 25 grams rather than in 125 grams. This is not in line with Article 5(5) of Regulation (EC) No 2073/2005.
82. The establishments used laboratories with testing methods for *Salmonella*, *E. coli*, and *Listeria monocytogenes* that differed from those in Annex 1 of Regulation (EC) 2073/2005. The competent authority does not routinely check if these methods provide at least equivalent guarantees to those specified in the regulation as required by Article 5(5) of Regulation (EC) No 2073/2005.
83. The LCA provided information about the methods used demonstrating that PCR Assay UNI 03/07-11/13 used for *Salmonella* analysis of cut fruits and vegetables was equivalent to EN ISO 6579-1 and that PCR Assay UNI 03/09-11/13 used for analysis of *Listeria* spp. was equivalent to EN/ISO 11290-1 and EN/ISO 11290-2. However, the audit team did not receive information about the equivalence of the analytical method used for *E. Coli*, ISO 7215:2005 with the reference method, ISO 16649-1 or 2. This is not in line with Article 5(5) of Regulation (EC) No 2073/2005.

### Conclusions

84. Microbiological sampling procedures for food of non-animal origin, intended for raw consumption, did not comply with the provisions of Regulation (EC) No 2073/2005. The use of other sampling and testing procedures had not been demonstrated to the competent authorities to provide at least equivalent guarantees. This approach may increase the risk of unsafe products entering the EEA market.
85. The competent authorities do not routinely verify that the methods used for analysis of FBOs samples are at least equivalent to those methods prescribed for analysing *Salmonella*, *Listeria monocytogenes* and *E.coli* in cut fruits and vegetables. This may lead to unreliable investigation and verification of microbiological safety of food of non-animal origin.

## **5.6 Rapid Alert System for Food and Feed**

### Legal Requirements

Article 50 of Regulation (EC) No 178/2002

Article 102 of Regulation (EU) No 2017/625

Section 1 of Chapter 3 of Regulation (EU) No 2019/1715

### Findings

86. Iceland has designated MAST as the national contact point for the rapid alert system for food and feed (RASFF) of the European Commission as required by Article 4 of Regulation (EU) 2019/1715. A designated deputy has also been nominated.
87. In line with Article 50 of Regulation (EC) No 178/2002 on the rapid alert system, responsibilities are defined, and procedures laid down in relevant guidelines.

Communication between the national contact point and the LCAs is mainly done by e-mail exchange.

88. The audit team investigated three different RASFF notifications related to fruits or vegetables. All the examples had been followed up with the relevant LCAs. In two of the examples, follow up action was required by the LCAs. The audit team noted that the LCAs follow up actions included different measures, including withdrawal, recall and information to the public by issuing press releases.
89. Evidence of communications and actions taken was presented to the audit team. In one instance, the LCA in a specific area did not respond to MAST in a timely manner to confirm if or what actions had been taken. Additionally, none of the three examples and the corresponding actions were reported back into the RASFF system as required by Article 50(5) of Regulation (EC) No 178/2002 and Article 22(3) of Regulation (EU) No 2019/1715.

### Conclusions

90. Iceland has established a system to deal with RASFF notifications, including involvement of all involved competent authorities, providing a framework to effectively handle and follow up notifications.
91. Iceland has the necessary procedures in place to ensure efficient and timely handling of RASFF notifications. However, the lack of reporting back to the system on actions taken following receipt of a notification undermines the effectiveness of the system.

## **6 Overall conclusion**

The audit found that Iceland's official control system for food of non-animal origin is in place. Approved establishments are regularly inspected, and the competent authorities have clear roles, responsibilities, and supporting procedures. There is also a system in place for managing RASFF notifications.

However, the audit identified several weaknesses that undermine the system's effectiveness. These include inconsistent enforcement of corrective actions, varied approaches to the organisation of risk-based controls and approval of food business operators, and insufficient coordination between competent authorities. Additionally, shortcomings in sampling and analytical procedures for microbial safety, such as pooling of samples and lack of verification on the equivalence of alternative methods, increase the risk of unsafe food products reaching the market.

The report includes four recommendations addressed to the Icelandic competent authorities aimed at rectifying the identified shortcomings and enhancing the control system in place.

## **7 Final meeting**

The final meeting was held on 17 September at MAST offices in Reykjavík with representatives from the Ministry of Industries, MAST and the LCAs. The Icelandic authorities did not fully agree with all the preliminary conclusions of the audit team. The audit team explained the rationale behind the preliminary conclusions and that more detailed and supported conclusions would be presented in this draft report.

At the meeting the audit team also explained that, based on a more detailed assessment of the information received during the audit, additional findings and conclusions could be included in the report.

## 8 Recommendations

To facilitate the follow-up of the recommendations hereunder, Iceland should notify ESA no later than 10 April 2026, by way of written evidence, of additional corrective actions planned or taken other than those already indicated in the reply to the draft report. In case no additional corrective actions have been planned, ESA should be advised. ESA should be kept continuously informed of changes made to the already notified corrective actions and measures, including changes of deadlines for completion and completion of the measures included in the timetable.

No	Recommendation
1	<p>The competent authorities should ensure that effective coordination, and cooperation is in place between the competent authorities in Iceland and that the procedures and arrangements in place ensure the effectiveness, appropriateness and consistency of official controls at all levels as required by Articles 4(2)(a), 5(1) (a) and (b), and 5(5) of Regulation (EU) No 2017/625.</p> <p>Recommendation based on conclusion: 30, 43, 44, and 45</p> <p>Associated finding: 25, 32, 33, 34, 35, 36, and 40</p>
2	<p>The competent authorities should take appropriate measures to ensure that the operator concerned remedies established non-compliances and prevents further occurrences of such non-compliances. as required by Article 138(1)(b) of Regulation (EU) No 2017/625.</p> <p>Recommendation based on conclusion: 75</p> <p>Associated finding: 54 and 55</p>
3	<p>The competent authorities should verify that sampling and analysis for microbial safety of food of non-animal origin fulfils the requirements of Article 14 of Regulation (EC) No 178/2002 and Articles 1, 3, 4 and 5 of and Annex I to Regulation (EC) No 2073/2005.</p> <p>Recommendation based on conclusion: 77, 84, and 85</p> <p>Associated finding: 72, 73, 81, 82, and 83</p>
4	<p>The competent authorities should verify that food business operators producing sprouts comply with the sampling and analysis relevant for sprout producers are correctly implemented, as required by Article 14 of Regulation (EC) No 178/2002, Articles 1, 3, 4 and 5 and Chapter 3.3 of Annex I to Regulation (EC) No 2073/2005.</p> <p>Recommendation based on conclusion: 76</p> <p>Associated finding: 62, 63, 64, 65, and 66</p>

**Annex 1 - List of abbreviations and terms used in the report**

BTSF	Better Training for Safer Food
ESA	EFTA Surveillance Authority
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EFSA	European Food Safety Authority
EU	European Union
FBO	Food Business Operator
FNAO	Food of Non-Animal Origin
GFSI	Global Food Safety Initiative
LCA	Local Competent Authority
MAST	Icelandic Food and Veterinary Authority
MANIAP	Multi Annual National Internal Audit Plan
RASFF	Rapid Alert System for Food and Feed
STEC	Shiga Toxin-producing <i>Escherichia coli</i>

## Annex 2 - Relevant legislation

The audit took into consideration all EEA law relevant for the scope of the audit. The following table lists the main legal acts of relevance, as amended and as adapted to the EEA Agreement by the specific and sectoral adaptations referred to in Annexes I and II to that Agreement, but the list may not be exhaustive:

No	EEA Reference	Title
a)	Point 11b in Part 1.1 of Chapter I and Point 31q of Chapter II of Annex I and Point 164 of Chapter XII of Annex II	Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)
b)	Point 13 in Part 7.1 of Chapter I and Point 41 of Chapter II of Annex I and Point 54zzzc of Chapter XII of Annex II	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
c)	Point 16 in Part 6.1 of Chapter I of Annex I and Point 54zzzh of Chapter XII of Annex II	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
d)	Point 11bd in Part 1.1 of Chapter I and Point 31qd of Chapter II of Annex I and Point 164d of Chapter XII of Annex II	Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components
e)	Point 52 in Part 6.2 of Chapter I of Annex I and Point 54zzzj of Chapter XII of Annex II	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
f)	Point 105 of Chapter XII of Annex II	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

g)	Point 75 of Chapter XII of Annex II	Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts
h)	Point 13I in Part 1.1 of Chapter I of Annex I	Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC

**Annex 3 - Iceland's comments to the draft report**

No comments to the draft report

**Annex 4 - Iceland's action plan for corrective measures****CAP – Corrective action plan ESA audit 2025 to evaluate official controls relating to microbial safety of food of NAO – 2025/ICE/2**

No	Recommendation	Responsible Authority	Corrective action	Date of compliance
1	<p>The competent authorities should ensure that effective coordination, and cooperation is in place between the competent authorities in Iceland and that the procedures and arrangements in place ensure the effectiveness, appropriateness and consistency of official controls at all levels as required by Articles 4(2)(a), 5(1) (a) and (b), and 5(5) of Regulation (EU) No 2017/625.</p> <p>Recommendation based on conclusion: 30, 43, 44 and 45</p> <p>Associated findings: 25, 32, 33, 34, 35, 36 and 40</p>	MAST and HES	<p>Internal audits:</p> <p>The controls currently carried out by the LCAs will be included in the risk-based matrix/system for the internal audit planning in Iceland. The risk classification of those controls will be initiated in the second half of 2026. The government plans significant changes on MAST and the LCAs, with preparation starting in 2026 and a new system up and running 1. January 2027 and therefore, it is not foreseen that the work can be initiated earlier. The multi annual plan for internal audits of official controls will then be revised based on the risk classifications and will include audits on all controls on food, including controls currently carried out by the LCAs, based on risk.</p> <p>Risk categorization of FBOs:</p> <p>Some revision of the current categorization system is needed. The work of the revision will start in the first half of 2026 with a working meeting to be held before the end of May 2026. Following the revision of the system, all FBOs will be categorized, and the work is to be completed in 2027 and by the end of that year all FBOs in Iceland will be risk categorized according to the same system.</p> <p>Approvals of FBOs:</p>	End 2027

			<p>Regarding the approval of food businesses, Iceland believes the approvals are currently done according to the legislation and in the same way in all LCAs. The general working procedure in all LCAs is that approval is provided following an audit when the FBO fulfills all the requirements of the legislation. Occasionally, a conditional approval is granted, given that the FBO meets all the infrastructure and equipment requirements but needs some time to remedy things to comply with relevant requirements that do not risk the safety of the food produced. The guidelines in the control handbook will be revised/updated to better represent the actual procedure, which in most cases does not include conditional approval, but allows for it in certain situations. This revision/update will be finished in the first quarter of 2026. Those guidelines will be followed for all approvals of FBOs (in all LCAs).</p> <p>Oversight of controls:</p> <p>To gain better oversight of control plans and control output/outcome on a national level, all controls and control plans will be included in the same IT system that will be used by all competent authorities in food control. The Icelandic government intends to build a new system for this. This will allow the introduction of, for example, dashboards and data visualizations to gain better oversight of plans and results nationally. The aim is that in 2027 all competent authorities will use the same system.</p>	
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2	<p>The competent authorities should take appropriate measures to ensure that the operator concerned remedies established non-compliances and prevents further occurrences of such non-compliances. as required by Article138(1)(b) of Regulation (EU) No 2017/625.</p> <p>Recommendation based on conclusion: 75</p> <p>Associated findings: 54 and 55</p>	MAST and HES	<p>The main reason for delays in following up on non-compliances and enforcement measures to ensure remedy of them is believed to be lack of resources (too few staff). To best deal with this, authorities need to find ways to better use of (focus) the resources given. There are several factors that need to be investigated such as further/better severity classification of non-compliances discovered, more targeted controls (not requiring all aspects of legislation to be controlled every year) and implementing a system for the performance classifications of FBOs allowing for systematic reduction of controls on FBOs that show good compliance and more time for follow up and enforcement where needed. This would allow for more time and better focus on follow up and enforcement. A workshop will be held in the second half of 2026 to start further investigating and deciding on measures to be taken. The work is planned to be completed by the end of 2027.</p> <p>Additionally, it is foreseen that the newly planned IT system for all national controls will help with prioritization by allowing for data visualization and information that help with focusing resources.</p>	End 2027
3	<p>The competent authorities should verify that sampling and analysis for microbial safety of food of non-animal origin fulfils the requirements of Article 14 of Regulation (EC) No 178/2002 and Articles 1, 3, 4 and 5 of</p>	MAST and HES	<p>Regarding the instance found during the audit relating to FBOs own sampling, the non-compliances have already been addressed to the FBO and will be followed up by the competent authority. See attached document: Att-1-Rec-3.</p>	2026-Q1

	<p>and Annex I to Regulation (EC) No 2073/2005.</p> <p>Recommendation based on conclusion: 77, 84 and 85</p> <p>Associated findings: 72, 73, 81, 82 and 83</p>		<p>The use of a non-verified method for <i>E. Coli</i>, has been discontinued by the relevant laboratory. See attached document: Att-2-Rec-3.</p> <p>The guidance document for Regulation (EU) 2073/2005 is being updated with an annex providing a list of testing methods currently known to be verified to be equivalent to the methods specified in the regulation. See attached draft document: Att-3-Rec-3. Control personnel are guided to address and follow up if they find information on other methods being used.</p> <p>A working procedure for routine audits of official laboratories is being developed and will be made a part of Mast quality manual. See attached draft document: Att-4-Rec-3. The audits will include verifying that the methods used by the laboratories are in accordance with the legislation. This work will be completed in the first quarter of 2026 and audits will be routinely done following on from that time.</p>	
<p><b>4</b></p>	<p>The competent authorities should verify that food business operators producing sprouts comply with the sampling and analysis relevant for sprout producers are correctly implemented, as required by Article 14 of Regulation (EC) No 178/2002, Articles 1, 3, 4 and 5 and Chapter 3.3</p>	<p>MAST and HES</p>	<p>Non-compliances discovered at the FBO during the audit have been addressed and are being followed up. Regular inspection frequency for the FBO has been set every 3 months for at least the next year. See attached draft documents: Att-5-Rec-4 and Att-6-Rec-4.</p> <p>During the revision of the risk categorization system (see response to Rec 1) the categorization of sprout producers will be specifically addressed.</p>	<p>2026-Q4</p>

	<p>of Annex I to Regulation (EC) No 2073/2005.</p> <p>Recommendation based on conclusion: 76</p> <p>Associated findings: 62, 63, 64, 65 and 66</p>		<p>A new guidance document on the requirements for sprout production will be developed. A team has already been assigned to the project, and the guidance is to be finished by end of June 2026. The publication of the guidance will be followed up with a training course for inspectors in summer/fall 2026.</p>	
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