

Brussels, January 2017

EFTA SURVEILLANCE
AUTHORITY

COUNTRY PROFILE – PART 1

Iceland

Competent authority control systems in the areas of food and feed safety, animal health and animal welfare

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INTRODUCTION

This country profile has been drawn up by Iceland in cooperation with the EFTA Surveillance Authority (“the Authority”) to present in a summary form the latest information available on the Icelandic control systems related to food and feed safety, animal health and welfare. Plant health is not part of the country profile as it does not fall under the Agreement of the European Economic Area (“the EEA Agreement”, “the Agreement”).

The information in this country profile has been compiled from:

- Recent written submissions and background documentation from the Icelandic competent authorities detailing how control systems are organised.
- The results of the EFTA Surveillance Authority’s missions to Iceland in recent years and, in particular, a general review mission in Iceland which took place in September 2016.

This country profile is presented in two main chapters:

Chapter 1 describes the overall organisation of the Icelandic authorities and the respective responsibilities of the relevant ministries in relation to the different components of the control system.

Chapter 2 gives a more detailed description of the different control systems that form the complete range of official controls in Iceland and cover the whole chain of animal, feed and food production.

This country profile is to be updated at least every three years pursuant to the EFTA Surveillance Authority’s missions or additional relevant information being submitted by the Icelandic competent authorities.

Acronyms are used extensively throughout this report for the sake of brevity. A list of acronyms, abbreviations and special terms is given in Annex I.

1 COMPETENT AUTHORITIES AND IMPLEMENTATION OF REQUIREMENTS

1.1. Designation of competent authorities

The main Icelandic legislation in relation to designation of competent authorities for food, feed, animal health and animal welfare are:

- Act No 93/1995 on Food;
- Act No 25/1993 on Animal Diseases and Preventive Measures;
- Act No 96/1997 on Slaughtering etc.;
- Act No 55/1998 on Marine products;
- Act on Veterinarians and Animal Health, No 66/1998;
- Act on Control of Feed, Fertiliser and Seed, No 22/1994;
- Act on the Food and Veterinary Authority, No 80/2005;
- Act on Hygiene and Pollution Control, No 7/1998;
- Act on Animal Welfare, No 55/2013;
- Act on Livestock management, No 38/2013;
- Regulation No 102/2010, incorporating 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;
- Regulation No 103/2010, incorporating Regulation (EC) No 852/2004 on the hygiene of foodstuffs;
- Regulation No 104/2010, incorporating Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin;
- Regulation No 105/2010, incorporating Regulation (EC) No 854/2004 laying down specific hygiene rules for the organisation of official controls on products of animal origin intended for human consumption;
- Regulation No 106/2010, incorporating 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;
- Regulation No 107/2010, incorporating Regulation (EC) No 183/2005 laying down requirements for feed hygiene.

Ministry of Industries and Innovation (MoII)

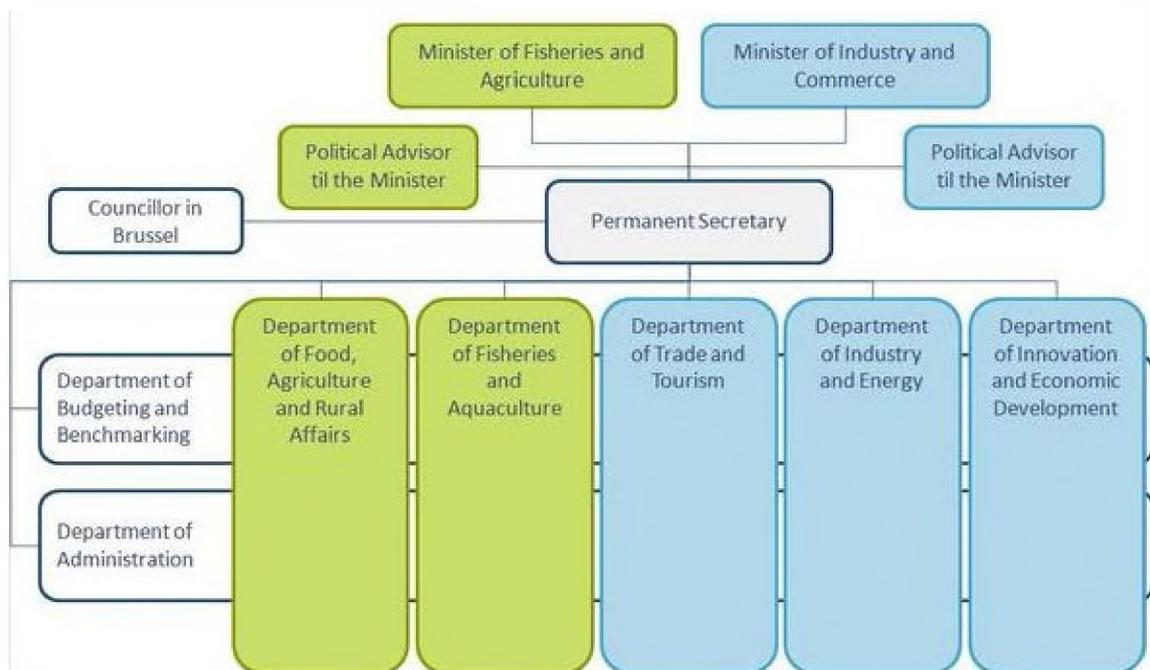
The Ministry of Industries and Innovation (MoII) is the lead Ministry for policy co-ordination and transposition of legislation concerning issues related to food and feed safety, animal health and animal welfare. Within the Ministry, the Department of food, agriculture and rural affairs is responsible for policy development/co-ordination and legislation (including the transposition of the EU legislation). The Ministry was formed with a merger of the former Ministry of Fisheries and Agriculture, the Ministry of Industry, Energy and Tourism and part of the Ministry of Economic Affairs and opened on 1 September 2012.

The MoII is responsible for issues related to:

- Fisheries and agriculture;

- Control of production and import of food and feed products;
- Culture of aquatic and marine species;
- Food and feed safety related issues;
- Animal health and welfare;
- Research and management of marine resources.

Picture 1. MoII organisation chart:



Icelandic Food and Veterinary Authority (MAST)

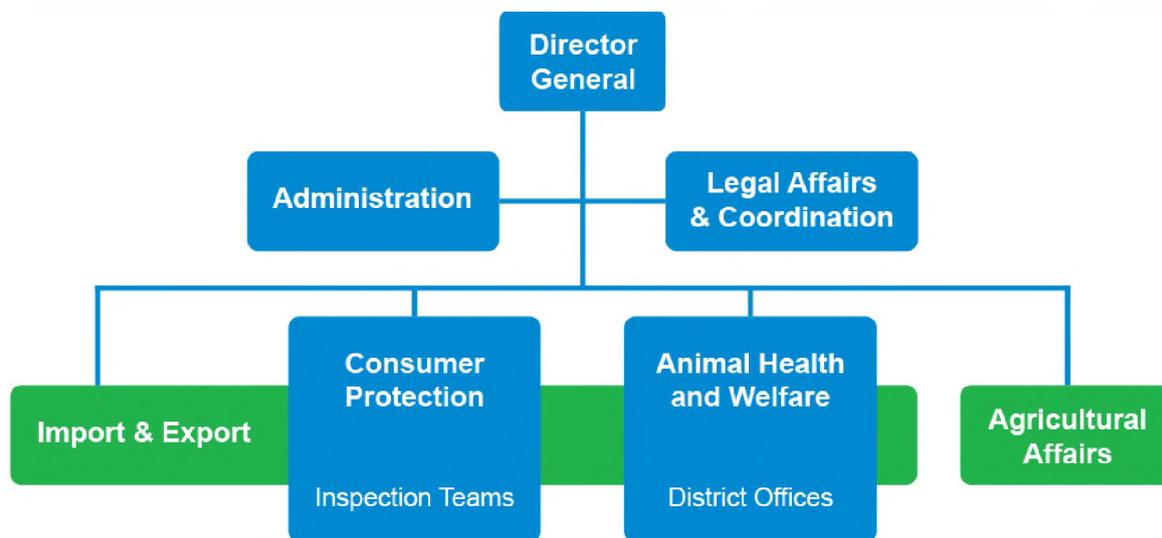
Since 1st of January 2008, MAST is the central competent authority for food and feed safety, animal health and animal welfare and operates under the auspice of MoII. The organisation and structure of MAST is based on provisions of Act (IS) No 80/2005. MAST operates six district offices and an office for import and export, and is responsible for operation of several Border Inspection Posts (BIPs) for control of import of foods from third countries (non-EEA States).

MAST's primary roles are:

- Food safety; control of all primary production, production of foodstuffs of animal origin and import and export control of all foodstuffs;
- Controls regarding animal health and animal welfare;
- Plant protection services;
- Feed (including fish meal), seed and fertiliser services;
- Meat classification services;
- Administration of organic production of agricultural products;
- Disease control and prevention (zoonoses and contingency plans);
- Consumer affairs and education;

- Administration and control of aquaculture;
- Agricultural affairs (subsidies etc.);
- Supervision of domestic food control by the independent Municipal Environmental and Public Health Offices (Local Competent Authorities (LCAs)); coordination of official controls to ensure that they are implemented in the same manner. MAST may in this regard issue guidelines for the LCAs to follow. For further clarification see chapter on coordination between Competent Authorities (CAs).

Picture 2. *MAST Organisation chart:*



Management: DG and Directors of Offices, including the CVO

Directorate of Fisheries (DoF)

The Directorate of Fisheries is an agency of the Ministry of Industries and Innovation. The Directorate's task is to monitor fishing activities and to administer the fisheries management system in Iceland. This involves issuing of fishing permits, distribution of quotas and overseeing the daily operation of the individually transferable quota system. The Directorate collects data on all landed catch from landing sites in real time as well as information on processing and exports of fish products. The Directorate monitors the operation of fishing vessels, the weighing of landed catch and processing of fish both on site and through electronic surveillance such as through vessel monitoring systems which the Agency runs in cooperation with the Coast Guard of Iceland. The Directorate employs approximately 75 people. The Directorate works in close cooperation with the Marine Research Institute of Iceland, the Coast Guard and the Food and Veterinary Authority of Iceland, as well as other agencies serving the fisheries sector, both in Iceland and internationally.

The DoF is responsible for fisheries management in the Icelandic exclusive economic zone as well as Icelandic fisheries outside Icelandic jurisdiction. The Directorate also has administrative responsibilities and monitors fishing of salmonids in lakes and rivers and oversees whaling.

Ministry for the Environment and Natural Resources (MoE)

Ministry for the Environment and Natural Resources formulates and enforces government policy for environmental affairs, nature conservation, wildlife management, pollution and waste management, environmental monitoring and surveillance.

Environment Agency (UST)

The Environment Agency operates under the auspice of MoE and its organisation and structure are based on provisions of Act (IS) No 90/2002. UST has the role of promoting environmental protection and sustainable use of Iceland's natural resources, as well as public welfare, by ensuring a healthy environment, safe consumer goods and enhancing hygiene and safety in public facilities. UST manages eco-labelling, labelling and handling of toxic and other hazardous substances. It conducts the evaluation of environmental impact assessment and development plans. It is responsible for the management and supervision of designated protected areas, assessment of conservation effects and registration of unique nature sites. UST is the competent authority for the implementation of the Water Framework Directive. UST has a wide-reaching administrative role, for instance concerning pollution issues (water, waste, air, soil), health and safety, nature and wild animal protection, wildlife conservation and management, monitoring of environmental quality, hunting management, biological diversity, the registration and marketing of pesticides and certification systems for professional users of pesticides as well as genetically modified organisms. The agency provides information and gives advice to the public, businesses and regulatory authorities. UST supervises and coordinates the work of LCAs (see below). Generally, the supervision and the coordination is mostly based on organised communication, formal requests, meetings for coordinating actions, organisation of country wide control actions, and issuance of guidelines. The UST meets with LCAs twice a year. Furthermore, there are specialised working groups in different sectors where the specialised staffs of both UST and LCAs meet regularly to discuss ways to improve controls and the implementation of legal requirements. Also UST has published guidelines for implementation in specific fields. LCAs can send formal requests asking UST for review, information, interpretation and opinion on certain matters arising or according to formal procedures laid out in relevant legislation.

Municipal Environmental and Public Health Offices (LCA)

Iceland is divided into 10 LCA districts, each comprising between one and fifteen municipalities. Each LCA district staff operates under the jurisdiction of a local public health committee, comprising control district staff, several politically appointed members and one member representing the confederation of Icelandic Employers. Each LCA has control duties within its districts related to food safety, environmental protection and general hygiene. The organisation and structure of the LCAs is based on provisions of Act (IS) No 7/1998 on Hygiene and Pollution control. The district chief epidemiologist attends in general the meetings of the local public health committees.

Ministry of Welfare (MoWF)

The Ministry of Welfare is responsible for administration and policy for health and health insurance issues in Iceland, as prescribed by law, regulations and directives, including:

- Public health;
- Patient rights;
- Operation of hospitals, health centres and other providers of health services;
- Promotion of information technology in the health services;
- Pharmaceutical affairs (including veterinary medicines);
- Health Insurances.

The Directorate of Health (DoH)

The Directorate of Health operates under the auspice of the MoWF. The Chief Epidemiologist at the DoH is responsible for health security and general and public

measures on communicable diseases and other threats to health. The Chief Epidemiologist is also the chairperson of the Joint Committee on Health Security and Communicable Disease Control (JC), a supervisory body appointed under the MoWF.

The Icelandic Medicines Agency (IMA)

The Icelandic Medicines Agency operates under the auspice of the MoWF. IMA’s responsibilities are for example assessing quality and safety of medicinal products, inspections to confirm that relevant regulatory requirements are fulfilled and consumer protection.

Ministry of Education, Science and Culture (MoEd)

The Ministry of Education, Science and Culture includes the Institute for Experimental Pathology of the University of Iceland which undertakes some analytical work in relation to official controls.

Ministry of Finance (MoF)

The Ministry of Finance oversees State finances. The Ministry provides advice to the government on its policy areas, and provides services and information to the general public. Its responsibilities include customs issues (see Directorate of Customs below) and international co-operation.

Directorate of Customs

The Directorate of Customs (under the jurisdiction of the Minister of Finance) was established in 1929. Its main role is to control import, transit and export and collect duties, taxes and other state revenues.

MAST cooperates with the Directorate of Customs as regards export and import control including controls at BIPs and follow up of Rapid Alert System for Food and Feed (RASFF) notifications.

Other institutions

Veterinary Council

Under the Act on Veterinarians and Animal Health Service (IS) No 66/1998, the Veterinary Council deals with national issues such as import of live farm animals and reproductive materials. The Council can be requested by the Minister to discuss and evaluate the import of other live animals or animal products as well as other issues regarding animal health.

Joint Committee on Health Security and Communicable Disease Control (JC)

The JC is a supervisory body appointed by the MoWF to ensure that relevant information is obtained, assessment is made and appropriate measures are taken, to control and eliminate the spread of infectious diseases.

The Chief Epidemiologist of the DoH is chairperson of the JC. MAST has two representatives, a specialist on food safety and another on animal diseases. An environment specialist and a radiation specialist are also appointed to the Committee.

Table 1. *The main relevant authorities with responsibility for feed and food safety, animal health and animal welfare in Iceland.*

Central level		Website
MoII	Ministry of Industries and Innovation	www.atvinnuvegaraduneyti.is
MoE	Ministry for the Environment and Natural Resources	www.umhverfissraduneyti.is

MoWF	Ministry of Welfare	www.velferdarraduneyti.is
MAST	Icelandic Food and Veterinary Authority	www.mast.is
UST	The Environment Agency	www.ust.is
DoH	Directorate of Health	www.landlaeknir.is
IMA	Icelandic Medicines Agency	www.lyfjastofnun.is
DoF	Directorate of Fisheries	www.fiskistofa.is
DoC	Directorate of Customs	www.tollur.is
Municipal Environmental and Public Health Offices (LCAs)		
HKK	LCA for Hafnarfjordur and	www.heilbrigdiseftirlit.is/
HER	LCA for the City of Reykjavik	http://reykjavik.is/thjonusta/heilbrigdi-seftirlit-reykjavikur
HKJ	LCA for Kjos area	www.eftirlit.is/
HVL	LCA for Vesturland area	No website
HVF	LCA for Vestfjordur area	www.isafjordur.is/thjonusta/adrar_stofnanir/Heilbrigdiseftirlit_Vestfjarda/
HNV	LCA for Nordurland west area	www.hnv.is/
HNE	LCA for Nordurland east area	www.akureyri.is/hne/
HAUS	LCA for Austurland area	www.haust.is/
HSL	LCA for Sudurland area	www.heilbrigdiseftirlitid.is
HSN	LCA for Sudurnes area	www.hes.is/Heilbrigdiseftirlit_Sudurnesja/HES.html

Coordination between Competent Authorities

MAST and LCAs have been designated as the competent authorities for food safety controls as provided for in Article 4.1 of Regulation (EC) No 882/2004.

The division of responsibilities between the competent authorities is established in the Icelandic Food Act (IS) No 93/1995. The official controls for which MAST is directly responsible are listed in Article 6 of that Act and according to Article 22 the LCAs are responsible for all other official controls, including official controls of food business operators (FBOs) producing food of non-animal origin and all official controls of the retail market.

According to Article 22 of the Food Act 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 required to follow. MAST shall ensure cooperation of all official controls and shall in that respect make sure that control procedures are cost-efficient and designed to avoid as far as possible the duplication and overlap of efforts. MAST shall cooperate closely with LCAs and provide advice and services in the field of food control within the limits of its capacities and as required by the circumstances.

These provisions do not imply that MAST has the responsibility to carry out controls nor to organize the controls for the LCAs. The LCAs have to bear these duties themselves, including the organization and implementation of the controls and if necessary the application of enforcements measures.

If there is an overlap of competencies between MAST and LCAs, the division of responsibilities must be agreed upon between the CAs. If the CAs cannot agree as to who is responsible the Ministry will decree where the competencies should lie.

MAST may delegate some of its responsibilities to other CAs through contractual agreements. No such contracts are currently in force.

There are several mechanisms for co-operation between MAST and the LCAs

- A Food Safety Group 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, organise monitoring / inspection projects, harmonise the work of LCAs and discuss and carry out other activities.
- Twice a year meetings between MAST and the LCAs are held in the spring with the Managers of the ten LCAs and in the autumn with all LCA inspectors.
- Joint monitoring/inspection projects focusing on certain aspects of food safety are done each year (2-3 annually). The projects are planned and coordinated by the Food Safety Group.
- Working groups are established as needed with members from both LCAs and MAST to work on certain topics, such as updating the inspection manual, developing risk-based prioritisation of official controls and drafting guidelines clarifying certain requirements of FBOs.

Coordination within MAST

There are several mechanisms in place to ensure effective coordination within the Central Competent Authority (MAST):

- Weekly meeting of Directors. Every week the Director General, The Chief Veterinary Officer (CVO) and other Directors meet to discuss current issues, plan and coordinate activities.
- Monthly meetings with the Ministry. Each month MAST Directors meet with Ministry representatives to discuss current issues and coordinate activities.
- Weekly meetings of the CVO with district veterinary officers (DVOs). Other staff participate in the meetings as needed.
- Weekly or monthly staff meetings within each office. Each month (or every other month) there is a staff meeting within each Office at MAST to provide information to all staff, discuss current issues and coordinate activities.
- Annual general staff meeting. Each year there is a full day meeting for all staff members of MAST. Each meeting focuses on certain issues or relevant themes associated with the work done at MAST.
- Monthly coordination meeting for staff carrying out official controls for fishery products to discuss current issues and coordinate activities.
- Information meetings. Once or twice a month a staff member of MAST presents to colleagues what they are currently working on and what their main responsibilities are.
- An advisory board meets on an *ad-hoc* basis to discuss and decide on issues related to interpretation of requirements of the hygiene package. The board decides on how to proceed with issues and uncertainty that have come up during official controls.

- *Ad-hoc* coordination, planning and discussion meetings and working groups are continually operating.
- An intranet has been set up within MAST to facilitate information flow between staff, announce events and report news, training activities and other necessary information. It replaces the weekly newsletter.

Coordination between and within LCAs

Iceland's ten LCAs undertake many coordinating activities, with the Association of Municipal Environmental and Public Health Offices (SHÍ) playing a substantial role. SHÍ was founded in 1999 with the purpose to safeguard health and environment in Iceland, and to promote effective, independent and professional controls in accordance with Act (IS) No. 7/1998 on Public Health and Pollution Control.

SHÍ has several mechanisms in place aiming at increasing the cooperation between LCAs and synchronising Iceland's health and environment monitoring as regards policy formulation and discussions about enacting laws and regulations on sanitary practices and pollution prevention. SHÍ meetings are normally attended by the local public health committee Chair and the Manager of each of Iceland's 10 LCAs, while additional meetings within the SHÍ structure are attended by the LCA Managers.

Some of the means used to achieve SHÍ objectives are as follows:

- Two SHÍ meetings are held every year with the participation of LCA Managers and local public health committee chairs to review policies and inter-regional coordination.
- Every autumn, SHÍ organises a two-day meeting during which LCA officials and local public health committee attend, as well as the national coordinating agencies (the Environment Agency of Iceland and the Icelandic Food and Veterinary Authority) and the ministries concerned.
- The Board of SHÍ meets regularly, 4 to 6 times a year. Each LCAs may refer matters to the Board and vice versa. Some of the Board's roles include further coordination of the different regions and service as their representative and link to ministries and other government bodies. In addition, SHÍ is a consultation body which provides opinions to the parliament and to ministries.
- The LCA Managers meet regularly, 4 to 8 times a year, by teleconference or in person. The discussions include points which the Regional Managers and other LCA officials find to be pressing, as well as points of policy towards coordinating activities.
- Within their group, the LCA Managers are involved in active e-mail correspondence, which is a useful way of responding to varied tasks, sharing experience and exchanging opinions.
- Internally, the different LCAs are engaged in ongoing coordinating efforts among their staff, ranging from informal endeavours to weekly consultation meetings, depending on the size and staff numbers of the particular region.

Delegation of specific tasks related to official controls

There is no delegation of official controls within the meaning of Article 5 of Regulation (EC) No 882/2004.

1.2. Resources for performance of controls

Legal basis for controls

According to Article 30 of the Food Act (IS) No 93/1995, the CAs and their staff have full access to the premises and documentation of FBOs. The Foodstuffs Act also requires the FBOs to undergo inspections and assist the CAs in the process (Article 24 (1)).

Resources for performance of controls

MAST and the 10 LCAs set the level of fees independently. Regulation (IS) No. 567/2012 deals with the funding of MAST through inspection fees which contribute to 30% of MAST operational costs. The remaining 70% is financed from the state budget. The fees are directly linked to inspection activity and the level of fees is based on actual cost for each activity.

The LCAs are financed through inspection fees collected from inspected bodies and direct funding from local municipalities. The level of fees is based on actual cost for each activity. The fees are published in the Icelandic Official Journal.

Staff qualification and training

MAST has developed a training programme for employees and staff, which undergo initial training, continuous and *ad-hoc* ongoing training. Directors of all district offices are requested to prepare plans and requirements for training and continuous education for their staff although there is no system in place for assessment of training needs and evaluating training effectiveness.

LCA inspectors all have a university degree in subjects relevant to their tasks. Furthermore, before being authorised by the Ministry of the Environment as public health inspectors they have to participate in a training course arranged by MAST and undertake practical training at a LCA district office.

Table 2. *Total number of staff including administrative staff.*

Acronym	Organisation	Number of Staff
MAST	The Food and Veterinary Authority	86 FTE*
	Administration	11
	Quality Manager	1
	Office of animal health and welfare	12
	Office of food safety and consumer affairs	16
	Office of legal affairs	8
	Office of import and export	10
	Office of agricultural affairs	5
	District offices (DVOs and OVs)	26
Acronym	Organisation	Number of Staff
UST	Environmental Agency	73
DoF	Directorate of Fisheries	74
IMA	Icelandic Medicines Agency	59
DoC	Directorate of Customs	250
LCAs	Local Competent Authorities (10 districts)	30 (food control)
Total		572

* *FTE: Full time employees. Total number of MAST employees 01.08.2016 is 89. In addition to permanent staff MAST hires about 15 veterinarians for official controls and as assistants in slaughterhouses during the autumn, and additional staff for meat classification. This would amount to about 4 FTE.*

Conflict of interest

Legal provisions are in place with regard to conflict of interest under various acts - Article 20 of the Government Employees Act (IS) No 70/1996 applies to MAST staff and Section II of the Administrative Act (IS) No 37/1993 applies to MAST and LCAs staff. Official veterinarians (OVs) are allowed, under some conditions, to carry out general veterinary services but DVOs work exclusively on official controls and may not provide general veterinary services.

MAST pays subsidies, provided by the annual budget, to private veterinary practitioners (PVPs) to carry out veterinary services in ten remote areas through formal agreements. These remote areas are defined in a regulation.

1.3. **Organisation and implementation of official controls**

Registration/approval of food business operators

According to Act (IS) No 93/1995 on Foodstuffs, all FBOs (for food of animal and non-animal origin) need approval following a visit, except for sheep and horse farms and vegetable growers, which need to be registered. Freezer and factory vessels are approved; other fishing vessels need to be registered.

As a general rule, MAST issues approval to FBOs that fall under the scope of Regulation (EC) No 853/2004, and the LCAs licences all other FBOs. In certain circumstances the LCAs are the responsible authority for issuing approvals to FBOs that need to be approved according to Regulation (EC) No 853/2004, such as when production of animal products, in accordance with the Regulation, is not the main activity of the FBO business.

Only those FBOs that fall under the scope of Regulation (EC) No 853/2004 are given approval numbers according to Regulation (EC) No 854/2004. All approval numbers for FBOs are issued by MAST. These FBOs are also listed on the website of MAST as approved establishments. (<https://skyrslur.mast.is/>).

Standardized procedures for approval of establishments for food of animal origin and feed production are in place.

Risk-based prioritisation of controls and control activities

MAST and LCAs organise their controls on a risk basis. Different systems are applied for different sectors although all systems are based on the same principles.

Food of animal origin and feed

The control frequency of establishments producing food of animal origin or producing feed (except primary production) is established based on a risk classification system. The control frequency of each establishment is calculated based on the risk of the production and the processing method, the extent of labelling and packaging of consumer products and the complexity of the production process.

The risk category of each establishment is identified based on three risk factors: (1) the nature of the production and the product; (2) the size of the production or the establishment; (3) the consumer group. Each risk factor gives a risk score, the higher the risk the higher the score. The total risk score indicates the risk category of the establishment from 1, the highest risk, to 8, the lowest risk. The risk category indicates the comparative risk of the establishment and subsequently the necessary minimum control frequency in hours per year of official controls within the establishment. All sectors of food and feed processing are evaluated according to the same system.

Additional control time can also be added due to the complexity of the operations of the establishment. Additional time is also allocated to establishments based on the nature and

extent of their labelling and packaging of consumer products. In 2017 – 2019, these additional controls will be in the form of audits of labelling and labelling procedures in establishments packaging products intended for the final consumer. When added together this provides the total time for official controls within each establishment in hours per year.

Food of non-animal origin

The LCAs have adopted a risk classification system based on the same principles that is being used to establish the control frequency of FBOs producing food of animal origin and feed, adapted to the sectors under LCA controls. The system was published in January 2015 and the LCAs are in the process of fully implementing the necessary changes to their official control systems according to an implementation plan. According to the plan, the organisational changes of official controls will be fully implemented as of 1 July 2017.

Primary Production

A preliminary risk prioritisation has been made for different sectors of primary production which focus on: hazard identification; risk evaluation, i.e. frequency and severity of risk; exposure assessment, i.e. how much does the industry produce in a year; and factors that diminish the risk during primary production and during processing. The risk prioritisation provides indication for control objectives, identified risk areas for controls and evaluates the inherent risk of different sectors of primary production with regard to consumer safety.

A risk classification model has been developed to evaluate the necessary frequency of official controls. It has the same basic structure as the model for food of animal origin and feed. The risk class of each primary production sector is based on a risk score for two main risk factors: (1) risk for animal welfare; (2) risk for food safety. These factors have been evaluated for each sector of primary production. Primary producers are categorised based on their main production. In addition each producer is also evaluated according to (3) the size of the main production. Based on the size of production, the risk category can be adjusted in accordance with the risk evaluated for each sector. The largest establishments are considered to be an increased risk from the average while for the smallest establishments the risk category can be reduced. The risk classification of the main production of each primary producer sets the frequency of inspections each year, stretching from 2 inspections per year to one inspection every 5 years. Factors concerning the complexity of the operations of the primary producer affect the time needed for each inspection but do not have a direct impact on the frequency of inspections.

The development of the risk classification model was based on the preliminary risk prioritisation and also took into account recent developments in Europe for risk evaluation of primary producers, particularly with regard to risk factors for animal welfare.

Performance evaluation and reporting of control activities

In addition to the risk based prioritisation of controls the evaluation of performance of FBOs during past controls affects their total control time or frequency of inspections. Based on their performance evaluation FBOs are categorized into three performance categories: A, B and C. Each performance category has a performance index that affects the total control time of the FBOs.

All new FBOs start in performance category B, which has the performance index 1,0. When multiplied with the FBOs total control time it does not have any effect on the time allocated for official controls within the establishment through the risk classification process. FBOs in this performance category are considered to have a satisfactory situation with internal working procedures and established good hygiene practices.

FBOs that are moved to performance category A have their total control time multiplied with the performance index 0,5 and thus receive a 50% deduction of their allocated control time. These FBOs are considered to have excellent internal procedures and hygiene

practices, HACCP or HACCP-based procedures are established and effective, non-compliances are minimal, not repeated and fixed immediately.

FBOs that are moved to performance category C have their total control time multiplied with the performance index 1,5, which means that their total control time is increased by 50%. This applies only to regular official controls and does not include additional control time due to follow up in cases of infringements. FBOs in performance category C have had several and repeated non-compliances or a serious non-compliance. They have not made appropriate arrangements and enforcement procedures are in progress.

The performance evaluation of FBOs is based on inspection manuals that are part of the work procedures for official controls of food of animal origin and feed. Work procedures for approval of establishments, official controls as well as follow up and enforcement procedures are all established in the Quality Manual of MAST. All information regarding the official controls of FBOs are kept in the database IS-leyfur which contains an active list of all approved establishments producing food of animal origin or feed. All necessary information on each establishment is accessible through IS-leyfur, i.e. the risk category, the total number of hours for official controls, the number of hours already used, the number of hours left, the performance category, previous reports, non-compliances and status of non-compliances. IS-leyfur also automatically calculates the performance of the FBOs based on the inspection reports and notifies senior level staff at MAST when an FBO can be moved between performance categories. All inspection reports are filled out directly into the database and an electronic copy is sent to the FBOs after each inspection. The database is accessible via password controlled access on the internet.

The same performance evaluation system will be implemented for FBOs falling under official controls of the LCAs alongside the new risk classification system. A new inspection manual has been developed for the LCAs, based on the same principles as the inspection manuals for MAST.

All the necessary information on primary producers is currently being transposed into IS-leyfur and it will be used as the database for official controls on primary producers in the future. A performance evaluation system based on the same principles as the system for food of animal origin and feed is also being developed for primary producers.

Several databases have been developed to keep records of live animals, their health status and their treatment with veterinary medicines.

Sampling and laboratory analysis

The CA designates laboratories to carry out analysis of samples taken during official controls. To be designated, a laboratory must have accredited testing methods. If no laboratory has accreditation for a testing method, a foreign accredited laboratory is chosen, having regard to practical experience and proximity.

Four laboratories have been designated to handle all of the samples analysed in Iceland. All four are accredited, but not for all of the analysis they perform. These laboratories are accredited according to the international standard ÍST EN ISO/IEC 17025, for the general requirements on competence of testing and calibration laboratories and according to Icelandic Regulation (IS) No 351/1993 on the operation of accredited testing laboratories.

The LCAs use both official and private laboratories accredited for analysis of samples of food and water for human consumption. The LCAs have their own contract with the laboratories. Some samples are sent for analysis to laboratories in other Member States of the EEA. A list of official laboratories is published on MAST's website

(<http://mast.is/matvaelastofnun/eftirlitsnidurstodur/rannsoknastofur/>).

Laboratories

Matis laboratory (Ministry of Industries and Innovation)

The Matis laboratory was established by Act (IS) No 68/2006 on the Icelandic Food Research Ltd. According to the Act, the laboratory has certain food safety obligations. The CA’s contract with Matis laboratory covers the analysis of official samples for the most common foodborne zoonotic agents. Matis is the National Reference Laboratory (NRL) for many areas including *Salmonella*, pesticide residues and heavy metals.

Keldur - The Institute for Experimental Pathology of the University of Iceland (Ministry of Education)

The Institute for Experimental Pathology analyses official samples for food-borne pathogens and animal diseases (duties laid down in Act (IS) No 67/1990). The laboratory also has a department for fish diseases established by Act (IS) No 50/1986. According to the Act, the laboratory and CA are obliged to co-operate on measures to control/prevent fish diseases. Keldur is the NRL for *Campylobacter*, parasites (in particular *Trichinella*, *Echinococcus* and *Anisakis*), transmissible spongiform encephalopathies (TSEs), fish diseases, bivalve mollusc diseases and crustacean diseases.

Department of Immunology, University hospital (Ministry of Welfare)

The laboratory is used by MAST and LCAs for the identification/confirmation of zoonotic agents such as *Salmonella* serotypes. Staff at this laboratory may also be consulted by the CAs regarding disease control and prevention, in both animals and humans.

Private laboratories

A few private laboratories in Iceland analyse samples for food and feed businesses and to a limited extend samples for official controls.

Other laboratories

The CA also uses laboratory services in other Member States of the EEA for analysis of various samples related to official controls.

Table 3. *List of laboratories used for official controls by MAST:*

Field of analysis	Laboratories in Iceland	Laboratories in EU and EEA
<i>Salmonella</i>	Matis ohf. Keldur, Syni hf, Promat	
Phytoplankton / algae in seawater	Marine Research Institute Iceland	
Monitoring of biotoxins		Marine Institute (Ireland)
Monitoring the viral and bacteriological contamination of bivalves molluscs	Matis ohf.	
<i>Listeria monocytogenes</i>	Keldur, Matis ohf. Syni hf.	

Field of analysis	Laboratories in Iceland	Laboratories in EU and EEA
Coagulase positive Staphylococci, including <i>Staphylococcus aureus</i>	Matis ohf.	
<i>Escherichia coli</i> , including Verotoxigenic E. coli (VTEC)	Matis ohf, Keldur, Syni hf.	
<i>Campylobacter</i>	Matis ohf, Keldur, Syni hf.	
<i>Trichinella</i>	Keldur, Promat.	
Veterinary medicines and contaminants in food of animal origin.	Keldur, Matis ohf.	Livsmedelsverket Sweden, SVA Sweden, Födevarestyrelsen Danmark, Eurofins Food&Agro, Sweden
TSE	Keldur	Norwegian Veterinary Institute and UK Veterinary Laboratories Agency – for verification of results from Keldur
Residues of pesticides (a-d)	Matis ohf.	Livsmedelsverket Sweden
Heavy metals in feed and food	Matis ohf.	
Mycotoxins		SVA Sweden, Eurofins Hamburg, Eurofins Food&Agro, Sweden
Dioxins and PCBs in feed and food		Födevarestyrelsen Danmark, Eurofins Hamburg
Feed		LUFA Nord-West, Germany

Table 4. NRLs designated by the Ministry of Industries and Innovation.

I. REFERENCE LABORATORIES FOR FEED AND FOOD	
1.Reference laboratory for milk and milk products	Matis ohf
2.Reference laboratories for the analysis and testing of zoonoses (<i>Salmonella</i>)	Matis ohf
4.Reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs	Matis ohf
5.Reference laboratory for <i>Listeria monocytogenes</i>	Matis ohf
6.Reference laboratory for Coagulase-positive Staphylococci, including <i>Staphylococcus aureus</i>	Matis ohf
7.Reference laboratory for <i>Escherichia coli</i> , including Verotoxigenic E. coli (VTEC)	Matis ohf
8.Reference laboratory for <i>Campylobacter</i>	Keldur

9.Reference laboratory for parasites (in particular Trichinella, Echinococcus and Anisakis)	Keldur
10.Reference laboratory for antimicrobial resistance	Keldur
12.Reference laboratories for residues of veterinary medicines and contaminants in food of animal origin	Livsmedelsverket SE
13.Reference laboratory for transmissible spongiform encephalopathies (TSEs)	Keldur
17.Reference laboratories for residues of pesticides (a)(b)(c)(d)	Mátis ohf
18.Reference laboratory for heavy metals in feed and food	Mátis ohf
II. REFERENCE LABORATORIES FOR ANIMAL HEALTH AND LIVE ANIMALS	
6.Reference laboratory for fish diseases	Keldur
7.Reference laboratory for mollusc diseases	Keldur
15.Reference laboratory for crustacean diseases	Keldur

Other NRLs have still to be designated by the Ministry of Industries and Innovation.

National accreditation bodies

Iceland's accreditation body ISAC (Icelandic Board for Technical Accreditation), a division of the Icelandic Patent Office, assesses the competence of laboratories according to Act (IS) No 24/2006 on accreditation. The assessment is carried out by SWEDAC (Swedish Accreditation Body) on behalf of ISAC according to an agreement between the two accreditation bodies. ISAC and SWEDAC are members of the European co-operation for Accreditation (EA). SWEDAC is also a signatory to the EA Multilateral Agreement for Laboratories (EA MLA) and a member of the International Co-operation for Laboratory Accreditation (ILAC).

Transparency and confidentiality

The MAST website provides easily accessible news coverage of topics pertaining to food safety and animal/plant health, publications and legislation. Part of the information is also available on the English version of the website.

Concerning data protection, Article 24 (2) of the Foodstuffs Act (IS) No 93/1995 states that staff of the CA may not disclose any professional information regarding FBOs. There are also restrictions on the right to information due to private interest in Article 5 of the Information Act (IS) No 50/1996. According to the General Penal Code No 19/1940 (article 136), a civil servant or former civil servant revealing work sensitive information may be subject to imprisonment.

Annual reports are published on MAST website, <http://www.mast.is>

1.4. Enforcement measures

Measures in case of non-compliance

The Food Act (IS) 93/1995 has been amended to include enforcement measures. MAST has developed detailed guidelines on how to follow up non-compliant cases.

Depending on the seriousness of a case, the inspectors may choose to use the following measures listed in Article 30 in the Act on Food (IS) No 93/1995: issue safeguards or precaution; inform the general public of the nature of the risk to health; order

decontamination of food; stop or limit the production and placing on the market of food, detain food and/or destroy it; shut down the activities of a food business; and withdraw the operating licence.

While MAST and LCAs have legal powers to impose daily fines until the corrective action has been implemented, they have not used it to date. The daily fines issued by the CAs are subject to Regulation (IS) No 767/2010, which stipulates the maximum fines per day of 500.000 ISK. The daily fines are subject to an administrative complaint to the MoII. Serious infringements may be reported to the police and eventually to the courts for possible measures under criminal law.

The CAs may also order tasks to be performed at the expense of the business responsible for executing the task. Such costs and daily fines may be collected without a prior judgment or settlement.

In general, LCAs do not report their non-compliant cases to MAST, unless they are related to FBOs designated to LCAs by MAST or if there are any serious public health issues. The IS-leyfur database clearly identifies different degrees of non-compliance and actions to be taken.

Sanctions

Sanctions, as described in Article 55 Regulation (EC) No 882/2004, may be imposed by the court. Article 31 of the Food Act (IS) No 93/1995 provides for a maximum imprisonment of 4 years in case of serious or repeated violations of law. There are no limits set out in law regarding the amount of fines. Serious infringements may be reported to the police and eventually to the courts for possible measures under criminal law.

The legal basis for sanctions is the Acts (IS) No 93/1995 on Food (see Article 31), No 55/1998 on Fishery Products (see Article 32) and No 96/1997 on Slaughtering, etc. (see Article 21).

1.5. Verification and review of official controls

Verification procedures

MAST has several mechanisms in place to verify the effectiveness and appropriateness of official controls.

Senior officers at the Office of Food Safety and Consumer Affairs are responsible for harmonisation of official controls within their specific sectors. A senior officer is also responsible for general harmonization between sectors and general implementation and training of new control procedures.

The official control time for all establishments producing food of animal origin and feed is estimated through the same risk classification system to ensure a harmonized evaluation of the risk across sectors, the appropriate allocation of resources for official controls across sectors and to ensure the effective implementation of official controls. The system also ensures that the official controls allocated to each FBO are based on transparent and sound criteria and that the FBOs' risk and performance is evaluated in the same manner, without regard to the sector they belong to or where they are geographically located. The same system will be implemented for all FBOs under the control of the LCAs in 2016/2017.

All control staff across sectors work according to the same general documented procedures which are established in MAST's Quality Manual. During harmonization efforts and inspections with control staff, the officers responsible check whether control staff are using the appropriate procedures, they help them to effectively implement these procedures in their work and they ensure that the procedures are followed in a consistent manner. Regular

meetings are also held with control staff to ensure the appropriate implementation and effectiveness of the controls.

An advisory board is in place to discuss and decide on issues relating to interpretation of the requirements of the hygiene package. The board decides on how to proceed with issues and uncertainty that have come up during official controls. This ensures that there is a harmonized resolution of control issues and interpretation of the legislation.

Through the database IS-leyfur the progress and results of official controls can be monitored and extrapolated. Information is collected on for example the progress of official controls in all sectors, harmonization between inspectors, frequencies and types of non-compliances. Results are continually monitored and they are also collected and aimed to be compiled annually in a more systematic manner.

Annually the control system is reviewed and information is collected from senior officers and control staff on how the control system is working and what needs to be improved to ensure the effectiveness of official controls. Information is collected through surveys and meetings with senior staff and representatives from control staff.

The LCAs shall report annually on the progress of their official controls of the previous year. Guidelines are being developed for the harmonized reporting on official controls from the LCAs. They will be published in 2017.

DVOs conduct *ad-hoc* visits to slaughterhouses either weekly or monthly, depending on the need in each area. As of yet there are no formal reports made from these visits. During seasonal slaughtering the senior officer responsible for meat processing and slaughterhouses also visits all slaughterhouses to verify controls being done and assess the general conditions.

An evaluation of the effectiveness of official controls is also due to be examined through long term and strategic objectives being developed as a part of the MANCP. Indicators will be established to evaluate whether the long term objectives are being achieved.

Audit system (internal or external audit)

An internal audit system has been developed and approved by the MoII. The system is based on the requirements of Decision 2006/677/EC on audit guidelines and the ISO 19011:2002 standard. The Quality Manager of MAST is responsible for the internal audit process as the Chief Auditor, under the authority of an audit committee and an audit steering committee. The Quality Manager is independent of all other organization units at MAST. The internal audit teams consist of MAST specialists who have received training as internal auditors at Better Training for Safer Food (BTSF) training on audit systems and internal auditing and a TAIEX seminar on internal audits of official controls. A training course has also been given in Iceland in 2016, before internal audits of MAST and the LCAs started.

The audit steering committee is responsible for the internal audit system and receives consultation and assistance from the audit committee. The audit committee approves the annual audit plans, evaluates the audit system and suggests changes based on their assessment to ensure an independent scrutiny of the audit process. The follow-up of audit results is the responsibility of the audit steering committee.

A five-year plan (multi-annual national internal audit plan (MANIAP)) has been issued and approved by the audit steering committee and covers responsibilities based on Regulation (EC) No 882/2004 and responsible authorities, i.e. MAST, LCAs and Laboratories. An annual risk-based audit plan has also been developed and approved by the audit committee, which is based on the multi-annual programme, as well as any recent developments, previous audit findings and identified risk areas.

The internal audit system developed by MAST was formally approved by the MoII in 2014. In 2015 and 2016 the auditors have been receiving the necessary training, the audit committees have been established and the audit plans formally issued and approved according to the principles of the system for internal audits.

1.6. **Multi-annual national control plan (MANCP) and annual reports**

MAST has control plans for the various control systems and is in the process of developing a three-year MANCP. The first edition will be published and implemented in 2017. The development of the MANCP will be an on-going process and it will be revised and improved as new control procedures are officially implemented.

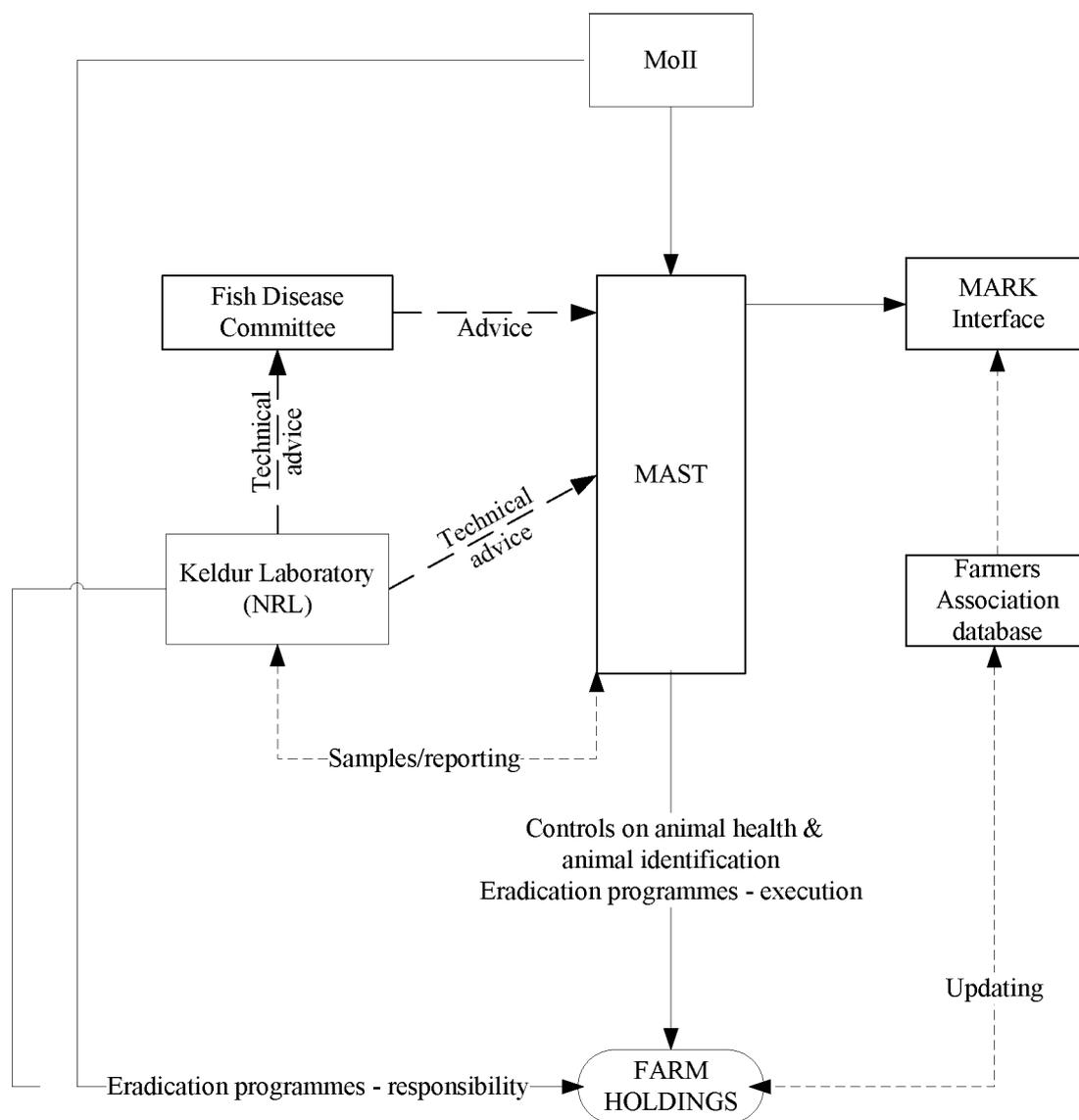
Each year MAST publishes on its website an Annual Report which provides information on the work done in the previous year and results of controls and control findings.

Table 5. Overview of the distribution of responsibilities in relation to control systems and operational levels.

Sector	Policy co-ordination	Co-ordination of controls	Implementation of controls	Laboratories	Risk assessment, scientific advice
1. Animal Health	MoII	MAST	MAST	The Institute for experimental pathology at Keldur	MAST and the Institute for experimental pathology at Keldur
2. Food of Animal Origin	MoII	MAST	MAST	Mátís Laboratory	MAST and Mátís Laboratory
3. Imports of animal and food of animal origin	MoII	MAST	MAST	Mátís Laboratory The Institute for experimental pathology at Keldur	MAST
4. Feedingstuffs	MoII	MAST	MAST	Syni Laboratory Service. LUFA	MAST
5. TSEs/ABP	MoII	MAST	MAST	The Institute for experimental pathology at Keldur, Mátís Laboratory	MAST and the Institute for experimental pathology at Keldur
6. Veterinary medicines - authorisation, marketing and distribution	MoWF	MoWF	Icelandic Medicines Agency		MAST and IMA
Veterinary medicines - residues	MoII	MAST	MAST	Livsmedelsverket Sweden, SVA Sweden, Födevarestyrelsen Danmark	
7. Foodstuffs and Food hygiene	MoII MoE	MAST UST (GMOs)	MAST LCA	Mátís Laboratory, Syni Laboratory Service. Rannsóknáþjónustan Promat hf	MAST and Mátís Laboratory
8. Imports of food of plant origin	MoII	MAST	MAST		MAST
9. Plant protection products - authorisation, marketing and use	MoE	UST	UST	N/A	MAST and UST
Plant protection products - residues	MoII	MAST	MAST	Mátís Laboratory	
10. Animal Welfare	MoII MoE	MAST UST	MAST	N/A	MAST
11. Plant Health	MoII	MAST	MAST	N/A	MAST

2 ORGANISATION OF RESPONSIBILITIES IN RELATION TO CONTROL SYSTEMS

2.1 Control system for animal health



MAST Icelandic Food and Veterinary Authority

MARK Livestock database

MoII Ministry of Industries and Innovation

NRL National Reference Laboratory

The EEA legislation on veterinary matters applies to Iceland, except for the provisions concerning live animals, other than fish and aquaculture animals, and certain products. Council Directive 2006/88/EC on animal health requirements for aquaculture and its products and the prevention and control of certain diseases has been fully transposed. Directive 90/425/EEC concerning veterinary and zootechnical checks applicable in intra-Community trade has been transposed (except for live animals and certain products).

Act (IS) No 25/1993 on animal diseases covers major animal diseases including those for which EU legislation exists. Iceland prohibits import of live animals except of live fish, fish germplasm, crustaceans and molluscs. Iceland participates in the Animal Diseases Notification System (ADNS).

Iceland has transposed Directive No 2003/99/EC on the monitoring of zoonoses and zoonotic agents. It has also transposed Decision No 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable diseases and Regulation (EC) No 2160/2003 on the control of salmonella and other specified food-borne zoonotic agents. Iceland applies a zero tolerance for *Salmonella* spp. in broilers and eggs and operates a control programme for *Campylobacter*. *Salmonella*-positive broilers flocks are destroyed and *Campylobacter*-positive broilers must be frozen.

Competent authorities and animal health controls

MAST, in conjunction with MoII, is responsible for surveillance, contingency plans, and preventive measures against animal diseases. The CA seeks to eradicate endemic disease, control the transmission of infectious agents and improve the general health and welfare of animals.

Inspections are typically carried out by DVOs or OVAs according to: Act (IS) No 25/1993 on Animal Diseases and Preventive Measures; Act (IS) No 66/1998 on Veterinarians and Animal Health Services; Act (IS) No 96/1997 on slaughtering etc. and Act (IS) No 38/2013 on Livestock Management (fish farming, cattle, pigs and poultry).

Holding registration, animal identification and movement controls

Iceland has transposed the EU legislation on identification and registration of cattle (Regulation (EC) No 1760/2000), pigs (Directive No 2008/71/EC) and sheep and goats (Regulation (EC) No 21/2004). EU rules for horses are not covered by the EEA Agreement.

Farm holdings are registered in a national interface (MARK), the operation of which MAST oversees. The Icelandic Farmers Association manages its daily operation as well as its further development.

Act (IS) No 38/2013 on livestock management and Regulation (IS) No 916/2012 on identification of livestock lay down the principles for animal identification and registration of their movement.

The identification system for animals is based on ear tagging. Records are maintained on farm registers and databases for domestic animals. Information in MARK is retrieved from databases used by the Farmers Association for breeding purposes. All stakeholders have access to information in MARK and keepers of livestock are required to keep their records updated. Livestock keepers are also responsible for recording diseases identified, medical treatments and preventive measures. When livestock is transported, a copy of their health-card must accompany them.

A livestock database - BUSTOFN - in operation since November 2010, is primarily for livestock owners (cattle, sheep, goats and horses) to enter information on the numbers of their livestock and other related information. This database will be connected to MARK and other livestock databases (HUPPA (bovine), FJARVIS (ovine) and FENGUR (horses)). BUSTOFN is accessible to all on MAST website. Personal information on livestock owners is restricted to designated persons.

Livestock keepers are responsible for keeping records of all animals in their herd in a herd-book. The herd-book and health-card records have to be retained for at least 10 years, even if production stops. If requested by the DVO, keepers must provide information on origin

and destination of all animals in their ownership, animals produced and sold as live animals and slaughtered animals.

Identification mark and traceability

Control on the application of identification marks is included in MAST inspection tasks. Traceability control is also included in inspection procedures. Identification and registration rules per animal species are as follows:

Cattle

Bovine animals must be identified according to Regulation (IS) No 916/2012 and Regulation (IS) No 968/2011 incorporating Regulation (EC) No 1760/2000 on the identification of bovines with later amendments.

Sheep and goats

Ovine and caprine animals must be identified according to Regulation (IS) No 916/2012 and Regulation (IS) No 973/2011, incorporating Regulation (EC) No 21/2004 on the identification of ovines and caprines.

However, in the implementation regulation, farmers are only required to put identification tag in one ear of sheep and goats. When ovine or caprine animals are sold between herds, they have to be identified with two tags. Sheep may be moved within a region without a movement document (e.g. during the summer, animals may be moved to highland grazing and returned to their home farm in the autumn).

National programmes (surveillance, prevention and eradication of fish disease).

A Fish Disease Committee has been established to provide advice for the MoII and for MAST regarding problems related to fish diseases. The chairman of the Committee is the CVO and other representatives are experts from the national laboratory at Keldur, the Institute of Fresh Water Fisheries, the Directorate of Fisheries and the Marine Research Institute. All fish farms have been included in the official national health control programme since 1985. The surveillance also includes farms producing wild salmon. Since 1993, EEA legislation on disease control measures has been followed, and since December 2008 with the implementation of Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (Regulation (IS) No 1254/2008). Canadian requirements have been respected since 2003. Surveillance is partly carried out by regular "on-site" health inspections, under the supervision of the veterinary officer for fish diseases, and partly via laboratory work at the official fish disease laboratory at Keldur in Reykjavik which has close co-operation with the EU Reference Laboratory (EURL) on virus diseases in Denmark. Surveillance takes place for: Viral Haemorrhagic Septicaemia (VHS); Infectious Haematopoietic Necrosis (IHN); Infectious Pancreatic Necrosis (IPN); Infectious Salmon Anaemia (ISA) and Bacterial Kidney Disease (BKD) (notifiable diseases under Act (IS) No 25/1993). Only Bacterial Kidney Disease has been detected. The veterinary officer for fish also deals with mollusc and crustaceans diseases.

All infectious diseases of concern in the aquaculture industry are of bacterial origin, mainly in the farming of Atlantic salmon (*Salmo salar*), Arctic char (*Salvelinus alpinus*) and Atlantic cod (*Gadus morhua*). The main bacterial diseases are: Atypical furunculosis (*Aeromonas salm. ssp. achromogenes*); Bacterial Kidney Disease (BKD - *Renibacterium salmoninarum*); Winter ulcers (*Moritella viscosa*); Enteric Redmouth (*Yersinia ruckeri*); Vibriosis (*Vibrio anguillarum*); and Cold water vibriosis (*Vibrio salmonicida*). All of these diseases except BKD, are effectively controlled by vaccines. Iceland has carried out an

active eradication programme against BKD since 1985 including: a ban on transport and trade; sanitation/disinfection; fallowing and surveying period before the farm is permitted to recommence trade. Up to date no clinical viral fish disease has been detected in Iceland, but through the national monitoring program of both wild and farmed fish some fish virus have been isolated. With viral screening of the Atlantic salmon stock some few samples have been found to be positive for the low/non-pathogen ISAv (HPR0). In addition, VHS virus was for the first time detected in lumpfish of wild origin in Iceland in October 2015 although this detection did not have a connection to the salmonid aquaculture farm sites.

Contingency plans

MAST has a generic contingency plan for each species which is extended to specific disease situations. The contingency plan for animal health is included in MAST quality manual.

In the event of an outbreak of a serious contagious animal disease, MAST is the main disease control centre and its district offices act as the local disease control centre. Assistance is to be provided by Keldur laboratory (see below).

A memorandum of understanding on animal health emergencies has been signed by the competent authorities in the Nordic and Baltic countries. The aim is to provide support and assistance to the countries concerned affected by an animal disease outbreak, when resources are not sufficient to meet the needs of the outbreak emergency. Simulation and other training exercises are performed on a regular basis.

In cases of food-borne diseases, infectious animal diseases of zoonotic nature, emergencies and crisis, MAST co-operates with the Chief Epidemiologist, who is responsible to the MoWF. MAST co-operates with the LCAs and coordinates the work. In such cases, the Joint Committee on Health Security and Communicable Disease Control reviews the situation and decides whether a given situation should be considered an emergency or a crisis.

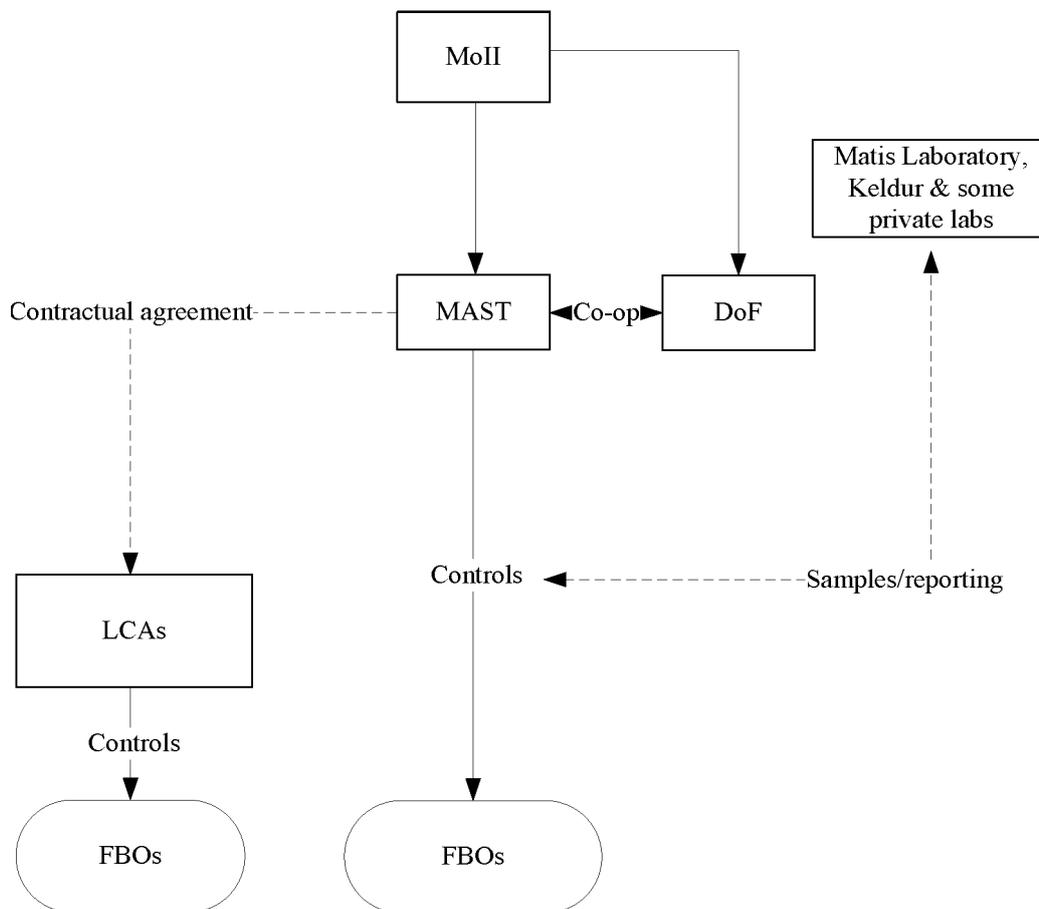
Laboratories

The Institute for experimental pathology at Keldur is responsible for diagnosis of diseases in animals. It has an advisory role for MAST regarding animal diseases (Act (IS) No 67/1990). A bio-safety level 3 laboratory facility was built following the Avian Influenza outbreaks in Europe. The institute has made agreements with the Danish National Veterinary Institute, Swedish National Veterinary Institute and the Veterinary Laboratory Agency in the UK, covering services urgently needed to confirm or rule out suspicion of an outbreak of an exotic or other animal virus disease.

The Keldur laboratory has two agreements with the Technical University of Denmark (DTU) to provide capacity, technical assistance and human resources in the case of a crisis. The diseases covered by the agreement of January 2003 are: foot-and-mouth disease; swine vesicular disease; classical and African swine fever and virus enteritis in pigs; and other high risk infectious diseases of group A in animals, as far as the capacity of DTU permits. The diagnostic service covered by the agreement of October 2004 is to confirm or rule out suspicion of an outbreak of the exotic fish virus diseases: Infectious Salmon Anemia; Infectious Haematopoietic Necrosis; Viral Haemorrhagic Septicaemia; Salmonid Alpha Virus and Infectious Pancreatic Necrosis.

Viral analyses are also carried out at the Food, Veterinary and Environment Agency of the Department of Fish and Animal Diseases in Faroe Islands and PatoGen Analyse in Norway.

2.2. Control system for food of animal origin



DoF	Directorate of Fisheries
FBO	Food Business Operator
LCAs	Municipal Environmental and Public Health Offices
MAST	Icelandic Food and Veterinary Authority
MoII	Ministry of Industries and Innovation

Competent authorities

MAST is responsible for food safety controls covering primary production, official control in slaughterhouses, cutting plants, meat plants, dairy plants, egg packaging centres, egg processing plants, fish processing plants and vessels and control of live bivalve molluscs, as well as control of food import and export.

MAST supervises the work of the LCAs who are by law responsible for controls of the retail market, including meat and fish processing in retail outlets, food businesses producing food of non-animal origin and food businesses producing composed food (processed food of animal origin and of plant origin). MAST has issued an inspection manual for the LCAs.

(<http://mast.is/library/Lei%C3%B0beiningar/SkodunarhandbokHES1511.pdf>)

MAST can also assign some of its tasks to LCAs by a formal contract. The tasks that can be contracted out include the approval of the FBOs, the official controls and the collection of control fees. No tasks have been assigned to the LCAs.

Registration and approval of establishments and vessels

According to Act (IS) No 93/1995 on Foodstuffs, primary producers of food of animal origin must be approved following an official control visit, except for premises for sheep production, horse farms and vegetable growers, which should only be registered. All food producing and processing establishments (including freezer vessels and factory vessels) must be approved by MAST and other fishing vessels only need to be registered. MAST keeps an updated list of approved establishments producing food of animal origin, which is available on MAST website.

Fish farms

Under Act (IS) No 71/2008 on Aquaculture, the responsibility for approving fish farming facilities now lies with MAST.

Shellfish growers (Bivalve molluscs)

MAST is responsible for the licensing and registration of shellfish (Live Bivalve Molluscs - LBM) growers according to Act (IS) No 90/2011 on culturing of shellfish.

MAST is also the CA for classification of production areas, monitoring of toxic algae and marine biotoxins and approval of dispatch centres according to Regulation (EC) No 853/2004 and 854/2004.

Organization and implementation of official controls

See description of risk-based prioritization and performance evaluation systems in chapter 1.3.

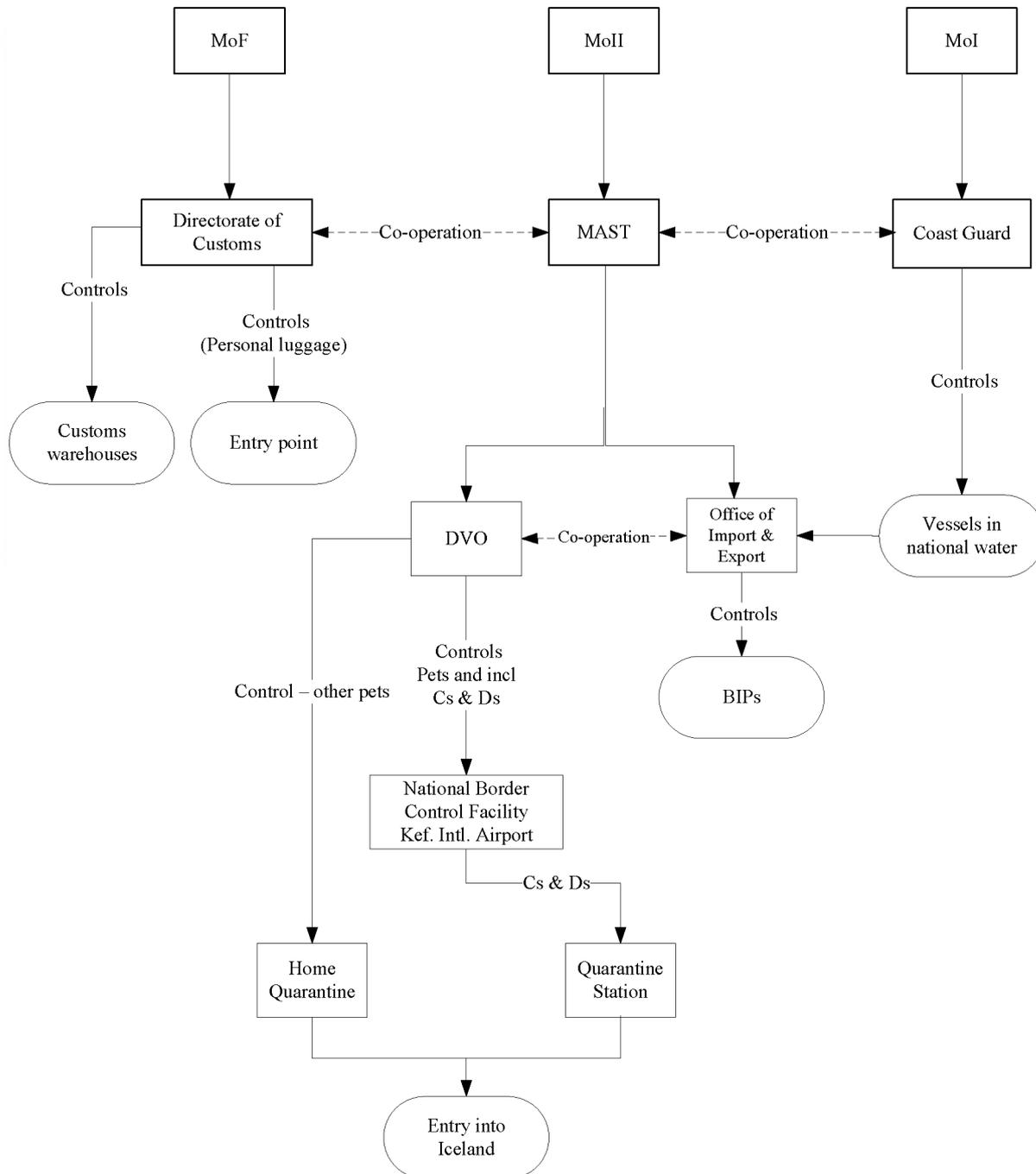
Laboratories

MAST has a contract with Matís laboratory for analysis of official samples for the most common food pathogens. Also Keldur and two private laboratories in Iceland analyse samples for food and feed businesses and some official control samples.

The designated laboratory for phytoplankton/algae is the Marine Research Institute in Iceland. For marine biotoxins, samples are sent to the Marine Institute in Ireland.

Contaminants/pollutants are analysed by Matís and Eurofins laboratories.

2.3. Control system for imports of animals and food of animal origin



- BIP** Border Inspection Post
- DVO** District Veterinary Officer
- MAST** Icelandic Food and Veterinary Authority
- MoF** Ministry of Finance
- MoII** Ministry of Industries and Innovation
- MoI** Ministry of the Interior

The EEA legislation on imports of products of animal origin from third countries applies to Iceland, however Iceland is exempt from Annex I of the EEA Agreement concerning trade in live animals other than fish and aquaculture animals. This exemption also applies to germplasm such as ova, embryos and semen.

Importation of live animals into Iceland is covered by specific Icelandic Acts. Permission for importation of live pet animals as defined by Regulation (IS) No 935/2004 is under MAST responsibility. Permission for importation of other live animals is the responsibility of the Ministry of Industries and Innovation. For the latter, a positive recommendation by MAST is required.

Importation of raw meat and raw eggs is subject to an import permit from the Ministry of Industries and Innovation.

Veterinary checks are in line with Council Directive 91/496/EEC on the organisation of veterinary checks on animals entering the Community from third countries and Council Directive 97/78/EEC on the organisation of veterinary checks on products entering the Community from third countries.

The deadline for completion of the rejection procedure for non-compliant consignments is limited to 60 days.

Table 6. *The following seven BIPs are in Iceland:*

Name of the BIP	Type	Approval EFTA Surveillance Authority Decision 367/11/COL
Akureyri	Port	HC-T(1)(2)(3), NHC(16)
Hafnarfjörður	Port	HC(1)(2)(3), NHC-NT(2)(6)(16)
Keflavík	Airport	HC(2),NHC(2),O(15)
Ísafjörður	Port	HC-T(FR)(1)(2)(3)
Reykjavík (Eimskip)	Port	HC(2), NHC(2)
Reykjavík (Samskip)	Port	HC-T(FR)(1)(2)(3), HC-NT(1)(2)(3), NHC-NT(2)(6)(16)
Þorlákshöfn	Port	HC-T(FR)(1)(2)(3), HC-NT(6),NHC-NT(6)

Competent authorities

MAST's Office for Import and Export is responsible for control at the Border Inspection Posts (BIPs). National border control facilities are operated by MAST at Keflavik International Airport for the control of importation of pet animals (cats and dogs). The Directorate of Customs is responsible for checks of personal luggage for travellers. The Coast Guard is responsible for monitoring vessels in national waters. MAST is also working in close cooperation with the Directorate of Customs as regards filtering out consignments for inspection by MAST.

Import controls

Import controls of products of animal origin and live fish from third countries is in accordance with EU legislation. For imports of food of animal origin, pre-notifications are received through the TRACES system. MAST has direct access or receives cargo manifests from freight companies for crosscheck purposes.

Consignments requiring veterinary checks by MAST are identified in the customs computer system (using the CN codes) and flagged for further attention. For cross check purposes, MAST receives lists of consignments of food of animal origin from Customs and then filters information according to the origin of the consignments: EEA or third countries.

MAST regularly organises seminars for Customs on import controls and on the different procedures for release of a consignment from BIPs, either for free circulation, for channelling, re-import or for transit.

Veterinary checks on food of animal origin

The main legislation governing importation of products of animal origin is: Act (IS) No 55/1998 on Fishery Products; Act (IS) No 93/1995 on foods; Act (IS) No 22/1994 on control of Feed, Fertilisers and Seed, Act (IS) No 25/1993 on Animal Diseases and their Prevention; Regulation (IS) No 168/2011 on import of aquaculture animals (entry into force of Regulation (EC) No 1251/2008) and Regulation (IS) No 1044/2011 on veterinary checks on imports of products of animal origin from third countries.

The frequency of veterinary checks on products of animal origin is determined according to Regulation (IS) No 1044/2011 that is in line with Decision 94/360/EC.

The frequency of laboratory tests on consignments is in accordance with a monitoring plan. The plan is based on the nature of the products and the risk they present, taking into account all relevant monitoring parameters, such as: frequency; number of incoming consignments and results of previous monitoring. The monitoring plan is revised annually.

Following satisfactory documentary, identity and physical checks, a Common Veterinary Entry Document (CVED) is issued. The importer subsequently takes the clearance import documents to customs for release of their goods.

Rejections

In the case of discrepancies detected or where requirements for importation in accordance with Regulation (IS) No 1044/2011 (Council Directive 97/78/EC) are not met, the consignment is rejected. In case of rejection, an announcement of a pending decision of rejection is sent to the importer. The importer has the right to object. Thereafter a decision of rejection is sent to the importer, who subsequently has the right to appeal to the MoII.

Fish – direct landing

For direct landings of fish from third country vessels, pre-notifications are received through the TRACES system. In the case of freezer vessel from a third country, a captain's declaration is required, while a health certificate is required from a factory vessel.

Personal imports

Travellers may bring in food products which have been heat-treated, without a certificate (Article 10 in Regulation (IS) No 448/2013).

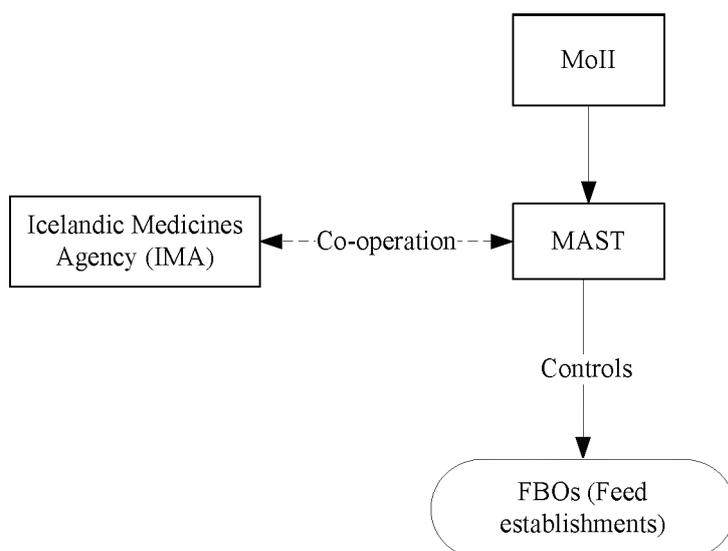
Transit / transshipments of consignments

The freight companies notify transshipments of products of animal origin to MAST. Time limits for such consignments are followed up and documented by MAST. Transshipments take place at Reykjavík Eimskip and Keflavik airport.

Customs warehouses and ship suppliers

Neither approved customs warehouses nor ship chandlers exist in Iceland.

2.4. Control system for feedingstuffs and animal nutrition



IMA	Icelandic Medicines Agency
MAST	Icelandic Food and Veterinary Authority
MoII	Ministry of Industries and Innovation
FBO	Feed Business Operator

Competent Authorities

MAST is the CA responsible for official controls on feed. MAST may assign some tasks to LCAs. The administrative work is carried out by MAST's Office of Food Safety and Consumer Affairs and, where appropriate, in co-operation with MAST's Office of Animal Health and Welfare. Informal co-operation is also in place with the Icelandic Medicines Agency regarding the definition of "feed" and "medicine" where there may be an overlap and with the Customs Authorities regarding imports.

Inspections are carried out by MAST according to Act (IS) No 22/1994 on control of feed, fertilisers and seeds and Regulation (EC) No 882/2004 on official controls to verify compliance to Regulations (EC) No 183/2005 on feed hygiene, (EC) No 1774/2002 on animal by-products and (EC) No 767/2009 on placing on the market and use of feed.

MAST official controls are focused on verification of internal quality management systems and sampling for FBOs in the higher risk groups. Control of the lower risk groups is primarily based on registration, documentation and import control.

The surveillance of primary producers at farm level is part of the regular surveillance system for animal welfare and production on farms.

Medicated feed controls

Iceland has implemented Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community. The directive was implemented through two national Regulations (IS) No 608/2013 for production and placing on the market and use of medicated feedingstuffs for

fish, crustaceans and molluscs and (IS) No 607/2013 for production and placing on the market of medicated feedingstuffs for animals.

The surveillance of medicated feedingstuffs is under the supervision of the Icelandic Medicines Agency. The medicines shall be mixed in pre-mixtures before they are mixed into the feed that is combined with normal feed. The preparation of the medicated feedingstuffs shall only be done by specially authorised feed operators.

Enforcement

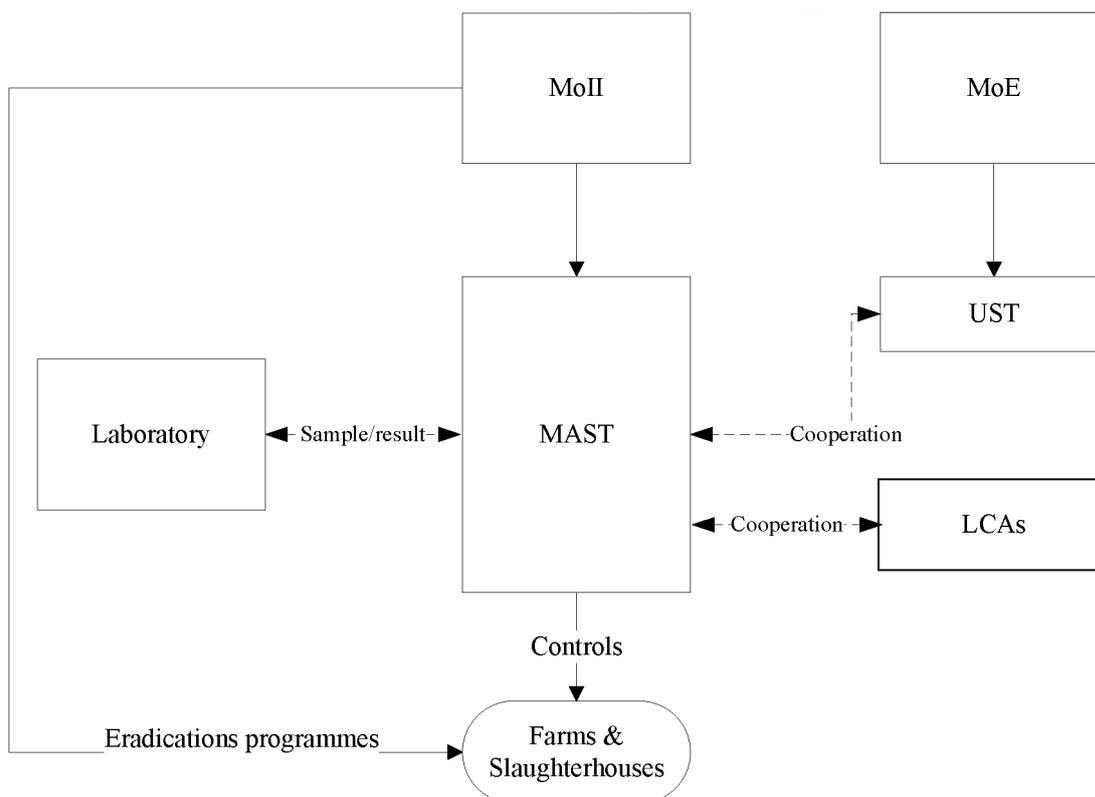
The legal basis for sanctions in cases of infringement is contained in Act (IS) No 22/1994 on control of feed, fertilisers and seeds. Documented procedures are in place in MAST Quality Manual on actions taken in cases of infringements.

Laboratories

MAST cooperates with two laboratories for analysis of feed:

- LUFA *Nord-West Institut für Futtermittel* in Germany can undertake a range of analysis, in their own laboratories or contract laboratories. It is accredited by *Deutscher Akkreditierungs Rat (DAR)*. The scope of accreditation covers all methods used, except for fluorine analysis for which method - CEN/TC 327 N620 (*Entwurf*) is used.
- Syni Laboratory Service is used for analysis of *Salmonella*. It is accredited for analysis of most common substances and microorganisms in accordance with the IST EN ISO/IEC 17025 standard. The laboratory analyses *Salmonella* with the following methods: NMKL Nr. 71, 5. edition 1999 and Vidas *Salmonella* 30702.

2.5. Control system for Transmissible Spongiform Encephalopathy (TSE)



LCAs Municipal Environmental and Public Health Offices

MAST Icelandic Food and Veterinary Authority

MoE Ministry of Environment

MoII Ministry of Industries and Innovation

UST Environment Agency

Competent authorities

MAST is the CA for all issues concerning TSE, including import controls, animal health controls, surveillance, monitoring and slaughterhouse controls based on EEA legislation. The Environment Agency (UST) is the CA for issues concerning disposal of contagious animal waste. UST co-operates with MAST which has an overall responsibility for the prevention of spread of animal diseases. In case of TSE the LCAs shall in co-operation with UST and MAST recommend how and where a contagious waste will be disposed of and how the transport of waste shall be carried out. The LCAs will also control that the process of disposal and cleaning of equipment and vehicles, are in line with the recommendation.

Regulation (EC) No 999/2001 on TSE was incorporated in Regulation (IS) No 41/2012.

Epidemio-surveillance

BSE has never been detected in Iceland. Since 2000 a survey has been carried out annually. Samples are taken at slaughterhouses from cattle over 24 months of age and cattle displaying behavioural or clinical signs that might be related with BSE. In 2004 and again in 2008 Iceland was recognised as a negligible BSE risk country by the OIE International Committee. According to the EEA JCD of October 2007, an agreement was made for

Iceland to implement Regulation (EC) No 999/2001 with derogation from the requirements to breed for genetic resistance (Iceland has an eradication policy – see below). According to the agreement, only lambs that are free of the VRQ gene may be used for repopulation.

Scrapie has been endemic in the country since 1878. A decision was made in 1986 to start an eradication programme. Areas where scrapie has been detected are kept under special surveillance for 20 years. Samples are taken annually from 3000 sheep at slaughter and sheep displaying clinical signs compatible with scrapie. The farmer is fully compensated for his loss for at least the two years that the farm must remain depopulated of sheep. Disinfection procedures carried out on the farm involve removal of all interior wooden material, hay and sheep manure from the sheep houses and their safe disposal. This is followed by disinfection.

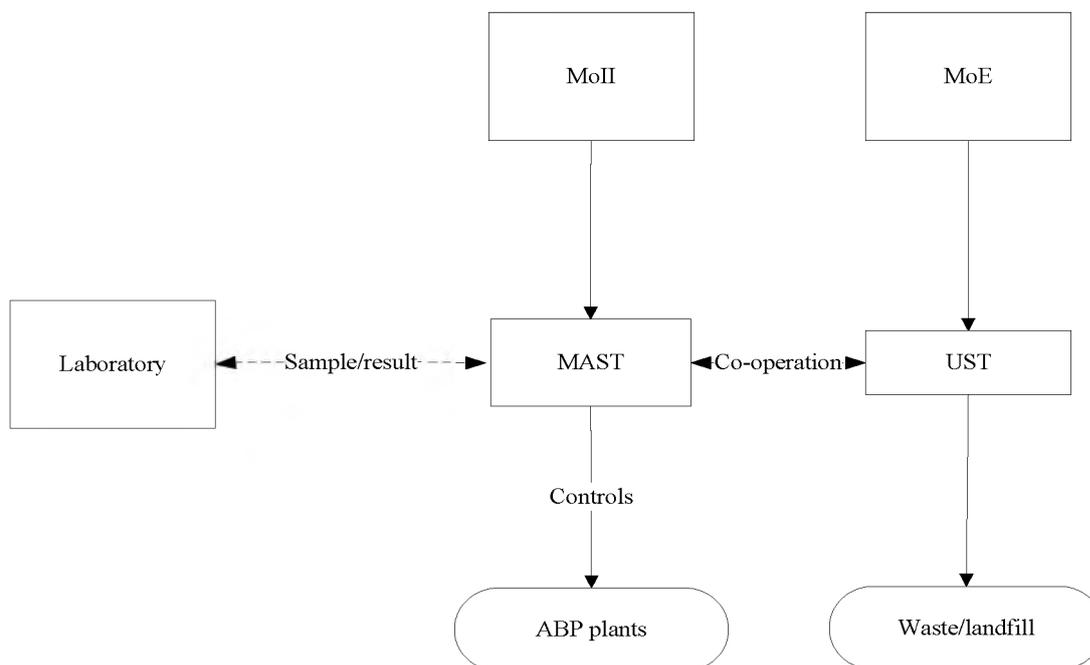
Total Feed Ban

Since 1968, it has been prohibited to import meat and bone meal and greaves for use in feeding stuffs for livestock (except pet food). The current legal reference regarding import ban of all meat and bone meal (MBM) is article 10 of Act (IS) No 25/1993. There has been a ban on feeding MBM to ruminants since 1978 and all food-producing animals since 2001. Fish-meal is readily available and is used as a protein source for food-producing animals instead of MBM. Almost all compound feed for livestock is produced domestically. The main importation is of additives, premixes and pure feed ingredients. There have been no registered imports of compound feedstuffs since 1968.

Laboratories

Keldur is the NRL for TSEs and is responsible for analysing samples taken by MAST officers in the field or in slaughterhouses. Keldur uses the Biorad system for routine analysis. All suspicious samples are also tested using Western Blot and Immuno-Histochemical methods. Some samples are sent to the EU reference laboratory for TSEs – Veterinary Laboratories Agency (VLA) in Weybridge- in the UK for confirmation.

2.6. Control system for Animal By-Products (ABP)



MAST Icelandic Food and Veterinary Authority

MoE Ministry of the Environment

MoII Ministry of Industries and Innovation

UST Environment Agency

Competent Authorities

MAST is the CA for animal by-products. UST co-operates with MAST regarding burial and burning of waste. Regulation (EU) No 1069/2009 will be implemented in Iceland early 2017. Iceland may decide to use a derogation for remote areas (material when at the time of the disposal the Specific Risk Material (SRM) has not been removed (category 1 material), category 2 material and category 3 material may be disposed as waste by burning or burial on site). However, the definition of a remote area still needs to be established.

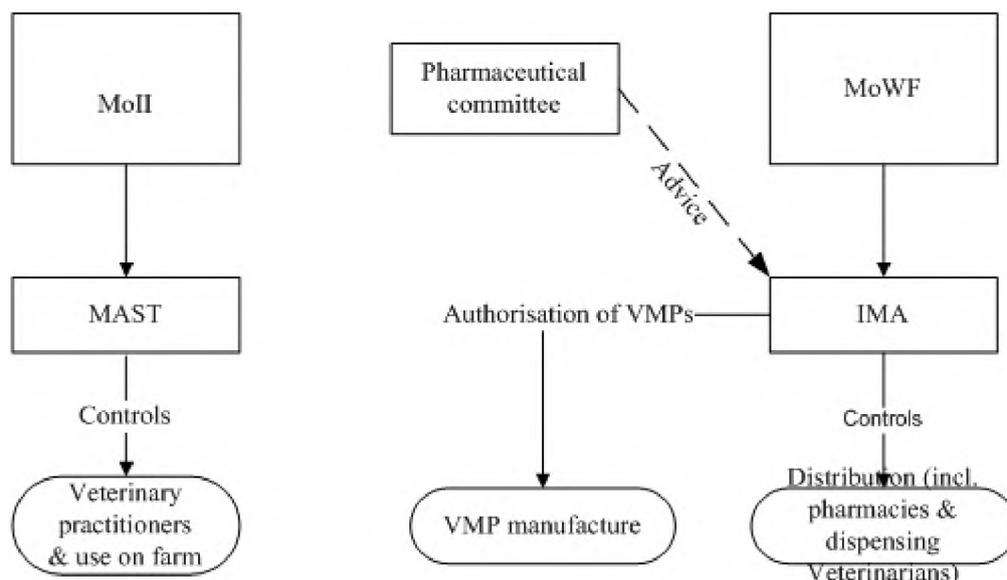
MAST issues approval for fish meal plants, MBM plants, feed plants using ABP, pet food plants, technical plants and composting plants on the basis of an inspection of the premises and own-check system. An updated list of approved ABP establishments exists and is published on MAST [website](#).

MAST is responsible for the official controls of fish meal plants, MBM plants, feed plants using ABP, pet food plants, technical plants and composting plants. Home slaughter is permitted in Iceland. All waste shall be delivered to a facility holding a valid permit to handle waste according to Article 10 of the Waste Act (IS) No. 55/2003. However, there is not a complete system for collection of home slaughter waste and fallen stock (with exceptions in populated areas). MAST has issued commercial documents and guidelines for the movement of ABPs.

Iceland has limited incineration capacity for carcasses potentially infected with TSE. Catering waste is currently disposed in landfill or subject to composting.

2.7. Control system for veterinary medicinal products (VMP) and residues

Veterinary Medicinal Products (VMP)



IMA	Icelandic Medicines Agency
MAST	Icelandic Food and Veterinary Authority
MoWF	Ministry of Welfare
MoII	Ministry of Industries and Innovation
VMP	Veterinary Medicinal Products

Competent Authorities

The Minister of Welfare is responsible for the implementation of legislation on VMPs.

Controls on the production, distribution and use of VMPs are divided between the Icelandic Medicines Agency (IMA) and MAST. IMA is responsible for licensing of, and official controls on, manufacture and distribution of VMP to pharmacy level, while MAST is responsible for the control of VMP use by veterinary practitioners and on farms.

Authorisation of VMP

In accordance with the Medicinal Products Act, the IMA, an independent regulatory authority under the auspices of the MoWF, issues marketing authorisations for medicines. In most cases this is done in collaboration with regulatory authorities in the EEA.

In accordance with the Medicinal Products Act, the Pharmaceutical Committee serves as the advisory committee of IMA. The Committee comprises seven persons with expertise in VMPs and pharmaceuticals.

PVPs can make a request to a VMP wholesaler to import EU approved VMPs. This import needs to be pre-approved by IMA which seeks a statement from MAST.

Prohibited substances

Regulation (IS) No 539/2000 on the authorisation of veterinarians to prescribe medicine establishes the provisions for prohibition of the use of certain substances. The legal basis

for the Regulation is Act (IS) No 93/1994 on Medicinal Products. Chapter II of the Regulation contains a list of substances prohibited for use as animal treatments.

Official controls on marketing/use of VMPs

The IMA is responsible for the control of manufacturing and distribution of VMPs according to Article 3 of Act (IS) No 93/1994. MAST supervises veterinary practitioners and controls the use of VMPs according to Article 11 of Act (IS) No 93/1994.

Control of VMPs at wholesale and retail level

According to IMA procedures, all wholesalers are inspected at least once every five years. There is a checklist for use during inspections of wholesalers which includes checks of the VMPs and purchases by PVPs.

VMPs are distributed mainly *via* practicing veterinarians who purchase VMPs from the wholesalers for use in their own practice and operate veterinary pharmacies selling VMPs to animal owners. Small quantities of VMPs are also distributed through other pharmacies. Retailers are required to be inspected based on risk once every four to ten years. Checklists are used during inspection of retailers and veterinary practitioners operating veterinary pharmacies.

Feed mills

Production and distribution of medicated feed is permitted in Iceland. IMA is responsible for control and authorisation of manufacturers and distributors of medicated feed.

Private veterinary practitioners (PVPs) and farms

MAST is responsible for official controls on the proper use and storage of medicines on farms. Animal keepers are obliged to keep records on the health status of the animals and their medical treatment in a herd book for at least ten years.

Sheep farmers in remote areas may store/administer antibiotic drugs under specified conditions if the farmer has a contract with a PVP for the supply of the drugs and the PVP has permission from the CVO.

MAST is also responsible for the controls on the use of VMPs by PVPs. PVPs are required to enter their use of certain VMPs listed in Regulation (EC) No 1950/2006 into the database HEILSA with withdrawal times of six months. The registrations will appear automatically in the Equidea database WorldFengur. HEILSA includes information on animal health and veterinary treatment of horses, cattle and sheep. HEILSA is an internet-based computer system in which the practising veterinarians are obliged to register their prescription of medicines to horses and cattle, and have an option to register prescription of medicines to sheep. Veterinarians with permission from the CVO to prescribe antibiotic medicine to sheep without starting the treatment themselves, are obligated to register those prescriptions in HEILSA. HEILSA was launched in the beginning of June 2011. There are four types of access to the system:

- a) Access for PVPs,
- b) Access for MAST veterinary specialists,
- c) Access for DVOs in MAST, and
- d) Administrative access by the CVO, the veterinary officer responsible for the control of prescription of veterinary medicines, the veterinary officer responsible for the development of the system and the programmer.

The system is developed by the farmers' union IT department in cooperation with MAST and operated according to instructions from MAST.

In cases where veterinarians are not fulfilling the requirements concerning registration in HEILSA, the Ministry of Industries and Innovation can take appropriate measures against the veterinarian. In worst cases, the veterinarian would lose his license to practice as a veterinarian.

Usage of HEILSA

a) PVPs

Within three days after a visit the PVPs shall register the date of the visit, the identification of the animals, diagnoses, and type and amount of medicines used. If the treatment includes a medicine which requires a temporary ban of slaughter or milk delivery, the veterinarian is obliged to inform the animal owner about the withdrawal period by a written notification and register the dates in HEILSA within 24 hours. The veterinarian shall also enter information if he has ordered further treatment, including instructions for use and has the opportunity to enter the expiry date for the medicine and lot number. Fig. 1 shows the main registration window in HEILSA. The veterinarians can look up a particular animal or farm and see all registered diagnoses and treatments, but are not able to see which veterinarians entered the data.

b) Veterinary specialists at MAST

In addition to the above mentioned possibilities for application, veterinary specialists at MAST can look up certain diagnoses or medicines for a particular district or the whole country. They can also display a list of animals which are within the withdrawal period for slaughter or delivering of milk.

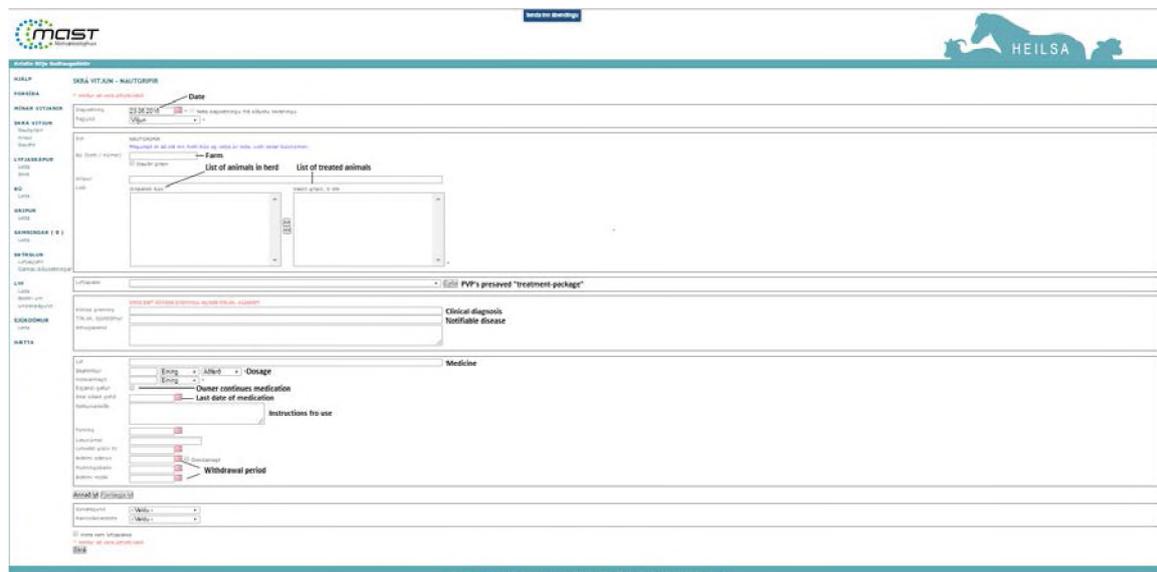
c) DVOs at MAST

DVOs can in addition to the above described usage, display a list of medicines each veterinarian has prescribed and see the names of the PVPs.

d) The officer responsible for the control of prescription of veterinary medicines at MAST

The officer at MAST who is responsible for the control of prescription of veterinary medicines can, in addition to the above described usage, make changes to registrations in HEILSA if necessary and add new users, medicines etc. into the database.

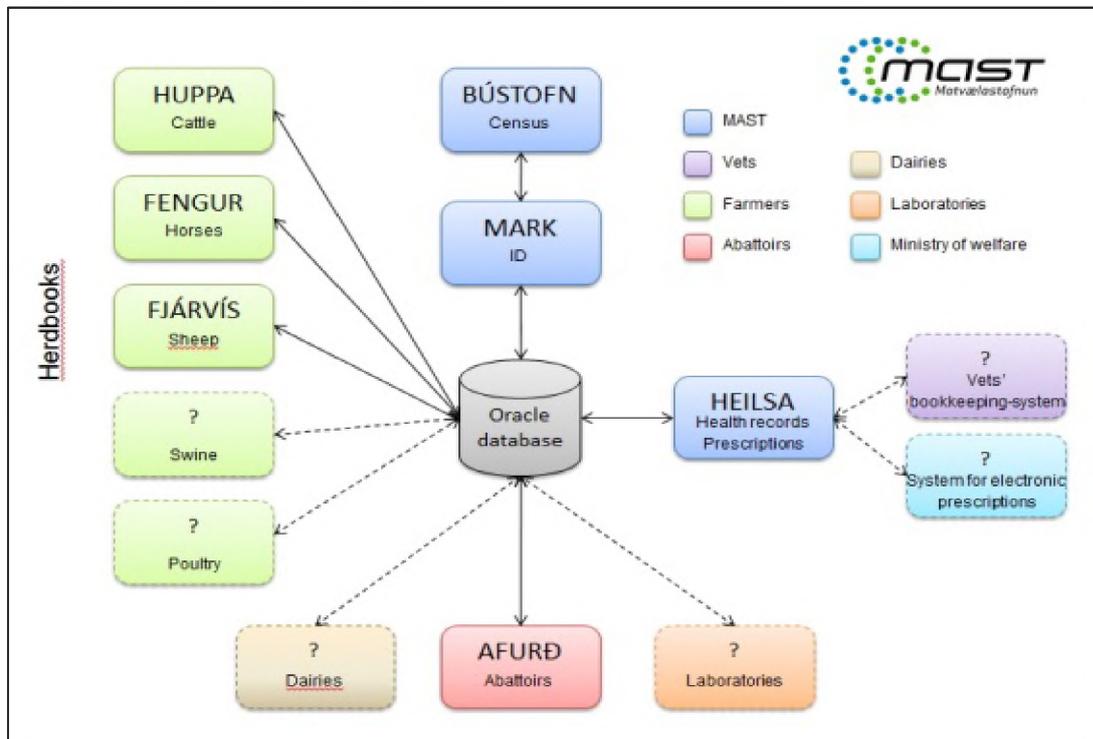
Picture 3. Window for registration of disease diagnosis and prescription of medicines.



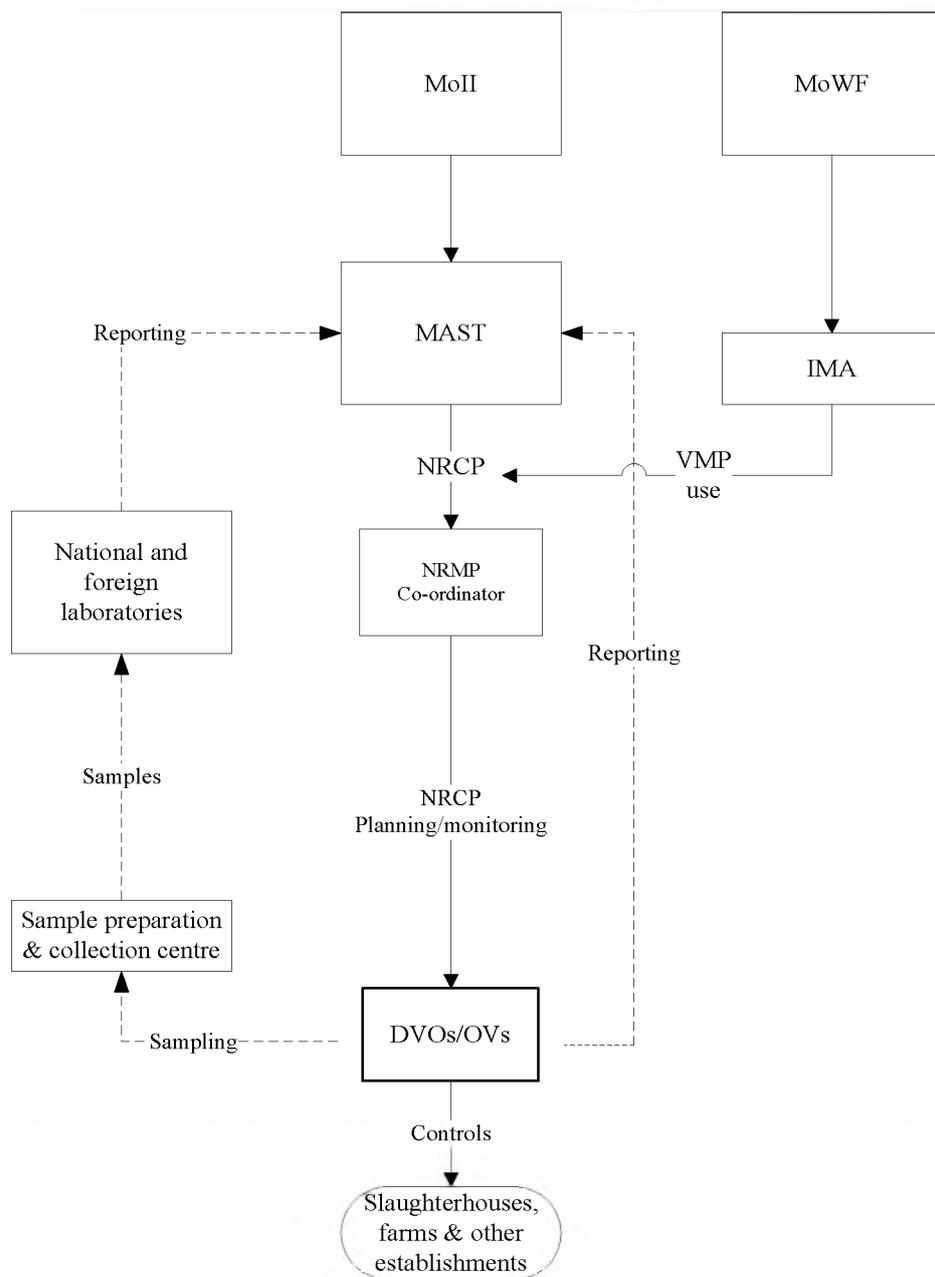
Links to other systems

HEILSA is linked to MARK, the system in which the registration of animal's identification (ID) is handled. MARK is on the other hand linked to BÚSTOFN, a system which contains information about number and location of animals. HEILSA is also linked to the electronic herd books for sheep, cattle and horse farmers (Fjárvís, Huppa and WorldFengur). In a near future HEILSA will also be connected to various other systems, e.g. the computer systems of the abattoirs, laboratories, dairies etc. and the aim is also to make the electronic prescriptions made in HEILSA legal. A bridge between HEILSA and Dagfinnur, one of the available book-keeping systems for veterinarians, has been made to make the registration easier for the veterinarian. Abattoirs get an email from HEILSA every day with information about which animals are in a slaughter ban. An overview of the connections of the various systems is shown in fig. 2.

Picture 4. *Links between the various computer systems*



Residues



DVOs/OVs District Veterinary Officers/Official Veterinarians

IMA Icelandic Medicines Agency

MAST Icelandic Food and Veterinary Authority

MoII Ministry of Industries and Innovation

MoWF Ministry of Welfare

NRCP National Residue Control Plan

VMP Veterinary Medicinal Products

Competent authorities

MAST is responsible for monitoring residues in live animals and animal products. The IMA has an input into the NRCP based on their data on VMP use.

Official controls on residues

Implementation of the National Residue Control Plan (NRCP)

The NRCP is based on total national production and the requirements of Council Directive 96/23/EC. The annual monitoring plan and the results are submitted annually to the Authority. MAST is responsible for supervision of the NRCP. The sampling plan is reviewed and evaluated annually. This takes into account the level of risk for residues in certain areas and animals.

Other residue control programmes including pre-export testing

MAST operates a monitoring programme for contaminants in feed. Dairy plants operate own-control programmes for antibacterial substances (every delivery is tested). Non-compliant results can be traced back to each farm and evidence of follow-up investigations by the dairy plants must be reported to the DVO.

Follow up of non-compliant results of official samples

In the case of non-compliant results, the MAST NRCP co-ordinator contacts the relevant DVO for follow-up.

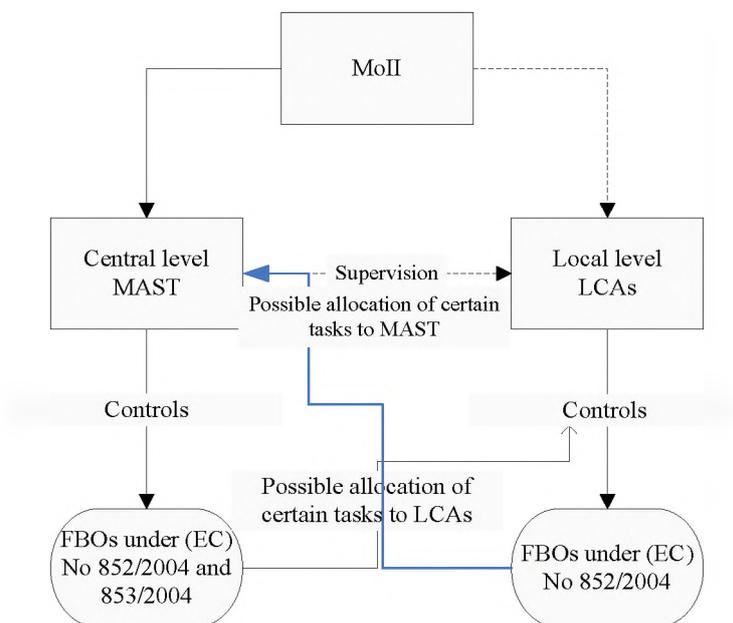
Laboratories

Five laboratories (one in Iceland and four laboratories in EU states) analyse samples for the Icelandic NRCP. MAST operates a dedicated sample collection and preparation centre located at the premises of the Institute for Experimental Pathology at Keldur.

Table 7. Summary of testing performed under the NRCP

Laboratory	Analysis
Matis laboratory	Chemical elements.
Livsmedelsverket Sweden	Antibiotics, Stilbenes, Steroids, RALs, Thyrostats, Beta-agonists, Chloramphenicol, Avermectins, Benzimidazoles, Anticoccidials, Pyrethrins, NSAIDs, Corticosteroids
SVA Sweden	Promazines, Mycotoxins
Eurofins labs	PCBs, chlorinated and phosphorus containing organic compounds.
Födevarestyrelsen Denmark	Analysis in fish from aquaculture excluding chemical elements.

2.8. Control system for foodstuffs and food hygiene



MAST Icelandic Food and Veterinary Authority

MoII Ministry of Industries and Innovation

FBOs Food Business Operators

LCAs Municipal Environmental and Public Health Offices

Competent authorities

The MoII is responsible for legislation on food safety, while the MoE is responsible for legislation on environmental protection and general hygiene. MAST is responsible for the supervision of LCA activities regarding food safety. In general, the LCAs are supervised by MAST although it has no direct legal power over the LCAs and may not give direct instructions or intervene in their day-to-day running. However, in cases of food-borne disease, MAST may intervene directly. According to the Food Act (IS) No 93/1995, MAST can also issue guidelines for specific areas that the LCAs must adopt.

MAST is the CA for all FBOs approved according to Regulation (EC) No 853/2004 and the LCAs are the CA for all FBOs that fall under the scope of regulation (EC) No 852/2004.

Official controls of food premises

Each LCA develops an annual risk-based control plan which shall be submitted to MAST before 1 December of each year. MAST compiles this information (i.e. the 10 LCA plans) to obtain an overview and facilitate a comparison between the LCAs in relation to: the number of FBOs to be inspected; frequency of inspections; and the number of samples to be taken for analysis.

A new risk classification and performance evaluation system for the LCAs was introduced by some LCAs in 2016. An inspection manual for official controls was issued in 2015 and should be fully implemented in 2017. MAST and the LCAs are jointly working on the implementing the manual. As of yet there is no harmonised national register or database of food establishments as each LCA has its own register.

Good Hygiene Practice Guides (GHP)

MAST, in cooperation with the LCAs, has issued general guidelines on Good Hygiene Practices. Several other guidelines have been issued and they are all available on MAST website. These guidelines include: small waterworks, personal hygiene, guidelines for packaging rooms etc.

Potable water

The Ministry of Industries and Innovation is responsible for the implementation and application of EEA legislation on official control of potable water. Directive 98/83/EC on the quality of water intended for human consumption, was incorporated into the Icelandic internal legal order by Regulation (IS) No 536/2001, which entered into force on 28 June 2001. According to Article 12 of that regulation, the LCAs are responsible for official controls under MAST's supervision. The ten LCAs are responsible within their municipalities for the surveillance of quality of potable water. MAST is responsible for supervision and coordination and issuing of guidelines.

Under the responsibility of the Environment Agency (Ministry of the Environment), the LCAs also play a role concerning provisions related to the necessary protection of the bodies of water used for the abstraction of drinking water and shall designate protective zones. LCAs can restrict the use of land and use and storage of polluting or dangerous substances in relation to abstraction sites for drinking water. LCAs are responsible for the implementation of Regulation (IS) No 797/1999 on the protection of groundwater and Regulation (IS) No 804/1999 on the protection of water from nitrogen compounds from agriculture and other businesses under the supervision of UST.

Food contact materials (FCM)

The Ministry of Industries and Innovation is responsible for the legislation on FCMs in Iceland. Official control of FCMs business operators (producers and importers) is under the responsibility of the 10 municipal control districts, the LCAs within their respective regions. In the end of 2013 an amendment to the Food Act (IS) No 93/1995 was made (Act (IS) No 143/2013) to clarify further the role of the LCAs regarding official control of FCM producers and importers. The official control of users of FCMs (food business operators) is the responsibility of the respective competent authority that is responsible for the main activities of the establishment, i.e. either LCAs (retail level, food of non-animal origin establishments) or MAST (food of animal origin establishments). MAST is in charge of coordination and supervision of LCAs, issues guidelines and is responsible for ensuring a harmonised approach for the controls by the LCAs.

RASFF

Iceland has been a full member of the RASFF system since 1994 with MAST as the National contact point (NCP). The system ensures that urgent notifications are sent, received and responded to quickly. NCP is on duty 24/7.

The NCP ensures the immediate transmission of information provided by national food and feed control authorities through the RASFF upstream to the European Commission through iRASFF. The Authority informs Iceland's NCP when Iceland is mentioned in the daily notification list.

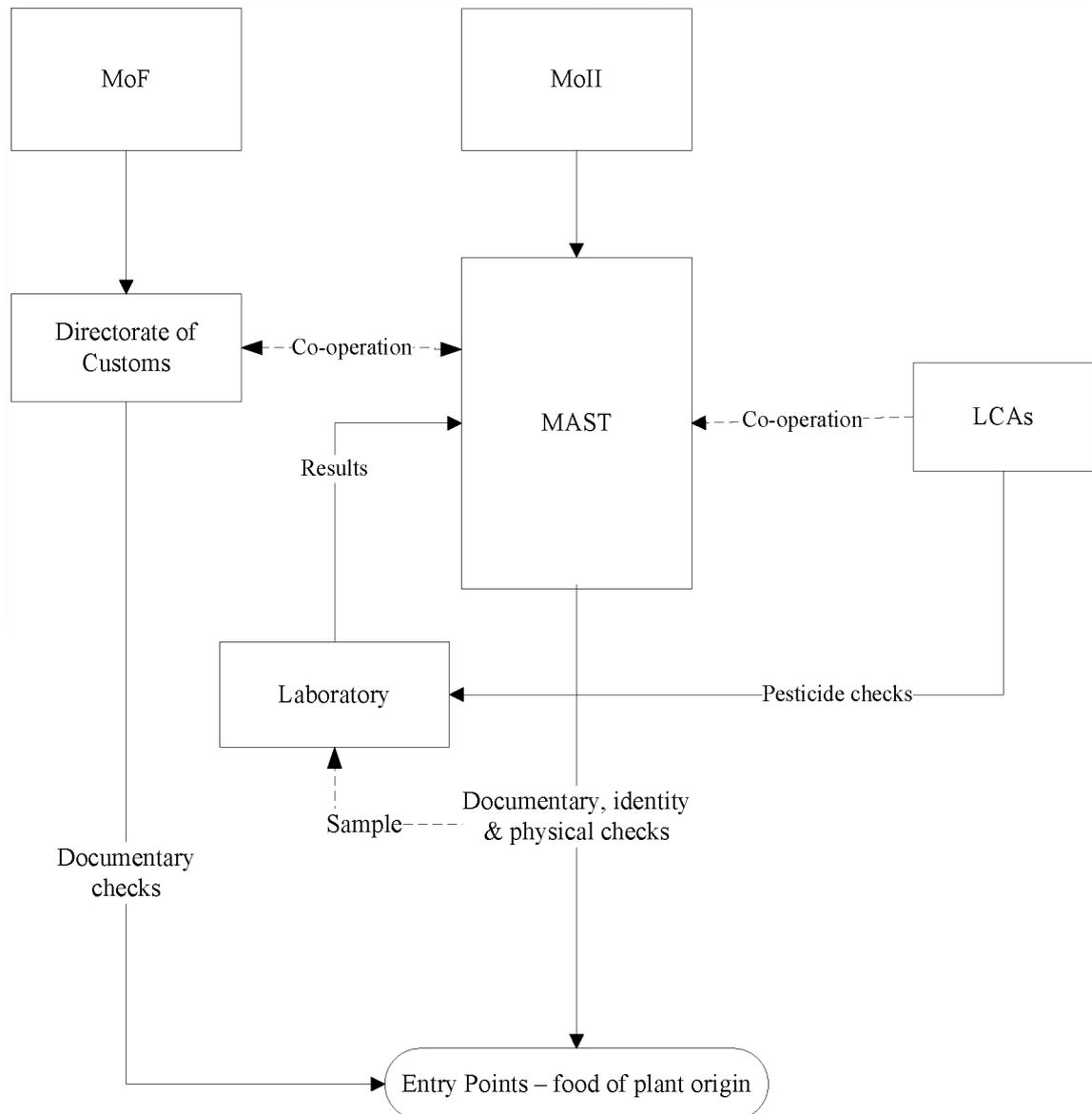
If a product has already been imported, action is taken to eliminate the hazard to human or animal health. The NCP informs the LCAs or the appropriate unit within MAST and coordinates the action to be taken (e.g. checks on the domestic market, recall and withdrawal of the product by the distributor). The investigation must take into account the distribution of the products and the nature of the notification. Details of cases are published on MAST's

website and sent to the press. In serious cases, an announcement is sent to the Chief Epidemiologist in Iceland. Iceland's response is conveyed to the EEA Member States *via* the RASFF system (iRASFF).

Laboratories

MAST has a contract with Matís laboratory for analysis of official samples for the most common food pathogens. Two private laboratories in Iceland analyse samples for food and feed businesses and some official control samples. There is a lack of laboratory capacity for FCMs and all samples sent to Denmark.

2.9. Control system for imports of food of plant origin



LCAs Municipal Environmental and Public Health Offices

MAST Icelandic Food and Veterinary Authority

MoF Ministry of Finance

MoII Ministry of Industries and Innovation

Competent authorities

The Office of Import and Export of MAST is responsible for import controls on food of non-animal origin in co-operation with Customs. LCAs are involved only if food is contaminated. In special cases the MoII may grant exemptions from the provisions of the import regulation to allow import of prohibited commodities.

Import controls

The main priorities for controls on imported foodstuffs are a) monitoring of pesticide residues (sampling allocated to one of the LCAs by informal agreement), b) participation

in RASFF and c) documentary checks on foodstuffs where specific import restrictions have been laid down in EEA Decisions or an import permit is required.

MAST co-operates with Customs to ensure that products subject to import restrictions are not imported without documentary checks by MAST prior to import. However, MAST has restricted access to the customs database (an old MS-DOS based system).

MAST charges fees for approval of the import of specific products (identified by tariff codes laid down in the relevant EEA Decisions).

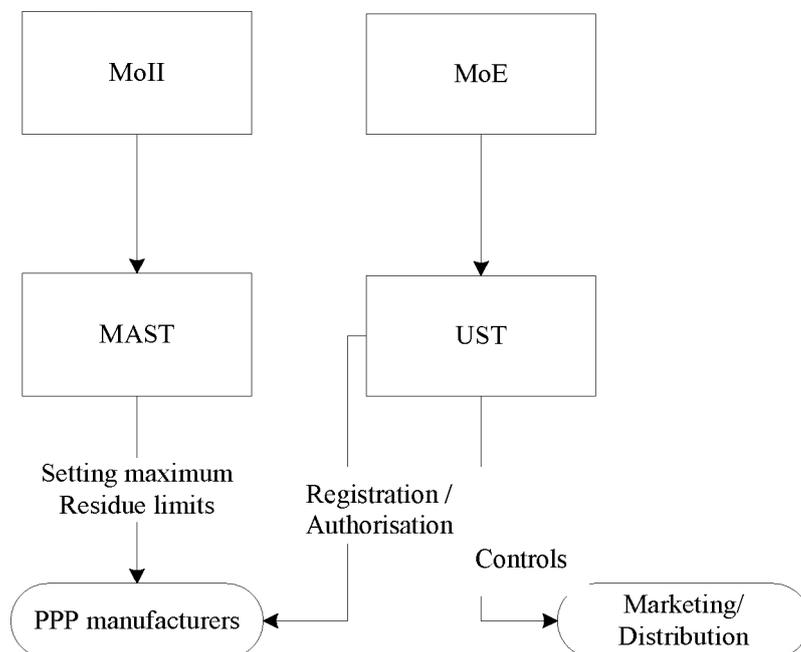
MAST has carried out only one physical check at the premises of the FBOs importing food of non-animal origin since the beginning of 2011. MAST inspects food of non-animal origin at the facilities of the BIPs. Further on, the list will be published on MAST's homepage (cf. Regulation (EU) No 669/2009 Articles 4 and 5). There are very few imports from third countries of food of non-animal origin to Iceland. Only about 10-15 Common Entry Documents (CEDs) are sent to the CA, office of import and export annually. Samples have been taken at BIPs according to the frequency listed in Annex 1 of Regulation (EU) No 669/2009 or other implementing EU import regulations regarding products of non-animal origin. This was done with separation in time to avoid cross-contamination with food of animal origin. All samples taken for analysis were packaged consumer units.

Laboratories

The CA contract with Matis laboratory covers the analysis of official samples for the most common food pathogens. Samples are sent to Analycen or SLV in Sweden for the analysis of mycotoxins.

2.10 Control system for plant protection products (PPP) and residues

Plant protection products



MAST Icelandic Food and Veterinary Authority

MoE Ministry of Environment

MoII Ministry of Industries and Innovation

PPPs Plant Protection Products

UST Environment Agency

PPPs must be granted an authorisation by the Environment Agency of Iceland (UST) before they are placed on the market according to the Chemicals Act (IS) No 61/2013. A transitional provision allows for granting a temporary registration to the products with valid registration at the date of entry of the Chemicals Act. A temporary registration will expire for each product in question when it has to be re-evaluated according to Regulation (EU) No 1107/2009 concerning the placing of PPPs preceding the renewal of the active substance it contains. Regulation (EU) No 1107/2009 has been incorporated in Iceland and will apply for granting authorisations to these products in Iceland.

Official controls on marketing/use of PPPs

The marketing of PPPs for professional use has to be notified to the Environment Agency (UST). A user permit issued by UST is required for professional use of PPPs. Import statistics on PPPs pesticides are collected by UST through the inspection of invoices from distributors at the time of customs clearance. Distributors must provide information on sales of PPPs for professional use.

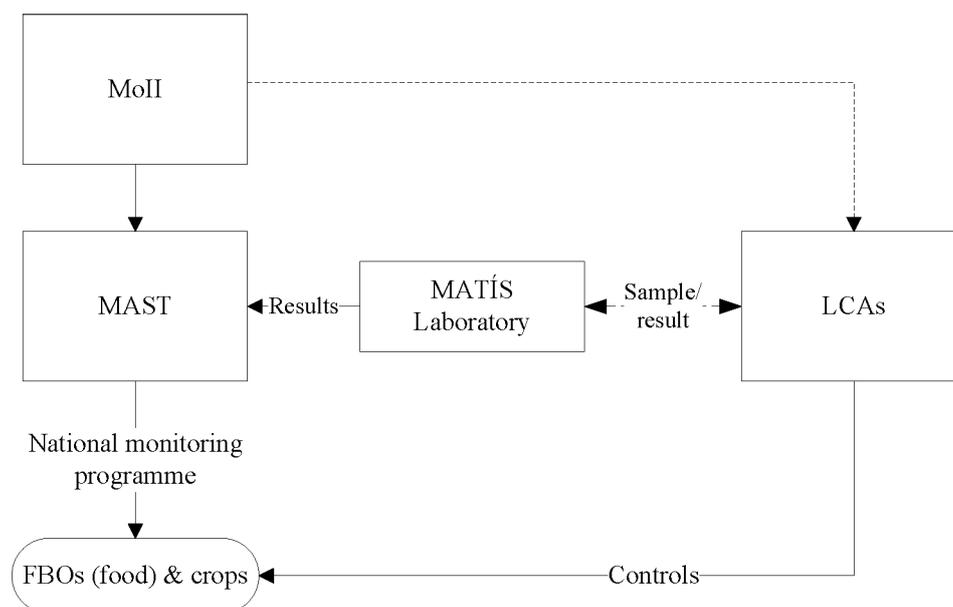
The Environment Agency is responsible for controls on marketing of PPPs and implements a market surveillance plan. Products that don't comply with legislation regarding authorisation, labelling, packaging etc. may be removed from the market.

A register of PPPs is available in UST's website. There are no controls at farm level and there are no laboratory checks on active ingredients.

Obsolete pesticides

The UST can confiscate any obsolete PPPs found on the market. Stocks of obsolete PPPs are treated as hazardous waste.

Residues



FBOs Food Business Operators

LCAs Municipal Environmental and Public Health Offices

MAST Icelandic Food and Veterinary Authority

MoII Ministry of Industries and Innovation

Competent authorities

(MoII is responsible for setting maximum residue limits (MRLs) of pesticides and control of pesticide residues. MAST is responsible for pesticide residue monitoring programmes. The sampling is carried out by the LCA in Reykjavik.

Official controls on residues

Sampling and monitoring plans

A multiannual sampling plan for pesticides residues, drawn up by MAST, is in place for the national monitoring programme. The sampling plan is based on import volumes and 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.

Import controls for pesticides are the responsibility of MAST. However for practical purposes, Reykjavik LCA, under an informal agreement with MAST, carries out all sampling and enforcement as almost all products are channelled through Reykjavik. An annual sampling plan, based on the multi-annual sampling plan, is drawn up by MAST. Samples are taken at warehouses in Reykjavik and occasionally at retail level. Each year around 280 samples of fruit and vegetables are taken. About 25% of samples are from domestic production.

Enforcement

When a pesticide residue exceeds the MRL, a new sample must be analysed to confirm the result. Enforcement action is taken if the pesticide residues in the repeat sample exceed the MRL. Provisions on MRLs are contained in Regulation (IS) No 672/2008 on maximum levels of pesticide residues in food and feed, incorporating relevant EEA legislation.

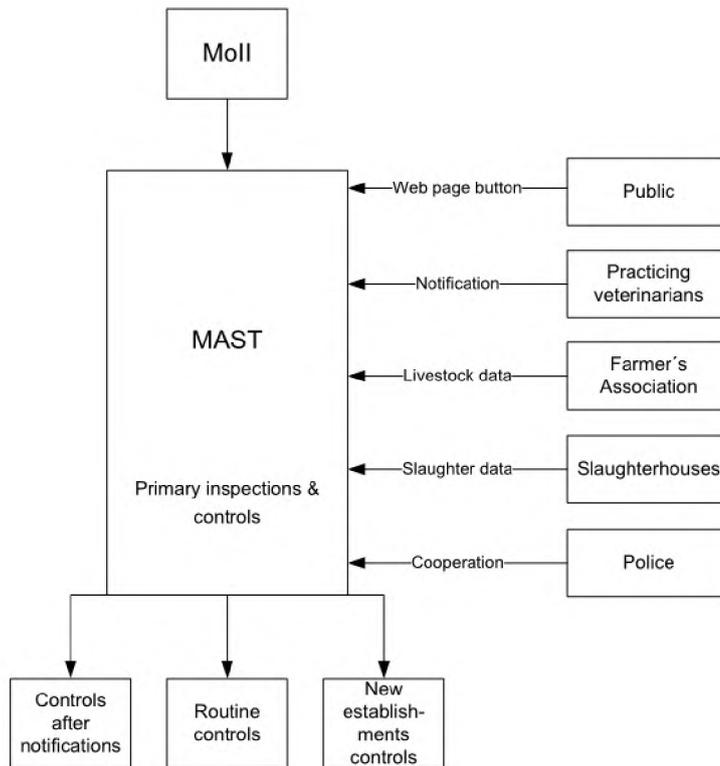
Export certification

There is no export of food of plant origin from Iceland.

Laboratories

Analysis of pesticide residues is performed by Matís laboratory. Matís has built up its capacity with new equipment and training of staff since 2014 and has managed to increase the number methods for pesticide residues analysis from 61 to 187 of which 96 have been accredited. Matrix is a limiting factor as Matis can analyse only fruits, vegetables, cereals, but not products of animal origin yet. Those samples have been sent abroad for analysis.

2.11. Control system for animal welfare



MAST Icelandic Food and Veterinary Authority

MoII Ministry of Industries and Innovation

Competent authorities

MAST is responsible for animal welfare and for ensuring that the Animal Welfare Act (IS) No 55/2013 and secondary regulations are followed. Iceland is not obliged to implement the EU *acquis* regarding animal welfare except rules concerning protection of animals at the time of killing. Regulation (EC) No 1099/2009 on the protection of animals at the time of killing has been incorporated with Regulation (IS) No 911/2012.

The system of official controls on animal welfare in Iceland is shown in figure 2.11. MAST commonly gets notification of concern from the public through a “concern button” on MAST web page. Animal farms are inspected according to a risk based assessment. All notifications from public are registered electronically in MAST system and followed up by Animal Welfare Inspectors (AWIs) or OV’s. The majority of inspections consists in routine inspections planned by DVOs and performed by OV’s and AWIs at farms and in different animal holdings in their region. OV’s perform daily official controls of animal welfare in slaughterhouses and DVOs and OV’s routine inspections/audits, occasionally with senior veterinary officers from central office for coordination purposes between districts. CVO and senior officers from central office (senior officer of coordination and veterinary senior officers) have the responsibility of supervising coordination between regions for inspections and follow up.

All inspections are registered and reports are written in the database IS-leyfur that also keeps records of follow ups. If needed cases are transferred to the legal department for enforcement.

Regulation (EC) No 1/2005 on the protection of animals during transport and related operations is not applicable to Iceland under the EEA Agreement but MoII and MAST have finalised a draft regulation which is to a large extent based on Council Regulation (EC) No 1/2005, including a registration system for licensed haulers.

ANNEX I – ACRONYMS, ABBREVIATIONS AND SPECIAL TERMS

ACRONYM	DESCRIPTION
ABP	Animal By-Products
ADNS	Animal Diseases Notification System
AWI	Animal Welfare Inspectors
BIP	Border Inspection Post / <i>Landamærastöð</i>
BKD	Bacterial Kidney Disease
BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority
CVED	Common veterinary entry document for products of animal origin and for live animals
CVO	Chief Veterinary Officer / <i>Yfirdýralæknir</i>
DoC	Directorate of Customs / <i>Tollstjórnin í Reykjavík</i>
DoF	Directorate of Fisheries / <i>Fiskistofa</i>
DoH	Directorate of Health
DTU	Technical University of Denmark
DVO	District Veterinary Officer / <i>Héraðsdýralæknir</i>
EA	European Co-operation for Accreditation
EC	European Community
EEA	European Economic Area / <i>Evrópska efnahagssvæðið</i>
EEA Agreement	Agreement on the European Economic Area
EFTA	European Free Trade Association
ESA	EFTA Surveillance Authority
EU	European Union
FBO	Food Business Operator / Feed Business Operator
FCM	Food Contact Material
FTE	Full Time Employees
GMO	Genetically Modified Organism(s)
HACCP	Hazard Analysis and Critical Control Points
IHN	Infectious Haematopoietic Necrosis
ILAC	International Co-operation for Laboratory Accreditation
IMA	Icelandic Medicines Agency
IPN	Infectious Pancreatic Necrosis
IS	(unique) Establishment Number
ISA	Infectious Salmon Anaemia

ACRONYM	DESCRIPTION
ISAC	Icelandic Board for Technical Accreditation
ISO/IEC	International Standards Organisation
ISK	Icelandic currency (Krona)
ISPM	International Standard for Phytosanitary Measures
IS-leyfur	A MAST database which contains an active list of all approved establishments producing food of animal origin or feed and information concerning official controls
IT	Information technology
JC	Joint Committee on Health Security and Communicable Disease Control
JCD	Joint Committee Decision
LBM	Live Bivalve Molluscs
LCA	Local Competent Authority / <i>Heilbrigðiseftirlit sveitarfélaga</i> (Municipal Environmental and Public Health Offices)
MANCP	Multi Annual National Control Plan
MANIAP	Multi-Annual National Internal Audit Plan
MARK	Icelandic interface for Domestic Animals
MAST	The Food and Veterinary Authority / <i>Matvælastofnun</i>
MBM	Meat and Bone Meal
MLA	Multilateral Agreement for Laboratories
MoE	Ministry of the Environment
MoEd	Ministry of Education
MoF	Ministry of Finance
MoI	Ministry of Interior
MoII	Ministry of Industries and Innovation
MoWF	Ministry of Welfare
MRL	Maximum Residue Limit
MS	Member State
NCP	National Contact Point
NRCP	National Residue Control Plan
NRL	National Reference Laboratory
NMKL	Nordic Committee on Food Analysis
OIE	World organisation for animal health
OV	Official Veterinarian
PONAO	Products of non-animal origin

ACRONYM	DESCRIPTION
PPP	Plant Protection Product(s)
PVP	Private Veterinary Practitioner
RASFF	Rapid Alert System for Food and Feed
SHÍ	The Association of Regional Health and Environment Authorities <i>/ Samtök heilbrigðiseftirlitssvæða á Íslandi</i>
SRM	Specified Risk Material
SWEDAC	Swedish Board for Accreditation and Conformity Assessment
TAIEX	Technical Assistance and Information Exchange instrument
TRACES	Trade Control and Expert System
TSE	Transmissible Spongiform Encephalopathy
UK	United Kingdom
UST	Environmental Agency
VHS	Viral Haemorrhagic Septicemia
VLA	Veterinary Laboratories Agency
VMP	Veterinary Medicinal products
Worldfengur	Equine Database (owned by the breeders)