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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
AUSTRIA
FROM 03 TO 13 SEPTEMBER 2013
IN ORDER TO EVALUATE THE OFFICIAL CONTROLS IN PRIMARY PRODUCTION OF
FOOD OF NON-ANIMAL ORIGIN

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Austria, carried out from 3 to 13 September 2013 under the provisions of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004.

The objectives of the audit were to evaluate the system of official controls in the area of food hygiene for primary production of Food of Non-Animal Origin (FNAO) and system of official controls in the area of traceability and import of seeds intended for sprouting and sprouts, microbiological criteria for them and approval of sprouting establishments.

Although there are Competent Authorities (CAs) designated for the official controls of primary production of FNAO, the official control system for primary production of FNAO with exception of direct suppliers is not risk-based and covers only activities during and post harvest in a limited number of establishments. This means that the potential risks arising from microbiological contamination are not systematically taken into account in the planning of controls. The Austrian competent authorities plan to incorporate primary production in the risk based official control system.

Official controls in primary production of FNAO are carried out mainly as targeted actions for microbiological safety and follow established procedures for food processing establishments, based only on requirements established in Annex II of Regulation (EC) No. 852/2004 but not those in Annex I of Regulation (EC) No. 852/2004. The shortcomings identified regarding the sampling procedure could reduce the reliability of laboratory results.

The legislation on seeds for sprouting and sprouting establishments has not yet been fully implemented.

The report makes a number of recommendations to the CAs, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AGES	Austrian Agency for Health and Food Safety
AMA	Austrian Agriculture Organisation
BGBI	Federal Law Gazette of the Republic of Austria
BMG	Ministry of Health
BMLFUW	Ministry of Agriculture, Forestry, Environment and Water Management
CA(s)	Competent Authority(ies)
CC	Cross Compliance
CCA	Central Competent Authority
EFSA	European Food Safety Authority
EU	European Union
FAO	Food of Animal Origin
FBO(s)	Food Business Operator(s)
FNAO	Food of Non Animal Origin
FTE	Full Time Equivalent
FVO	Food and Veterinary Office
GAP	Good Agricultural Practices
GHP	Good Hygiene Practices
LMSVG	The Food Safety and Consumer Protection Act
MANCP	Multi Annual National Control Plan
MS(s)	Member State(s)
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operating Procedure
Sprouts	the product obtained from the germination of seeds and their development in water or another medium, harvested before the development of true leaves and which is intended to be eaten whole, including the seed
STEC	Shiga Toxin Producing <i>Escherichia Coli</i>
VTEC	Verocytotoxin Producing <i>Escheriachia Coli</i>

1 INTRODUCTION

The audit formed part of the Food and Veterinary Office's (FVO) planned audit programme and was carried out in accordance with 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.

The audit took place in Austria from 03 to 13 September 2013. The audit team comprised three auditors from the FVO.

Representatives from the Central Competent Authority (CCA) - the Ministry of Health (BMG), accompanied the audit team for the duration of the audit. An opening meeting was held on 03 September 2013 with the CCA. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit team and the control systems were described by the authorities.

2 OBJECTIVES

The objectives of the audit were to:

- Evaluate the system of official controls in the area of food hygiene for primary production of Food of Non Animal Origin (FNAO);
- Evaluate the system of official control in the area of traceability of sprouts and seeds intended for sprouting, microbiological criteria for them, approval of sprouting establishments and import controls.

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

In particular, the audit evaluated within this sector the implementation of:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs, in particular Article 4 (1) and Annex I and Regulation (EC) No 882/2004 on official controls, in particular Title II;
- Regulation (EC) No 178/2002, in particular, Article 18 regarding traceability.
- Regulation (EU) No 208/2013, Regulation (EU) No 210/2013 and Regulation (EU) No 211/2013 and Regulation (EC) No 2073/2005 regarding microbiological requirements for sprouts and seeds for sprouting.

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

Table 1. Audit visits and meetings

Visits/Meetings	Comments	
Competent Authorities		
Central	3	Opening meeting (BMG, CAs from the provinces Upper Austria, Lower Austria, Burgenland) meeting with the Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) closing meeting (BMG, CAs from the provinces of Upper Austria, Lower Austria, Burgenland)

Regional	3	Upper Austria, Lower Austria, Burgenland
Producers	1	Sprouting establishment and importer of seeds
	2	Leafy vegetable farms
	2	Vegetable farms
	1	Raspberry farm
	1	Strawberry farm
	1	Blueberry farm

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation, in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

EU legal acts quoted in this report refer, where applicable, to the last amended version. Full references to the EU acts quoted in this report are given in Annex 1.

4 BACKGROUND

Information on the existence of direct or indirect risk to human health deriving from food or feed is disseminated via notifications through the Rapid Alert System for Food and Feed (RASFF) to all Member States (MSs) and to the exporting country. From 2011 up until the time of the audit there were 170 notifications concerning pathogenic micro-organisms in fruits and vegetables.

The European Food Safety Authority (EFSA) adopted a scientific opinion on the risk posed by FNAO: <http://www.efsa.europa.eu/en/efsajournal/pub/3025.htm>.

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

From 2008 to 2011 there was an increase in the number of reported outbreaks, cases, hospitalisations and deaths associated with FNAO. In order to identify and rank specific food/pathogen combinations most often linked to human cases originating from FNAO in the EU, a model was developed using seven criteria: strength of associations between food and pathogen based on the food-borne outbreak data from EU Zoonoses Monitoring (2007-2011), incidence of illness, burden of disease, dose-response relationship, consumption, prevalence of contamination and pathogen growth potential during shelf life.

The top ranking food/pathogen combinations were :

- leafy greens eaten raw as salads/*Salmonella spp.* and *norovirus*;
- bulb and stem vegetables; tomatoes; melons; sprouts/*Salmonella spp.*;
- fresh pods, legumes or grain/pathogenic *Escherichia coli*.

The EFSA adopted a scientific opinion on the risk posed by shigatoxin producing *Escherichia coli* and other pathogenic bacteria in seeds and sprouts, after the outbreaks of shigatoxin producing *Escherichia coli* in May 2011 in the European Union. The EFSA report can be found at: <http://www.efsa.europa.eu/en/efsajournal/pub/2424.htm>.

The consumption of sprouts was identified as the most likely origin of the outbreaks. Over 4000 human cases were reported and 55 people died. In its opinion EFSA concluded that the contamination of seeds with bacterial pathogens is the most likely initial source of sprout-associated outbreaks. Due to the high humidity and the favourable temperature during sprouting, bacterial pathogens present on dry seeds can multiply on the sprouts.

In view of the number of large outbreaks and the high number of RASFF notifications concerning primary products of non-animal origin the FVO decided to undertake an audit series to MSs on primary production of FNAO.

5 FINDINGS AND CONCLUSIONS

5.1 RELEVANT NATIONAL LEGISLATION

Legal Requirements

Article 291 of the Treaty on the Functioning of the EU establish that MSs shall adopt all measures of national law necessary to implement legally binding Union acts.

Findings

The main national legislation in the context of this audit is The Food Safety and Consumer Protection Act (LMSVG), Federal Law Gazette of the Republic of Austria (BGBl) I No. 13/2006, which also enables the implementation of Regulation (EC) No 882/2004 and Regulation (EC) No 852/2004.

The Ordinance BGBl II No. 108/2006 establishes the hygiene requirements for the direct supply (as defined by Article 1(2)(c) of Regulation (EC) No 852/2004) of small quantities of primary products, including harvested wild products. However, small quantities are not defined.

The BMG is responsible for drafting legislation within the scope of this audit. All legislation is made available to the public on the BGBl website: <http://www.ris.bka.gv.at>

The audit team noted a technical mistake in the German language version of Regulation (EU) No 211/2013. In part II of the Certificate laid down in Annex to the Regulation there are requirements for sprouts only while in the English version there are requirements for seeds and sprouts.

The audit team was informed by the CCA that the LMSVG will be amended to formally incorporate the requirements of Regulation (EU) No 210/2013, which is now implemented through legislation

covering food of animal origin. It is foreseen that the amendment will be in force in 2014.

Conclusions

National legislation is not yet fully in line with relevant EU legislation, however the requirements of Regulation (EU) No 210/2013 are applied. All relevant legislation is publicly available.

Additional national legislation covers the direct supply of small quantities of primary products.

5.2 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS

5.2.1 Designation of Competent Authorities and Resources for Official Controls

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires MSs to designate the CAs responsible for official controls.

Article 4 of Regulation (EC) No 882/2004 requires the CA to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available.

Article 6 of Regulation (EC) No 882/2004 requires CAs to ensure that staff performing official controls receive appropriate training, and are kept up-to-date in their competencies.

Findings

The main legislation establishing the responsibilities of the CAs is the LMSVG. The CCA within the scope of this audit is the BMG - Department II/B/13 (food legislation, food safety and food quality). The CCA is responsible for co-ordination of the monitoring of FNAO and training of staff. At regional level the Provincial Governor implements the federal food policy. The provincial CAs are required to follow the instructions issued by the BMG.

The CAs stated that they are responsible for the official control of primary production of FNAO during or post harvesting. However, the audit team was not provided with evidence of official controls during harvesting.

The CCA stated that the primary production of FNAO before harvest is the subject of private controls on the request of some primary plant products purchasers.

There are 248 Full Time Equivalent (FTE) food inspectors in Austria.

The training requirements are set out in the national Regulation on the Training of Inspectors No 275/2008 amended by Regulation No 322/2009, which lays down the duration and content of training. Module II of the obligatory basic training includes a session on primary production of FNAO.

The audit team was informed by the CAs that training has not been provided on new EU legislation on sprouting and seeds intended for sprouting and none was planned. The FVO noted that inspectors met had problems with implementation of new legislation on sprouting and seeds for sprouting. (See also chapter 5.2.4.2.)

In Lower Austria there are 32 food inspectors, four of them are at central provincial level. They all carry out inspections of primary production of FNAO.

In Upper Austria there are 40.5 FTE food inspectors, nine of them at central provincial level. The scope of their activities also covers primary production of FNAO.

In all of the provinces visited the inspectors met demonstrated a good knowledge of general hygiene provisions.

Every food inspector has a minimum of a secondary school education plus specific food safety training ranging between five and nine months duration or they are physicians or veterinarians.

Conclusions

The CAs in the context of this audit are designated in accordance with the requirements of Regulation (EC) No 882/2004, however, there is no designation of authorities responsible for primary production prior to harvest (see Section 5.2.3).

Staff have received training for the implementation of official controls. However, training has not been provided on new legislation regarding sprouts and seeds for sprouting.

5.2.2 Registration / Approval of Establishments

Legal Requirements

Article 6 of Regulation (EC) No 852/2004 requires that Food Business Operators (FBOs) shall notify the appropriate CA of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with view to its registration. It also requires that FBOs ensure that establishments are approved by the CA when approval is required under national law or by a decision adopted by the Commission.

Article 2 of Regulation (EU) No 210/2013 requires that establishments producing sprouts are approved by the CA in accordance with Article 6 of Regulation (EC) No 852/2004.

Article 31 of Regulation (EC) No 882/2004 requires MSs to establish procedures for FBOs to follow when applying for the registration/approval of their establishments. It also provides for reviewing compliance with conditions of approval and for the withdrawal of approvals.

Findings

There is a procedure in place for the registration of food establishments. Within the scope of this audit only the farms directly supplying their produce (regardless of quantity) on their farms or through retail in Austria (hereinafter referred to as “direct suppliers”) are entered into the register.

The other farms solely producing FNAO (selling their produce for further processing or for export) are registered by the CAs only if they had been visited in connection with investigation of outbreak or complaint.

Food establishments are registered on the basis of the activities with the highest food safety risk. The other activities that are under the control of the CA are entered as a note to the registration. There are currently no registered establishments importing or packing seeds intended for sprouting, as they were not considered to be a stage of production, processing and distribution of food by the CA.

Provinces only register establishments which are known to them. According to the 2010 Activity Report of the provinces published by the BMG, there are about 142,000 establishments, of which 10,694 are farms.

The audit team was informed by the CA that farms are registered by the BMLFUW and this database is accessible to the BMG and the provinces. The provincial inspectors met by the audit team stated, that this database does not include information relevant to their activities.

In Lower Austria the CA has registered approximately 800 farms; however, it was not possible to distinguish establishments producing FNAO.

In Upper Austria there are 1659 farms registered, of which 554 produce FNAO. However, according to the data provided by the BMLFUW there are around 26,000 farms producing FAO and FNAO.

In two provinces visited the audit team confirmed that the farms producing FNAO are registered only if they are direct suppliers. The other farmers only producing FNAO are register only if they were inspected in connection with a complaint received or due to an outbreak.

The procedure for approval of establishments producing sprouts is laid down in the Food Hygiene Licensing Regulation (*Lebensmittelhygiene-Zulassungsverordnung*), BGBl, II No 231/2009. The names of the approved establishments are published on the BMG website. Currently, two approved sprouting companies are listed. The audit team noted that there was one sprouting company, which was not approved by the CA. (See also chapter 5.2.4.)

The sprouting establishment visited by the audit team had been approved. The establishment was approved despite the fact that the inspection had identified a number of non-compliances.

Conclusions

There are procedures in place for the registration of establishments. According this procedure are registered only farms producing FNAO that are direct suppliers, other farms are registered only on a case to case basis.

The approval of the sprouting company visited did not ensure that it complies with the requirements as set out in Annex I of Regulation (EC) No 852/2004 and in the Annex to Regulation (EU) No 210/2013.

5.2.3 Organisation and Scope of Official Controls

Legal Requirements

Article 17 of Regulation (EC) No 178/2002 requires that MSs shall enforce and monitor and verify that the relevant requirements of the food law are fulfilled by the FBOs at all stages of production,

processing and distribution.

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency, taking account of (a) identified risks; (b) the FBOs' past record as regards compliance; (c) the reliability of any own checks that have already been carried out; and (d) any information that might indicate non-compliance.

Findings

The audit team was informed by the CCA that primary producers of FNAO including sprouting establishments are not included in the risk categorisation system as laid down in the Multi Annual National Control Plan (MANCP). If the primary producer is categorised it is only because he is registered as a direct supplier. This activity falls within the risk category covering wholesalers, retailers and distributors. This means the frequency of official controls is once every three or four years.

The audit team was informed by the CCA that a working group is currently drafting an amendment to the current risk categorisation system in order to incorporate primary production of FNAO. It is foreseen that this will be implemented in 2015. The audit team was informed that from 2014 sprouting companies will fall within the current “ risk category seven” and an inspection will take place every two years.

The audit team was informed in the provinces visited that primary producers of FNAO not supplying directly, would be visited only in cases of suspicion, in the case of a complaint received or non-compliant laboratory results of sampling. The CAs inspectors met stated that fields are visited only during harvest for sampling purposes in case of suspicion or complaint received.

According to the data provided in Lower Austria they control approximately 40 out of 800 registered directly supplying farms annually. In Upper Austria the CAs stated that 70-100 out of 554 registered directly supplying farms are controlled annually. The audit team noted that these inspections cover only post harvest activities such as packaging, sorting and selling.

The sampling is carried out according to the risk based inspection and sampling plan, which is produced each year by the BMG in co-operation with the Austrian Agency for Health and Food Safety (AGES). In addition to risk based plans, several targeted national or provincial priority actions are carried out each year.

The plan for laboratory testing (microbiological and chemical), developed by the AGES, includes the scope of possible tests for each group of foodstuffs. The plan for laboratory testing for 2013 establishes obligatory testing of small fruits and berries for *Escherichia coli* and testing of strawberries for Shiga Toxin Producing *Escherichia coli* (STEC).

A national priority action for the microbiological safety of pre-packed sprouted seeds, strawberries and lettuces was carried out in 2012. In the same year a national priority action on nitrate contamination of spinach and lettuce was organised. The national priority action in 2008 focused on *norovirus* contamination of berries grown close to the ground and the same action was carried out in 2013.

In 2012, 34 samples of sprouted seeds were analysed, all were tested for the presence of STEC and 31 for *Salmonella spp.* Two of them were not-compliant due to microbiological contamination and

the CA imposed measures according to Article 5 of the LMSVG. In 2013 four samples of sprouts were tested, all were tested for STEC and one for the presence of *Salmonella spp.*.

In Burgenland the audit team was informed that in 2011 a specific province control action focused on *Escherichia coli* contamination of fruits and vegetables was carried out. There were no cases of non-compliance.

In Burgenland in 2011, 37 samples were taken of primary plant products for microbiological testing. There were no cases of non-compliance.

The activities in primary production of FNAO before harvest are not the subject of official controls for compliance with the hygiene provisions as laid down in Annex I of Regulation (EC) No 852/2004, because the CAs do not consider plants before harvest to be food.

Conclusions

Official controls on primary production to verify compliance with requirements in Annex I to Regulation (EC) No 852/2004 cover only establishments registered as processing establishments or direct suppliers, wholesalers which are categorised as processing or trading establishments and farms are only covered if they are direct suppliers or in case of suspicion of non-compliance. Furthermore, the official controls do not cover the observance of hygiene requirements in Annex I to Regulation (EC) No 852/2004 relevant for pre-harvest and for harvesting and therefore FBO's compliance with those requirements cannot be ensured.

5.2.4 Implementation of official controls over FBO's obligations

Legal Requirements

Article 10(2)(b)(i) of Regulation (EC) No 882/2004 requires that official controls on food include, the inspection of primary producers' installations, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of food.

Article 10(2)(c) of Regulation (EC) No 882/2004 requires that official controls on food include, inter alia, checks on hygiene conditions in food businesses.

Article 10(2)(d) of Regulation (EC) No 882/2004 requires that official controls on food shall include the assessment of procedures on good hygiene practices and good farming practices, taking into account the use of guides established in accordance with Union legislation.

Article 4(1) of Regulation (EC) No 852/2004 requires that FBOs carrying out primary production and associated operations listed in Annex I must comply with the general hygiene provisions laid down in part A of Annex I to that Regulation.

Article 7 of Regulation (EC) No 852/2004 requires that MSs encourage the development of national guides to good practice for hygiene in accordance with Article 8, which requires MSs to assess national guides and forward to the Commission national guides complying with the requirements of that Article.

Article 8 of Regulation (EC) 852/2004 requires that if national guides to good practice are developed, they shall be developed and disseminated by food business sectors and when they

concern primary production and those associated operations listed in Annex I, they should take into consideration recommendations contained in Part B of Annex I to Regulation (EC) 852/2004.

Part B of Annex I to Regulation (EC) 852/2004 states that national guides referred to in Articles 7 to 9 of this Regulation should contain guidance on Good Hygiene Practices (GHP) for the control of hazards in primary production and associated operations.

Article 18 of Regulation (EC) No 178/2002 establishes traceability requirements in food.

Article 15(1) of Regulation (EC) No 882/2004 requires that official controls on food include regular official controls on FNAO imported into the EU.

Article 3 of Regulation (EU) No 208/2013 establishes traceability requirements for all stages of production processing and distribution of batches of seeds intended for the production of sprouts and for the batches of sprouts.

Regulation (EU) No 211/2013 establishes the certification requirements for imports into the European Union of sprouts and seeds intended for the production of sprouts.

Annex I of Regulation (EC) No 2073/2005 establishes general rules for sampling and testing of seeds and sprouts and the spent irrigation water.

Findings

To date, 24 sets of sector-specific guidelines for GHP and Hazard Analysis and Critical Control Points have been drawn up. However, the audit team was informed that primary production of FNAO has not been covered in these guides.

All farmers are obliged to be members of the chamber of agriculture. This membership provides for training on GAP, specialised guidelines and instruction documents. Most of the farmers have been certified under private sector GAP scheme as this is a requirement of their customers.

The audit team visited seven primary producers of different kinds of fruits and vegetables (strawberries, blueberries, leafy and bulb vegetables). All of them were also direct suppliers to the market or processors.

All inspectors used the official procedural instructions for checks on “other” production establishments. All inspections covered harvest and post-harvest activities on farms. All inspectors covered general hygiene requirements established in Annex II to Regulation(EC) No 852/2004. One of the inspectors met explained that Annex II is used because the farms for primary plant products are not covered by the risk categorisation system.

One inspector did find a number of non-compliances relating to the construction of the facility and cleanliness. However the facility was not assessed against criteria in Annex I to Regulation(EC) No 852/2004.

One of the inspectors met did not notice possible contamination of lettuce from water used for washing. All inspectors, with one exception, adequately assessed the traceability requirements. The same inspector did not identify the clients and in one case he did not check traceability at all. The audit team noted that the inspection in case of suspicion of microbiological contamination

covered only general hygiene provisions for harvest and did not focus on other possible source of that contamination during pre- harvest stage (e.g. contamination of soil, used irrigation water, use of fertilisers, disposal of waste and prevention of animal and pest entering the fields).

During one of the inspections the sampling of blueberries under the national sampling plan was carried out. See also chapter 5.2.5.

5.2.4.1 *Other Control Systems*

The AMA is a body responsible for the planning of Cross Compliance (CC) checks on farms. The CC controls cover, *inter alia*, general food safety provisions as laid down in Articles 17-20 of Regulation(EC) No 178/2002. post harvest and use of pesticides and fertilisers during growth in approximately 1% of all farms annually (producing FAO, FNAO). Out of these farms 20-25 % are farm producers of FNAO.

In the provinces visited by the audit team, CC controls are carried out as follows :

- In Lower Austria CC controls are carried out by AMA. The reports are assessed by the provincial veterinary service and forwarded to AMA.
- In Upper Austria CC controls are carried out by the Department of Agriculture and Forestry and by the Veterinary Service unit of the province. Both CAs receive a list of planned inspections from the AMA. Results are provided directly to the AMA.

5.2.4.2 *Official Controls on Imports and Sprouting Establishments*

The sprouting establishment visited produces approximately 1,000 tons of sprouts every year. Mungbean sprouts account for 95 percent and the rest are radish sprouts, alfalfa sprouts etc. The FBO imports mungbeans directly from China and buys other seeds from Italy. Clients mainly include catering establishments and retail shops in Austria and in some other MSs. The establishment is categorised as risk level seven with one visit every two years. The inspection focused on general food hygiene provisions. The inspector identified a number of non-compliances in the construction of the facility, which were not detected during a recent approval visit. The inspector satisfactorily assessed traceability of seeds and sprouts. However, the inspector did not notice that the FBO did not carry out preliminary testing of all batches of seeds used for sprouting. The FBO did not carry out sampling and testing of sprouts or of spent irrigation water as required by Annex I of Regulation (EU) No 2073/20005. The inspector adequately assessed the total weight of the representative sample taken by the FBO, however, he did not note that sub-samples were not taken as required by Regulation (EC) No 2073/2005. The assessment of the labelling requirements was correctly undertaken. The inspector met stated that he had not received any instructions and training from the CA on the implementation of new legislation. See also chapter 5.2.1.

The certificate for imported seeds intended for sprouting are checked at sprouting companies, during official controls.

The inspector met in the sprouting company satisfactorily assessed the certificate (in English) accompanying an imported batch of seeds used for sprouting. The audit team noted that the certificate was signed by a registered factory inspector and stamped with the stamp of the producer which is contrary to legal standards.

Conclusions

Official controls on primary plant products are carried out during and post harvest at processing or trading food establishments.

The primary producers of FNAO visited were assessed against the general hygiene provisions as laid down in Annex II of Regulation (EC) No 852/2004, but not against provisions laid down in Annex I to the same Regulation.

The traceability assessment in most cases was adequately undertaken, with the exception of two cases.

There are national guides for GHP but none have been developed for primary producers.

The official controls did not include the assessment of procedures for GAP, as required by Article 10(2)(d) of Regulation (EC) No 882/2004.

The assessment of the sprouting establishment was adequately undertaken; although non-compliant sampling procedure by FBO was not noted.

The assessment of documentation for the imported seeds in the sprouting company visited was not adequate.

5.2.5 Official Sampling Procedures

Legal Requirements

Article 11 of Regulation (EC) No 882/2004 establishes requirements for sampling.

Regulation (EC) No 2073/2005 establishes sampling rules and microbiological criteria for sprouts.

Findings

In Lower Austria the audit team observed a planned official sampling of onions. The inspector took 1 kg of onions and placed them in a non-sterile plastic bag, which was then sealed and labelled. The inspector took 2 parallel samples and the second one was left with the FBO to enable the FBO to obtain a supplementary expert opinion in case of non-compliance. The inspector met by the audit team stated that he never took samples of fresh produce for microbiological investigation and was not provided with sterile equipment and packaging material for such sampling.

In Upper Austria the audit team was informed that sampling for microbiological testing follows General sampling instructions VA-P030A 04. However, for such sampling the inspectors are not provided with sterile equipment and packaging material. In 2012, 48 samples were taken for microbiological testing in this province and there were no cases of non compliance.

In Upper Austria the audit team observed planned sampling of blueberries. The inspector took 1 kg of berries from an open cardboard box, and placed them in a non-sterile plastic bag, which was then sealed and labelled. The inspector took 2 parallel samples and the second one was left with the FBO to enable the FBO to obtain a supplementary expert opinion in case of non-compliance. The sampling plan for 2013 requires that each sample of berries should be tested for the presence of

Escherichia coli. The inspector was not aware of the scope of testing for the sample taken.

The audit team verified the sampling equipment provided to the inspectors. The equipment was not suitable for taking official samples for microbiological testing.

The audit team was informed that as a general rule the scope of the laboratory analysis is decided by the laboratory, and it is not made available to the inspector at the time of sampling. The scope of the analysis is made available to the inspectors only in cases of national specific actions. The assessment of the results is carried out by the laboratory. The FBO receives the laboratory results only in cases of non-compliance.

Conclusions

The observed handling with sample taken did not guarantee the analytical validity for microbiological testing, as required by Article 11 of Regulation (EC) No 882/2004, due to lack of sampling equipment.

5.2.6 Procedures for Performance and Reporting of Control Activities

Legal Requirements

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

Article 9 of the above Regulation requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Findings

In general, inspections are unannounced. Reports are provided to the FBOs in cases of non-compliance. All inspections and samples are recorded electronically in a database operated by the CAs.

The Standard Operating Procedure (SOP) No. VA–K 0208.04, Version 4.0, (“*Verfahrensanweisung für die Kontrolle von sonstigen Herstellerbetrieben*”) - procedural instructions for checks on other production establishments are used for official controls in primary production during and post harvest. The SOP includes several checklists; one of which is used for inspections of primary production during and post harvest. The SOP cover requirements established in Annex II of Regulation (EC) No 852/2004 but not those laid down in Annex I of the same Regulation. The audit team noted that inspectors met used the SOP.

Conclusions

Official controls are carried out in accordance with documented procedures as required by Article 8 of Regulation (EC) No 882/2004. However, these procedures are not completely relevant to primary production.

Reports are drawn up following all inspections where non-compliances have been found as required by Article 9 of Regulation (EC) No 882/2004.

5.2.7 *Co-operation Between and Within Competent Authorities*

Legal Requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination between CAs.

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

Findings

Co-operation between Federal level and provinces is described in the Country Profile (http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=AT).

In Upper Austria the audit team was informed that every quarter, meetings are organised with all inspectors to discuss any issues and problems which have arisen. At the first meeting of the year inspectors are informed of plans for inspections and sampling. At this meeting a representative from the AGES is present. The audit team was provided with evidence of such meetings.

Good cooperation between CAs was observed in the case of follow-up of non-compliant sprouts due to the microbial contamination.

Conclusions

There is co-ordination and co-operation between CAs in place as required by Article 4(3) of Regulation (EC) No 882/2004.

5.2.8 *National Enforcement Measures*

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take action to ensure that the operator remedies the situation.

Article 55 of Regulation (EC) No 882/2004 requires that MSs shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings

The implementing measures laid down in food legislation and indicated in the MANCP are available to the CAs.

The audit team was informed that no sanctions and measures were imposed in primary production.

Conclusions

There are national legal requirements in place to ensure that appropriate action is taken in cases of non-compliances.

6 OVERALL CONCLUSIONS

Although there are CAs designated for the official controls of primary production of FNAO, the official control system for primary production of FNAO with exception of direct suppliers is not risk-based and covers only activities during and post harvest in a limited number of establishments. This means that the potential risks arising from microbiological contamination are not systematically taken into account in the planning of controls. The Austrian CAs plan to incorporate primary production into the risk based official control system.

Official controls in primary production of FNAO are carried out mainly as targeted actions for microbiological safety and follow established procedures for food processing establishments, based only on requirements established in Annex II of Regulation (EC) No. 852/2004 but not those in Annex I of Regulation (EC) No. 852/2004. The shortcomings identified regarding the sampling procedure could reduce the reliability of laboratory results.

The legislation on seeds for sprouting and sprouting establishments has not yet been fully implemented.

7 CLOSING MEETING

A closing meeting was held on 13 September 2013 with representatives from all the CAs concerned. At this meeting the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and made some comments on the findings and preliminary conclusions.

8 RECOMMENDATIONS

The CAs are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of the translated draft audit report:

N°.	Recommendation
1.	Ensure that all staff performing official controls receive appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner, as required by Article 6 and Annex II of Regulation (EC) No 882/2004, and in particular in the area of seeds intended for sprouting and sprouts
2.	Ensure that all establishments (farms) producing food are registered as required by Article 6 of Regulation 6 of Regulation 852/2004.
3.	Ensure that approval of establishments producing sprouts follows the requirements of

N°.	Recommendation
	Regulation (EU) No 210/2013.
4.	Ensure that potential risks arising at primary production, including at the growing stage, are taken into account in the development of risk-based planning of official controls in line with Article 3 of Regulation (EC) No 882/2004.
5.	Ensure that official controls in primary production of FNAO including establishments producing sprouts and importing/packing seeds intended for the production of sprouts are carried out regularly, on a risk-basis and with appropriate frequency as required by Article 3 of Regulation (EC) No 882/2004.
6.	Ensure that CAs responsible for official controls on primary production of FNAO carry them out in accordance with documented procedures, as required by Article 8 of Regulation (EC) No 882/2004, which contain information and instruction relevant for the controls performed.
7.	Ensure that official controls in establishments producing sprouts verifies that the FBO's sampling and testing follows rules set out in Annex to Regulation (EC) No 2073/2005 as required by Article 1 of Regulation (EC) No 2073/2005.
8.	Ensure that official controls of FNAO include the assessment of good farming practices as required by Article 10(2) of Regulation (EC) No 882/2004.
9.	Ensure that the samples are handled such way to ensure their analytical validity as required by Article 11(7) of Regulation (EC) No 882/2004.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6663

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 208/2013	OJ L 68, 12.3.2013, p. 16-18	Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts
Reg. 210/2013	OJ L 68, 12.3.2013, p. 24-25	Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council
Reg. 211/2013	OJ L 68, 12.3.2013, p. 26-29	Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts

Legal Reference	Official Journal	Title
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs