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Final report

EFTA Surveillance Authority mission to

Iceland

from 3 to 7 March 2014

regarding application of EEA legislation

related to Primary production of food of non-animal origin

Please note that comments from the Icelandic competent authorities to factual errors in the draft report have been included in *underlined italic* print in the body of the report. Comments and information on the corrective actions planned by the Icelandic competent authorities are included in Annex 3.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority (the Authority) in Iceland from 3 to 7 March 2014.

This was the first mission carried out in Iceland with the objective to verify that official controls related to primary production of food of non-animal origin were carried out in compliance with the European Economic Area legislation.

The mission team found that the relevant EEA legislation had been transposed to national legislation. The legal powers to enforce the legislation were in place. Two competent authorities responsible for the official controls were designated, the Icelandic Food and Veterinary Authority (MAST) and the Local Municipal Environmental Health and Protection Offices (LCAs). Adequate training had been provided for the staff of both competent authorities. At the time of the mission a risk classification system was being drafted and new guideline on official controls was also under construction. MAST has designated laboratories that may carry out the analysis of samples taken during official controls.

The system in place for the official controls in this area was still at a preliminary stage consequently some shortcomings were identified, the main ones are listed here:

- The designated competent authority for growing and harvesting, MAST, did not carry out any official controls on regular basis. The official controls carried out by MAST were limited to ad-hoc cases.*
- Efficient and effective coordination and cooperation between the competent authorities can be improved as well as the consistency of the official controls, in particular since MAST was not carrying out official controls on regular basis and the LCAs to a various degree covered the control on growing and harvesting.*
- Although the competent authorities had designated laboratories that may carry out the analysis of samples taken during official controls full compliance with EEA legislation could not be ensured since not all methods used are accredited.*
- Iceland has not designated a National Reference Laboratory (NRL) for *Listeria monocytogenes*, *Escherihia coli* including verotoxigenic *E.coli* (VTEC) or pesticides.*

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

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1 Introduction

The mission took place in Iceland from 3 to 7 March 2014. The mission team comprised two inspectors and a legal officer from the EFTA Surveillance Authority (the Authority).

The opening meeting was held with representatives of the Ministry of Industry and Innovation (MoII) and representatives of the Icelandic competent authorities; Icelandic food and veterinary authority (MAST) and two Local Municipal Environmental Health and Protection Offices (LCAs) on 3 March 2014 at MAST head office in Selfoss. At the meeting, the mission team confirmed the objectives and the itinerary of the mission. The Icelandic representatives provided additional information to that set out in the reply to the Authority's pre-mission questionnaire.

Throughout the mission, a representative of the competent authority accompanied the mission team. In addition, representatives of the relevant district offices and local competent authorities participated during meetings and the visits to the different farms and establishments.

A final meeting was held at MAST's office in Reykjavík on 7 March 2014, at which, the mission team presented its main findings and some preliminary conclusions from the mission.

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

2 Objectives of the mission

The following main European Economic Area (EEA) acts fall within the scope of the mission:

- a) Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended and adapted to the EEA Agreement;
- b) Regulation (EC) No 852/2004 on the hygiene of foodstuffs, as amended and corrected in the EEA Agreement;
- c) Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, as amended and corrected in the EEA Agreement.

This assessment was carried out based on, and related to, the above mentioned legal acts and other relevant EEA legislation referred to in Annex 2 to this report. The assessment was further based on the reply to the pre-mission questionnaire of the Authority.

A particular focus was paid to the control systems in place for:

- Official controls of food business operators compliance with general and specific rules on the hygiene of food of non-animal origin in particular the production of food intended to be consumed raw, sprouts and pre-cut vegetables;
- The implementation of these rules by the food business operators.

The evaluation included the gathering of relevant information, and appropriate verifications, by means of interviews/discussions, review of documents and records, and

on-the-spot inspections, to demonstrate the normal control procedures adopted and measures in place to ensure that necessary corrective actions was taken when necessary.

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

Table 1: Competent authorities and establishments/sites visited during the mission

	Number	Comments
Competent authorities	6	An initial meeting and a final meeting between the mission team and the Icelandic competent authorities. In addition meetings with four different local competent authorities
Primary producers	5	One establishment producing sprouted seeds and four green houses producing various vegetables. All five establishments packed their own product at farm level
Laboratory	1	Designated official laboratory, analysing pesticides and microbiological parameters, and appointed as National Reference Laboratory for Salmonella.

3 Legal basis for the mission

The legal basis for the mission was:

- a) Point 4 of the Introductory Part of Chapter I of Annex I to the EEA Agreement.
- b) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (Surveillance and Court Agreement).
- c) Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States.
- d) Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Legislation relevant for the mission is listed in Annex 2.

4 Background - Previous missions

This was the first mission from the Authority to Iceland focusing on primary production of food of non-animal origin within the framework of the Food Hygiene Package which entered into force in Iceland 1 November 2011.

The final report from this mission can be found on the Authority's website (www.eftasurv.int).

5 Findings and conclusions

5.1 Legislative and implementing measures

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

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, not all relevant EEA legislation had been made part of the Icelandic legal order. The outstanding regulations were;

- *Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts*, introduced by way of simplified procedure into the EEA Agreement
- *Commission Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts*

At the final meeting 7 March, the Icelandic competent authorities informed the mission team that these two regulations had been incorporated in the Icelandic legal order 4 March 2014.

The mission team noted that approval requirements regarding primary producers in Iceland go beyond what is required by EEA legislation. According to Article 9 of the Icelandic Food Act No 93/1995 all food business operators should have an approval issued by the relevant competent authority. The same article exempts from this requirement the following; primary producers of vegetables, horse- and sheep farmers. However according to Icelandic law primary production is defined as growing and harvesting of vegetables. Consequently packing and distribution requires approval by the relevant LCA, also when carried out at farm level. The Authority has not been informed of these additional requirements for approval of certain establishments under national law.

Conclusions

The relevant EEA legislation has been made part of the Icelandic legal order as required by Article 7 of the EEA Agreement.

However, some delays were seen in the incorporation of the regulations relating to sprouts and seeds intended for the production of sprouts.

The Authority has not been informed of approvals required by national law as required by Art 6(3) of Regulation (EC) No 852/2004.

5.2 Competent authorities

5.2.1 *Designation of competent authorities, organisation and responsibilities*

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the official controls set out in the Regulation.

Findings

According to information provided by the Icelandic competent authorities in its reply to the pre-mission document of the Authority, MAST is the competent authority for all primary production of food of non-animal origin (growing and harvesting of vegetables). The LCAs are the competent authorities for packing activities and for the retail level.

At the opening meeting MAST provided additional information regarding the responsibilities of the designated competent authorities for the official controls of primary production of food of non-animal origin. According to Article 6 of the Food Act No 93/1995 MAST is the responsible competent authority for the official controls in the primary production phase of growing and harvesting. The LCAs are the designated competent authority for packaging activities carried out at farm level, even if pursuant to Annex I to Regulation (EC) No 852/2004 packing that does not substantially alter the nature of the product is considered an associated operation to the primary production to which the requirements in that Annex also apply. In the case of growers who are also packing at the production site, this means two competent authorities are responsible for the official controls of same requirements in the same establishment. In situations where more than one competent authority is responsible for an establishment, Icelandic law provides that the competent authorities can agree in writing which competent authority shall be responsible for the establishment. If the competent authorities cannot agree, the Ministry of Industry and Innovation is competent to decide. To date, no such agreements are in force, and the Ministry has not taken any decisions. In a letter dated 2 July 2012 MAST proposed to the Ministry to decide on who is the competent authority for these establishments. The Ministry replied with a letter dated 4 December 2012 stating that the Ministry does not consider that it has a legal basis to make this decision at a sectional level and, furthermore, the Ministry considered that it was not needed as it is clear according to national law who is responsible for the official controls in each case.

Conclusions

Competent authorities for the official controls of primary production of food of non-animal origin have been designated in line with Article 4(1) of Regulation (EC) No 882/2004.

5.2.2 *Coordination and cooperation within/between competent authorities*

Legal reference

Article 4(3) of Regulation (EC) No 882/2004 requires that efficient and effective coordination shall be ensured between all the competent authorities involved in official controls.

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities to ensure consistency of official controls at all levels.

Article 4(5) of Regulation (EC) No 882/2004 requires that when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Findings

According to information provided by the Icelandic competent authorities in its reply to the pre-mission document of the Authority, it is laid down in Article 22 of the Icelandic Food Act that MAST shall supervise and coordinate the work of the LCAs and ensure that official controls are implemented in the same manner throughout the country. In order to fulfil these tasks MAST may issue guidelines that the LCAs are supposed to follow. MAST shall cooperate closely with LCAs and provide advice and services in the field of food control. There are several mechanisms for co-operation between MAST and the LCAs:

- There is a Food Safety Group operational that meets 5-6 times annually. The group is chaired by MAST and consists of representatives from all LCAs as well as relevant staff from MAST. The main purpose of the group is to exchange information and harmonize the work of the LCAs. Meetings between MAST and the LCAs are held in the spring with the directors of the ten LCAs and in the autumn with all LCA inspectors.
- A few times each year a teleconference is organized between the Directors of the LCAs and the Director General of MAST, and other relevant staff, to discuss current topics and issues relating to official controls, coordination, etc.
- Joint inspections by MAST and LCAs.
- Working groups are also established as needed with members from both LCAs and MAST to work on certain topics, such as updating the inspection manual and developing risk-based prioritisation of official controls.

To date, MAST has not carried out any systematic controls in the primary production sector (see chapter 5.3.2). Certain ad-hoc inspections had been carried out by MAST on the basis of positive samples for pesticides reported by the LCAs.

The mission team noted:

- Following analytical results of an official pesticide sample that indicated the presence of a pesticide above the maximum residue limit (MRL) set in Icelandic regulation 672/2008 on pesticides and MRL thereof, the LCA stopped the harvesting and distribution of relevant crops until sampling results were below the MRL. MAST, the competent authority for growing and harvesting, was informed about this procedure via email, however there was no evidence of follow up on the use of pesticides at the farm carried out by MAST.
- An example of joint inspection where both the competent authorities (MAST and LCA) followed up on a positive analytical result of a pesticide sample. However, although pesticides were found on the farm and the lack of records of use of those pesticides was noted in the inspection report, neither of the two competent authorities followed up on this or requested corrective action.
- Although there was no formal agreement between MAST and LCA on division of responsibility for sprout producers MAST had contacted the LCA to verify that the

LCA was covering the full production, not only packaging activities, in these establishments. The contact was initiated by new legal requirements regarding the production of sprouts, and MAST also used the occasion to inform the LCA of the new legislation.

- The LCA in Reykjavík are at retail and distribution level sampling for pesticides according to a monitoring plan prepared by MAST. The monitoring plan covers both national production, trade and import products.
- Representatives of two LCAs were very clear on their legal competencies and consequently their responsibilities being restricted to packing activities and retail. Still, according to one of these LCAs their official controls sometimes include to some extent growing and harvesting. In another LCA it was considered as appropriate to include the whole procedure of the production; from receiving, storing, germinating and to the packing of the sprouts at the site of production, in the control procedure.
- In another LCA the representative met expressed some uncertainty as to what extent packing activities at farm level required an approval and therefore fell under the responsibilities of the LCA. Still, the LCA had issued an approval for the packaging activity at farm level as foreseen by Icelandic legislation following an application for the approval from the farmer due to a request from the distributor of the products.

Conclusions

Some examples were seen of coordination between MAST and LCAs, however, efficient and effective coordination and cooperation in the follow up of non-conformities could not be fully ensured as required by Article 4(3) of Regulation (EC) No 882/2004, in particular since none of the competent authorities involved had followed up identified non-compliances.

MAST does currently not carry out any regular official controls on primary production of food of non-animal origin and the LCAs cover only to a varying degree the growing phase of the primary production. Accordingly, consistency of official controls could not be ensured as required by Article 4(4) of Regulation (EC) No 882/2004.

5.2.3 Adequacy of personnel involved in the control system

Legal requirements

Article 6 of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff and to ensure that staff receives appropriate training.

Findings

According to information provided by the Icelandic competent authorities in their reply to the pre-mission document of the Authority, all of MAST staff carrying out official food control has a university degree in natural sciences, mainly food science, biology or veterinary medicine. Staff of the LCA is required by law to have a university degree in public health, natural sciences engineering or similar¹ and they are obliged to undergo in-house practical training. In addition to that MAST also provides a training course for new staff members of the LCAs. The course agenda includes among other aspects:

- legal aspects: the hygiene and control legislation

¹ See Annex 3 for comments from the Icelandic competent authorities

- Rapid Alert System for Feed and Food
- Plant protection products

The Ministry for the Environment is responsible for issuing an authorisation for the LCA inspectors. The general policy of the LCAs is to participate in as many seminars and trainings offered as possible. The participants shall once back in office inform their colleagues about the content of these seminars as appropriate.

The mission team noted that the staff of both MAST and LCAs had participated in numerous training courses both in Iceland and in other European countries. The courses had been provided by themselves and also by the European commission via the Better Training for Safer Food (BTSF) and Taiex programmes. Some officers/inspectors of both competent authorities had participated in course on the production of sprouts provided by Matís, (a government owned, independent research company and laboratory) covering microbiological risk assessment. The mission team noted that the information gained during various BTSF-courses was only shared within colleagues in the same competent authority, not between different LCAs or between MAST and LCAs and vice versa.

Conclusions

The staff met responsible for the official control on primary production of food of non-animal origin was generally found to be competent. Adequate training has been provided to the staff of MAST and the LCAs in line with Article 6 of Regulation (EC) No 882/2004.

5.3 Organisation of the controls

5.3.1 Registration of food business operators

Legal Requirements

Article 6 of Regulation (EC) No 852/2004 requires that every food business operator notifies the appropriate competent authority of each establishment under its control that carries out any stage of food production with the view to registration of the establishment.

Findings

According to information provided by the Icelandic competent authorities in its reply to the pre-mission document of the Authority, primary producers growing and harvesting vegetables are by Icelandic law obliged to notify and register their activities with MAST. Any changes such as growing of different species or closing down operation shall also be notified. Primary producers who are packing at the farm are required to apply for an approval issued by the relevant LCA.

The mission team noted that the approval was issued following an on-site inspection to the farm. In one of the LCAs the approval was issued following the inspection without an accompanying inspection report being issued. Another LCA visited issued an inspection report and discussed the results of the on-spot inspection in the division of food safety of the LCA before the approval was issued.

Conclusions

Food business operators are registering and notifying their activities in line with the requirements of Article 6(2) of Regulation (EC) 852/2004.

Approvals required under national law are issued following an on-spot visit, as required by Article 6(3) of the same Regulation.

5.3.2 *Prioritisation of official controls*

Legal Requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency.

Article 8 of Regulation (EC) No 882/2004 requires official controls to be carried out in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the same regulation requires the competent authority to draw up reports on the official controls that it carries out, describing the purpose, the control methods and the results of the official controls and, where appropriate, the action that the food business operator is to take.

Article 54 of the same regulation requires the competent authority to take action when non-compliances are identified and ensure that the operator remedies the situation

Findings

According to information provided by the Icelandic competent authorities in its reply to the pre-mission document of the Authority, MAST is not carrying out official controls on the food business operators under the scope of this mission on regular basis. The official controls by MAST on the primary production were at the time of the mission limited to ad-hoc cases when the LCA in Reykjavík notify non-compliances related to pesticide control samples taken at distribution and/or retail level. This was confirmed at the opening meeting. (See chapter 5.2.2)

Currently, MAST does not have an operational risk classification system for primary production of food of non-animal origin, however, such a risk classification system is being developed at the time of the mission. No changes in MAST's approach were foreseen until that work is finished. Once that system is in place the competent authority(ies) responsible for the official control on primary producers of food of non-animal origin, will use this system and organise and plan their controls accordingly. A draft version dated November 2013 was provided to the mission team. In this version, no role in the official controls in the scope of this mission is foreseen for MAST, only the LCAs.

One LCA was currently using a pilot version of the new risk classification system. The other LCAs have risk classification systems in place, based on guidelines issued in 2002. The system took into account the type of establishment, nature of the products, and could be adjusted according to the results of previous inspections.

Inspections carried out by the LCA are based on guidelines dated 21 May 2003 (“Meðferð og dreyfing garðávaxta”). This guideline covers only packing/distribution and not the growing and harvesting of the plants, i.e. the responsibilities of the LCAs.

Reports are drawn up following inspections, however, not all competent authorities issued reports from the initial on-spot visit to approve the establishment. Also, reports were of varying level of detail, not always mentioning purpose of the official controls, control methods applied, the results and actions to be taken by the food business operator.

A sampling plan for pesticides residues drawn up by MAST is in place for the national monitoring programme of pesticides. The sampling plan is based on import volumes, domestic production and past results from monitoring programme. It takes account of the pesticide residues most often analysed in a particular product and the co-ordinated EU monitoring programme.

For practical purposes, Reykjavik LCA carries out all sampling as almost all products are channelled through Reykjavik. Samples are taken at warehouses in Reykjavik and occasionally at retail level. Each year some 240 samples of fruit and vegetables are taken. Approximately 15% of samples are from domestic production.

Corrective action had not been requested following a joint inspection where lack of records for use of chemicals were identified in a green house (see chapter 5.2.2), however, the mission team also observed the effective use of enforcement measures; Written evidence was seen of effective enforcement with regard to deficient standards of premises, which included closing the production until the deficiencies had been corrected. Detailed records of the actions taken by both the competent authority and the food business operator were presented to the mission team.

Conclusions

Regular official controls of the on-farm packing of primary products under the scope of this mission are carried out regularly and are risk based. However, no regular controls have been carried out with regard to the growing and harvesting of primary products in Iceland which is not in line with Article 3 of 882/2004.

Although reports of the results of official controls are drawn up following an inspection these are not always fully in line with art 9(2) of the same Regulation and the competent authorities had not in all cases taken action to ensure that the operator remedied the situation for identified non-compliances as required by Article 54 thereof.

5.3.3 Laboratory network

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires competent authorities to have, or to have access to, adequate laboratory capacity.

Article 12 of the same Regulation requires the competent authorities to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for laboratories so designated.

Article 33(2)(c) of the same Regulation requires national reference laboratories to organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing.

Findings

According to information provided by the Icelandic competent authorities in its reply to the pre-mission document of the Authority, MAST has designated official laboratories and a list of these is available on MAST's website

MAST and LCAs use the laboratories Matís, Sýni hf. and Promat hf. for analysing official samples taken of food of non-animal origin, both for microbiological analysis and chemical and physical analysis. The laboratories are all accredited however not all of the analytical methods are.

The laboratory visited during the mission was accredited according to ISO 17025 and carried out analyses of all official samples of food of non-animal origin for pesticides. At the time of the mission, approximately 60 pesticides were analysed, 29 of these by accredited methods. In cases where the maximum residue limit (MRL) is exceeded by any of the pesticides for which the method is not accredited, the laboratory will run confirmatory test in-house; if the result is still non-compliant, samples will be sent to an external laboratory for verification by an accredited method.

An ongoing bilateral project between the Icelandic competent authorities and the German Federal Ministry of Food and Agriculture aims at increasing the number of pesticides that can be analysed to 300 by the end of 2014. The project includes training in sampling techniques for the LCA, new equipment in the laboratory and training of the laboratory staff. It is also intended to have the new methods accredited, although no time frame for this could be given.

The laboratory had not been able to participate in proficiency test for pesticides in 2013, however, they had participated in both 2011 and 2012. According to the documents presented to the mission team, the laboratory had in 2012 three unacceptable and one questionable result. No evidence was presented to the mission team concerning follow up of this proficiency test. However, according to the staff met, questionable results did not require specific follow up and the three unacceptable results had been traced to the standards used and that these were close to expiring. To correct the situation, new standards had been purchased and more attention was paid to how the standards were stored.

The mission team noted that:

- Not all pesticides were analysed by accredited methods and one example of a non-accredited method resulting in a false positive was seen.
- The analytical methods for microbiological parameters such as *Listeria Monocytogenes*, *Escherihia coli* and *Salmonella* were accredited.
- No national reference laboratory (NRL) has been appointed in Iceland for some of the parameters (*Listeria monocytogenes*, *Escherihia coli* including verotoxigenic *E.coli* (VTEC) and pesticides) relevant for this mission.

Conclusions

The competent authority has designated laboratories that may carry out the analysis of samples taken during official controls in line with Article 12 of Regulation (EC) No 882/2004, however, full compliance with that Article could not be ensured since not all methods used are accredited.

Iceland has not designated an NRL for each Community reference laboratory as required by Article 33 of Regulation (EC) No 882/2004, in particular for this mission NRLs for *Listeria monocytogenes*, *Escherihia coli* including verotoxigenic *E.coli* (VTEC) and pesticides should be mentioned.

5.4 General hygienic requirements

5.4.1 Good hygiene practice

Legal Requirements

Article 1(3) of Regulation (EC) No 852/2004 requires Member States to establish national rules concerning the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer.

Article 7 of Regulation (EC) No 852/2004 requires that Member States shall encourage the development of national guides to good practice for hygiene. Article 8 of the same Regulation lays down requirements for such national guides.

Findings

According to information provided by the Icelandic competent authorities in its reply to the pre-mission document of the Authority, Iceland has with regulation IS No 580/2012 established national rules concerning the direct supply of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer.

The Icelandic Association of Horticulture Producers (Sölufélag Garðyrkjumanna) has in cooperation with among other MAST and LCAs issued guidelines on good hygiene and manufacturing practice for producers of plant originated food.

The mission team noted that this guideline is aimed at the producers, it covers the growing and harvesting phase of the primary production as well as the packing and distribution. In the guideline a division is made between growing and harvesting on one hand and packing on the other. Further it is stated that for the growing and harvesting the requirements of Annex I to Regulation (EC) No 852/2004 are applicable. An electronic copy of this guideline was provided however it was not dated and none of the establishments visited during the mission was currently using this guideline. However, according to one of the producers who was a member of the Horticultural Association it is compulsory for all producers under the Horticultural Association to implement and use this guideline in 2014.

MAST has on its website general hygienic guidelines aimed at all food producers and in connection with the registration procedure they have guidelines covering the primary production of vegetables that take into consideration the requirements in Regulation (EC) No 852/2004. These guidelines are both aimed at the producer to inform him about the requirements and can also be used by the competent authority during inspections.

The LCAs are using guidelines dated 21 May 2003. Currently MAST is drafting a new guideline/handbook to be used by the relevant competent authority conducting official controls on production of food of non-animal origin, covering both the primary production and the later stages of processing and distributing (see also 5.3.2).

Conclusions

Iceland has established rules concerning the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer as required by Article 1(3) of Regulation (EC) No 852/2004

Guidelines have been, or are being, developed both for the industry and the competent authorities in line with Articles 7 and 8 of Regulation (EC) No 852/2004.

5.4.2 *Visits to establishments producing food of non-animal origin*

Legal Requirements

Article 4 of Regulation (EC) No 852/2004 requires that all food business operators carrying out primary production and associated operations listed in Annex I to that Regulation shall comply with the general hygienic provisions laid down in part A of Annex I of that Regulation.

Article 3 of Regulation (EC) No 2073/2005 requires food business operators to comply with the relevant microbiological criteria set out in Annex I.

Findings

The mission team visited several establishments which were growing, harvesting and packing primary products of non-animal origin. The overall impression was positive with regard to the hygienic conditions. The majority of the producers visited used biological pest control methods, and only occasionally used chemicals. Nevertheless the producers that did use chemicals did not keep any records of the use. This shortcoming had been identified by the competent authority during previous inspection, however it had not been followed up on with a request for corrective actions. It was also noted that only one of the establishments visited had in place documents that indicated how the activities carried out in relation to the production were performed in line with good manufacturing procedures (GMP) and general hygiene provisions.

One producer of sprouts visited had in place records of incoming consignments, including LOT numbers, as well as analytical results of samples from the seeds taken by a competent authority in another EEA State, were available. However, a copy of the import certificate for the seeds originating in a third country did not accompany the consignments of seeds originating from a third country.

The LCA had taken official samples from the sprouts and analysed after consultation with Matis for the following parameters: *E.coli* in 1g and total bacteria count at 30°C. Other examples of sampling to verify compliance with microbiological criteria were not seen. None of the establishments visited had in place a sampling plan in order to monitor compliance with microbiological criteria. This had not been addressed by the competent authority.

One establishment growing cucumbers used a private water source for irrigation. This water source was not controlled by the municipality, and the establishment did not carry out checks on the water, except for conductivity. Another establishment mixed hot and cold water from the distribution network for use in the production of sprouted seeds. Other producers were using municipality water of drinking water quality, controlled by the relevant LCA.

Deficiencies noted during the mission team's visits to the establishments were addressed by the relevant competent authorities and a report requesting corrective actions was issued to the establishment.

Conclusions

Although the producers generally demonstrated knowledge of the hygiene requirements relevant to their production, in most cases documentation to support confidence that the procedure are practiced as described was lacking which is not in line with Annex I to Regulation (EC) No 852/2004.

Furthermore, records regarding use of chemicals/pesticides on the farm were not kept as required in Annex I of Regulation (EC) No 852/2004.

Samples for *Salmonella* in sprouts and for *Listeria monocytogenes* in ready-to-eat foods had not been taken by the food business operators as required by Article 4 and Annex I to Regulation (EC) No 2073/2005.

6 Final meeting

A final meeting was held on 7 March 2014 at MAST's office in Reykjavík with representatives from the Ministry of Industry and Innovation, MAST and four LCAs. At this meeting, the mission team presented its main findings and some preliminary conclusions of the mission.

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

7 Recommendations

Iceland should notify the Authority, within two months of receiving the final report, by way of written evidence, of the corrective actions taken and a plan for corrective measures and actions, including a timetable for completion of measures still outstanding, relevant to all the recommendations hereunder. The Authority should also be kept informed of the completion of the measures included in the timetable.

No	Recommendation
1	Iceland should ensure that the Authority is informed of requirements regarding approvals of certain establishments required by national law, as is required by Article 6(3)(c) of Regulation (EC) No 852/2004.
2	The competent authorities should ensure efficient and effective coordination and cooperation between the different competent authorities responsible for the official control as required by Article 4(3) and furthermore, ensure that official controls are carried out consistently as is required in Article 4(4) of Regulation (EC) No 882/2004.
3	The competent authorities should ensure that that all stages of primary production is covered by official controls as required by Article 3 and 4(2)(a) of Regulation (EC) No 882/2004.
4	The competent authorities should ensure that laboratories analysing official samples have at their disposal accredited methods as required by Article 12 of Regulation

	(EC) No 882/2004.
5	Iceland should ensure that a national reference laboratory is designated for each Community reference laboratory as required by Article 33 of Regulation (EC) No 882/2004.
6	The competent authorities should ensure that the requirements of Annex I to Regulation (EC) No 852/2004, in particular as regards documentation of procedures and record keeping, are respected by the primary producers of food of non-animal origin.
7	The competent authorities should ensure that primary producers of food of non-animal origin take samples to monitor compliance with microbiological criteria as required in Article 4 and Annex I to Regulation (EC) No 2073/2005.

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

Authority	EFTA Surveillance Authority
BTSF	Better Training for Safer Food is a European Commission training initiative covering food and feed law, animal health and welfare and plant health rules. It trains national authority staff involved in official controls in these areas and aims to keep participants up-to-date in these areas and should help to ensure more harmonised and efficient controls.
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
Food Hygiene Package	<p>A term that refers to a group of European Regulations that represent a significant reorganisation of the regulatory framework for food and feed hygiene and safety. The package builds on general food law basis established by Regulation (EC) No 178/2002 of the European Parliament and the Council laying down the general principles and the requirements of food law, establishing the European Food Safety Authority and laying down procedures for matters of food safety.</p> <p>The Food Hygiene package includes several Regulations, inter alia, Regulations (EC) No 852/2004, 853/2004 and 854/2004</p>
GMP	Good manufacturing procedures
LCA	Local competent authority (Local Municipal Environmental Health and Protection Offices)
MANCP	Single integrated multi annual national control plan
MAST	Icelandic Food and Veterinary Authority
Matís	Government owned, independent research company and laboratory
MRL	Maximum Residue Limit
Simplified procedure	<p>A simplified procedure is derogation from the general procedures for incorporation of acquis laid down by the EFTA Standing Committee. As a general rule, legal acts have to be incorporated into the EEA Agreement by a Decision of the EEA Joint Committee before becoming applicable in the EEA EFTA States. Simplified procedures signify that acts which are subject to these procedures are no longer incorporated into the EEA Agreement by a Decision of the EEA Joint Committee in order to become applicable in the EEA EFTA States.</p>
Taiex	Technical Assistance and Information Exchange instrument managed by the Directorate-General Enlargement of the European Commission

Annex 2 - Relevant legislation

The following EEA legislation was taken into account in the context of this mission:

- a) The Act referred to at Point 1.2.74 of Chapter I to Annex I to the EEA Agreement, *Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States*;
- b) The Act referred to at Point 7.1.13 of Chapter I to Annex I to the EEA Agreement, *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*, as amended;
- c) The Act referred to at Point 1.1.11 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as amended.
- d) The Act referred to at Point 6.1.16 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs*, as amended
- e) The Act referred to at Point 6.2.52 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs*, as amended;
- f) The Act referred to at Point 54zzy of Chapter XII of Annex II to the EEA Agreement, *Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC*, as amended
- g) The Act referred to at Point 75 of Chapter XII of Annex II to the EEA Agreement, *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) *Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts*, introduced by way of simplified procedure into the legal order of EEA EFTA countries, cf. point 10 of Document No 1122043 of 15 April 2013 of the EFTA subcommittee I “List of acquis subject to simplified procedure”

Annex 3 Response from the Icelandic competent authorities

**Response to the draft report of the EFTA Surveillance Authority's mission to
Iceland,**

3 to 7 March 2014

Subject: Primary production of food of non-animal origin

General remarks

The competent authorities MAST and LCAs would like to request the following correction to the wording under 'Findings' in chapter 5.2.3 of the report:

- Staff of the LCA is required by law to have a ~~basic education~~ university degree in public health, natural sciences, engineering or similar and they are obliged to undergo in-house practical training.

No	Recommendation	Reaction of Icelandic authorities	Date of Compliance	Comment/attachment
1	Iceland should ensure that the Authority is informed of requirements regarding approvals of certain establishments required by national law, as is required by Article 6(3)(c) of Regulation (EC) No 852/2004.	A notification of the national rules of Iceland regarding approval FBOs will be sent to ESA.	1.07.2014	

2	<p>The competent authorities should ensure efficient and effective coordination and cooperation between the different competent authorities responsible for the official control as required by Article 4(3) and furthermore, ensure that official controls are carried out consistently as is required in Article 4(4) of Regulation (EC) No 882/2004.</p>	<p>The current provision (art. 6) in the Act on Foodstuffs No 93/1995 states that MAST shall carry out official controls of primary production of food of non-animal origin. In the explanatory note with provision it is however stated that the LCAs shall be responsible for official controls of all packaging and distribution of primary production of food of non-animal origin. In most cases this goes hand in hand with the growing and harvesting, as the packaging is carried out at the production site and rarely the producers alter the nature of the products.</p> <p>A recommendation will therefore be made to the ministry of Industries and Innovation for an amendment on the Act on Foodstuffs regarding the responsibility of official controls of primary production of food of non-animal origin, in such a way that all controls of primary production that fall under the scope of annex I of Regulation (EC) No 852/2004, be moved under the responsibility of the LCAs. With such an amendment the official controls of growing, harvesting, packaging and distribution will fall under the control of a single authority.</p> <p>In the meantime MAST will ensure that all stages of primary production are covered by official controls by.</p> <p>1. Focusing immediately on producers of sprouts.</p>	1.7.2014	
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		<p>A letter will be sent to producers and official control started in summer as well as sampling and analysis (microbiological criteria).</p> <p>2. All regular means and tools for harmonization of control will apply to this area. See e.g. Country Profile for Iceland 2014, chapter 1.3 on the organisation and implementation of official controls and ch. 1.1 on coordination between CAs.</p> <p>3. MAST will draw up a control plan for 2014-2015 or until the above mentioned amendment of the act is implemented.</p> <p>4. Parallel to changed emphasis in the control of pesticide residues, inspection visits to producers will also be used for sampling of certain products.</p>	<p>1.9.2014</p> <p>1.10.2014</p>	
3	The competent authorities should ensure that that all stages of primary production is covered by official controls as required by Article 3 and 4(2)(a) of Regulation (EC) No 882/2004.	See answer to recommendation 2.		
4	The competent authorities should ensure that laboratories analysing official samples have at their disposal accredited methods as required by Article 12 of Regulation (EC) No 882/2004.	This fall Swedac (Swedish board for accreditation and conformity assessment) will visit Matís laboratory to evaluate and accredit new equipment and methods to analyse plant protection product residues in fruits and vegetables. Following that visit, Matis expects to be accredited for analysing	1.1.2016	

		100 PPP residues. Work will continue in 2015 to get more residues and matrixes accredited.		
5	Iceland should ensure that a national reference laboratory is designated for each Community reference laboratory as required by Article 33 of Regulation (EC) No 882/2004.	Further designation of laboratories is in process in the ministry of Industries and Innovation in cooperation with MAST. Financing for some NRLs is on the draft budget for 2015. Outstanding NRLs will be listed and information sent to ESA regarding their status.	1.1.2015	
6	The competent authorities should ensure that the requirements of Annex I to Regulation (EC) No 852/2004, in particular as regards documentation of procedures and record keeping, are respected by the primary producers of food of non-animal origin.	<p>The remarks made on documentation of use of pesticide during the mission will be followed up during the summer.</p> <p>A letter will be sent to all primary producers of food of non-animal origin to remind them of the requirement of Annex 1 in 852/2004 as regards documentation of the use of pesticides.</p> <p>Regarding follow-up of comments made on documentation during regular official control – see recommendation 2 above.</p>	1.10.2014	
7	The competent authorities should ensure that primary producers of food of non-animal origin take samples to monitor compliance with microbiological criteria as required in Article 4 and Annex I to Regulation (EC) No 2073/2005.	<p>FBO's own sampling to comply with the microbiological criteria will be checked in the relevant establishments (sprouts).</p> <p>MAST will follow up the remark made by the LCA during the mission regarding lack of sampling by the FBOs. See attached document.</p>	1.09.2014	