Brussels, 26 April 2016
Case No: 76468
Document No: 802031

# Final report

# EFTA Surveillance Authority's mission to Iceland

# from 8 to 12 February 2016

# regarding the application of EEA legislation related to

# control of residues and contaminants in live animals and animal

# products, including controls on veterinary medicinal products

*Please note that comments from Iceland to the draft report are included in footnotes to the text of the report and information on the corrective actions already taken and planned by Iceland are included in Annex 3 to the report.*

***Executive Summary***

*This report describes the outcome of a mission carried out by the EFTA Surveillance Authority (the Authority) in Iceland from 8 to 12 February 2016 regarding application of EEA legislation related to control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.*

*The main legal framework for the national residue monitoring plan (NRMP) and use and distribution of veterinary medicinal products (VMPs), has been transposed into Icelandic legislation.*

*There have been no changes in the designation and responsibilities of the competent authorities since last mission was carried out by the Authority in 2011.*

*The Icelandic NRMP has improved in recent years but sampling of certain product groups and frequencies of sampling still do not meet the minimum requirements. Selection of substances to be tested within each of the mandatory residue subgroups is not decided based on all relevant risk factors.*

*Effectiveness of the NRMP is not ensured as the mission team noted limited cooperation within and between the competent authorities in the planning phase, incomplete supervision with regard to the implementation of the NRMP, clustering of sampling and deficiencies in the follow-up of non-compliant results.*

*For marketing, distribution and use of VMPs the mission team noted that VMPs are commonly dispensed to the public without the required veterinary prescription. Weak enforcement was seen regarding non-compliances detected in veterinary pharmacies and it was noted that inspection frequencies have dropped substantially in the last two years in veterinary pharmacies. Not all farms are inspected in Iceland by the competent authority regarding use of VMPs. Moreover, official controls carried out on farms and centrally regarding use of VMPs, are not always effective, also undermining the system in place in slaughterhouses regarding food chain information.*

*A National Reference Laboratory has not been designated for residues other than for heavy metal, however, Iceland has indicated that the designation process will be finalised in 2016.*

*Notwithstanding some evident improvements such as the introduction of an electronic database which could be a powerful tool for strengthening supervision and control of the use of VMPs, the mission team concludes that the present Icelandic residue monitoring controls do not ensure the implementation of all legal requirements with regard to monitoring of residues in food of animal origin and the distribution and use of VMPs.*

*The report makes a number of recommendations to Iceland, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.*

TABLE OF CONTENTS

# 1 Introduction

The mission took place in Iceland from 8 to 12 February 2016. The mission team comprised three inspectors from the EFTA Surveillance Authority (the Authority), a national expert and an observer from the European Commission. The opening meeting was held on 8 February 2016 at the MAST head office in Selfoss with representatives from the Icelandic Food and Veterinary Authority (MAST), representatives of the Icelandic Medicines Agency (IMA) and a representative of the Ministry of Industry and Innovation. At the meeting the competent authorities provided additional information to their reply to the pre-mission questionnaire. Throughout the mission a representative of MAST head office, and when relevant, representative of the visited district office of MAST, accompanied the mission team. Furthermore, representatives of IMA participated in relevant meetings. A final meeting was held on 12 February 2016 at the IMA's head office in Reykjavik, at which the mission team presented its main findings and preliminary conclusions from the mission.

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

# 2 Objectives of the mission

The objective of the mission was to assess the application by the Icelandic competent authorities of *Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products* and other relevant EEA legislation in the field of control of residues in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products (VMPs), the use of which may give rise to residues in animal products.

This assessment was carried out based on, and related to, the legislation referred to under Chapter 3 and Annex 2 to this document. Furthermore, the mission team followed up certain recommendations of the Authority's mission on control of residues and VMPs carried out in 2011 to Iceland (see Chapter 4). The meetings with the competent authorities and the visits to establishments and farms during the mission are listed below.

**Table 1: Competent Authorities, establishments, laboratories and farms visited during the mission**

| | Number | Comments |
|---|---|---|
| **Competent Authorities** | **4** | An opening meeting at the MAST head office and a closing meeting at the IMA head office. One meeting at the MAST head office with central and district representatives. One meeting with IMA head office representatives concerning authorisation, distribution and wholesale of VMPs. |
| **Laboratories** | **2** | Two laboratories with a role in the national residue monitoring plan and one of those designated as the National Reference Laboratory for heavy metals. |
| **Slaughterhouse** | **1** | One slaughterhouse approved for slaughtering cattle, pigs, sheep and horses. |
| **Wholesaler** | **1** | One wholesaler distributing veterinary medicinal products to pharmacies and veterinarians. |
| **Veterinary pharmacy** | **1** | One pharmacy specialised in veterinary medicinal products. |
| **Dairy plant** | **1** | One dairy plant with an own control system for analysing milk for antibiotic residues. |
| **Farms** | **3** | One pig farm, one broiler farm and one farm keeping cattle, sheep and horses. |

## 3 Legal basis for the mission

The legal basis for the mission was:

a) Point 4 of the Introductory Part of Chapter I of Annex I to the EEA Agreement;
b) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (Surveillance and Court Agreement);
c) *Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States*;
d) Article 21 of *Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC and*
e) Article 45 of *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules,* as amended.

The EEA legislation relevant for the mission is listed in Annex 2.

## 4 Background

In December 2011 the Authority carried out a mission to Iceland regarding controls of residues and contaminants in live animals and animal products and the competent authorities application of Directive 96/23/EC as well as the distribution and use of veterinary medicinal products as set out in Directive 2001/82/EC. The final report from that mission is accessible on the website of the Authority, www.eftasurv.int. After this mission, 15 recommendations were issued and thereof twelve recommendations were followed up on during the Authority's general follow-up mission to Iceland in December 2013. The mission team followed up on previously identified issues during the mission in February 2016 and in general, noted limited progress since the last Authority mission in 2011.

## 5 Findings and conclusions

### 5.1 Legislation and implementing measures

Legal requirements

Article 7 of the EEA Agreement states that acts referred to or contained in the Annexes to the Agreement are binding upon the Contracting Parties and shall be, or be made, part of their internal legal order.

Article 4(2)(e) of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have legal powers to carry out official controls and to take measures provided for.

Findings

According to information provided by Iceland in its reply to the pre-mission document of the Authority, the Ministry of Health is responsible for implementation of legislation on veterinary medicinal products (VMPs) and the Ministry of Industries and Innovation is

responsible for the implementation of legislation on residues, contaminants and certain substances in animals and animal products. The EEA legislation related to the scope of this mission has been transposed in Iceland.

According to information provided by Iceland in its reply to the pre-mission document of the Authority, the legal basis for imposing sanctions is found in article 18 in IS Act No 66/1998 on Veterinarians and Animal Health Services (as amended by IS Act No 55/2013 on Welfare of Animals, article 49), article 30, 30 a and 31 in IS Act No 93/1995 on Foodstuffs and article 18 and 21 in IS Act No 96/1997 on Slaughtering and Slaughtering products.

Conclusions

The national legislation is in line with the EEA agreement. Legal powers are in place to enforce the legislation.

## 5.2 Residue monitoring

### *5.2.1. Competent authorities*

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls, provide for efficient and effective co-ordination and cooperation between and within competent authorities. Article 6 of the same Regulation requires the competent authorities to ensure that staff receives appropriate training and keep the staff updated in their area of competence.

Article 4(2)(b) and (c) of Directive 96/23/EC lays down the requirements for central competent authorities in co-ordinating the activities of all bodies involved in residues controls.

Findings

The structure and responsibilities of the relevant competent authorities in Iceland are described in section 2.7 of the Icelandic Country Profile available at www.eftasurv.int.

According to information provided by Iceland in its reply to the pre-mission document of the Authority, The Icelandic Food and Veterinary Authority (MAST) is responsible for monitoring residues in live animals and animal products, for drawing up the national residue monitoring plan (NRMP) and for implementing the plan. The Icelandic Medicines Agency (IMA) is responsible for licensing and official controls on manufacture and distribution of VMPs down to pharmacy level including veterinary pharmacies, while MAST is responsible for official controls of VMP use on farms.

Regarding co-ordination and cooperation between and within competent authorities the mission team noted that the planning and supervision of the NRMP is mainly left to one employee at MAST. The responsible employee indicated to the mission team that background knowledge and training on issues related to pharmacologically active substances might be insufficient to complete the NRMP plan without expert input. Very limited evidence could be provided regarding inputs from IMA, relevant laboratories,

District Veterinary Officers, or other specialised officers within MAST in the NRMP planning phase (see also chapter 5.2.2.).

Conclusions

Iceland has designated competent authorities responsible for the official controls of residues and contaminants in live animals and animal products in line with Article 4(1) of Regulation (EC) No 882/2004.

Co-ordination and cooperation within and between the competent authorities is insufficient and does not meet the requirements of Article 4(3) and (5) of Regulation (EC) No 882/2004 and Article 4(2)(b) and (c) of Directive 96/23/EC.

### *5.2.2. Planning of residue monitoring*

Legal requirements

Article 5 of Directive 96/23/EC provides that Member States shall submit to the Authority a plan setting out the national measures to be implemented for the detection of residues or substances listed in Annex I to the Directive, and subsequently, Member States shall submit any update of residue monitoring plans previously approved on the basis of the experience of the preceding year or years, by 31 March at the latest of the year of the update.

Articles 3 to 6 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans. Annex II to that Directive sets out the substance groups to be detected by type of commodity, and Annexes III and IV to the Directive describes the sampling rules and levels that the plan must comply with. Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues in commodities not covered by the Directive.

Findings

On 1 April 2015, Iceland submitted the results of its residue monitoring for 2014 and the residue monitoring plan for 2015 to the Authority in accordance with Article 5 of Directive 96/23/EC. After assessment, the Authority found that the plan did not fully meet the requirements of Directive 96/23/EC and Commission Decision 97/747/EC. This concerned in particular low number of egg and poultry samples and lack of sampling at farm level for poultry and aquaculture animals. For poultry and aquaculture, all samples are foreseen to be taken at slaughter but according to Directive 96/23/EC, a certain percentage of samples for analyses of group A substances is to be taken at farm level.

According to information provided by Iceland in its reply to the pre-mission document of the Authority, a written procedure is in place outlining steps to be taken when drawing up the NRMP from initial gathering of information to the point of submitting a finalised plan to the Authority each year. It was explained to the mission team that excel workbooks are used to draw up the NRMP with built-in formulas to calculate the required number of samples for each species in each substance category. Required numbers of samples is calculated based on input regarding production volumes and information on the animal population where after samples are divided randomly to substance sub-categories. When these calculations are ready, a second excel workbook is used to allocate sample identification numbers, setting up sample matrixes and deciding on distribution of samples between the MAST district offices. A sampling request is then printed by MAST central office that accompanies the sampling equipment sent to the district offices.

The mission team noted that:

- Planning is seen mainly limited to allocating a number of samples for each mandatory residue substance group defined in Directive 96/23/EC based on previous years' annual production figures.
- There is no involvement of IMA in the planning process when MAST sets up the NRMP, although IMA is responsible for controls on marketing and distribution of VMPs.
- Data on actual use of different VMPs in Iceland is not used as background information when setting up the NRMP.
- No criteria has been set for the selection of substances to be tested within each of the mandatory residue substance groups and substances to be tested within each group have not been identified.
- Planning of the NRMP does not consider use of VMPs in feed and water.
- Very limited sampling is planned to be done on farms, except for milk. It was noted by the mission team that urine samples planned to be taken at farm level had been taken in the visited slaughterhouse.

Conclusions

The Icelandic national residue monitoring plan is not fully in line with the minimum requirements of Directive 96/23/EC regarding product groups and number of samples. The list of substances provided by the plan is limited to substance groups, and does not identify relevant substances on the basis of their actual use in Iceland. Further there is limited sampling planned to be carried out on water, feed and live animals, which is not in line with Articles 5 and 7 of Directive 96/23/EC. Therefore the planning process does not meet all requirements of Directive 96/23/EC.

*5.2.3 Implementation of the national residue monitoring plan*

Legal requirements

Annex III to Directive 96/23/EC and Commission Decision 98/179/EC lays down the rules regarding the sampling strategy for official sampling under the residue monitoring plan.

Findings

According to information provided by Iceland in its reply to the pre-mission document of the Authority, in the beginning of a sampling period, the MAST district offices receive boxes with sampling gear (labelled bags, seals, sheets to record sample information including general sampling instruction and a list of samples to be taken). The respective District Veterinary Officer also receives an e-mail with information about upcoming sampling and for the larger sampling lots, they also get an excel sheet with the list of samples to help them organize the sampling.

The mission team noted that:

- No central written procedures are in place regarding details on the overall implementation of the NRMP although a very rough drafted procedure was provided to the mission team regarding sampling, treatment and transport of samples.
- Sampling on farms is mostly unannounced and samples seen were traceable to the farm or animal of origin. Appropriate sampling material was used and samples were adequately sealed.
- Sampling is clustered and not evenly distributed throughout the year as sampling is mainly done in two periods, before summer and during the sheep slaughtering season in the fall.
- Long turnaround times were noted and had the potential to decrease effectiveness of follow-up in case of non-compliances (see also chapter 5.3.1)
- Although on the back of the standard sampling form there are general instructions and information for targeting sampling, sampling was not always targeted in practice. For example three out of four samples for residues of coccidiostats in sheep had been taken from adult animals although the instruction clearly indicated that young animals should be targeted.
- The sampling plan and form generally indicated the matrix for the sample, but did not indicate specific point of sampling (consequently muscle samples were not always suited for analysis) and which gender should be sampled.
- Samples that according to the NRMP should have been collected at farm level were seen collected at a slaughter house (urine).
- The completed sampling forms seen did not always comprise all relevant information, e.g. age and gender was sometimes missing (see also chapter 5.2.5).
- The sampling plan for aquaculture was not always respected as sampling from aquaculture animals was not done at all in one district according to set plan despite several requests from MAST central office. The competent authority informed the mission team that the samples for aquaculture not collected in 2015 would be collected during the mission.

Conclusions

The 2015 NRMP has been largely implemented as foreseen regarding set sampling frequencies according to requirements of Directive 96/23/EC. However, sampling is clustered and not appropriately targeted regarding detection of specific substances which is not in line with Annex III to Directive 96/23/EC and Commission Decision 98/179/EC.

### *5.2.4 Other residue monitoring programmes*

Legal requirements

Article 9 of Council Directive 96/23/EC foresees the application of self-monitoring by food business operators.

Findings

According to information provided by Iceland in its reply to the pre-mission document of the Authority, the dairy industry performs routine analysis of antibiotics in milk samples taken from each tanker truck arriving at dairy plants. A milk sample is also taken at regular

intervals at each farm from which the milk has been collected. Non-compliant test results shall be reported to MAST at district level.

The mission team noted that:

- The laboratory of the visited dairy plant performs a Betastar Combo test on the milk received from each tanker. Subsequently if the Betastar Combo Test is found positive a DelvoTest SP- NT is performed for confirmation.
- The Betastar Combo and DelvoTest SP- NT tests are screening tests which have limited and different coverage of the range of antibiotics available e.g. the Betastar Combo test does not cover Sulphonamides, Macrolides, Aminoglycosides and Fluoroquinolones.
- The dairy tests are general screening tests which can have greater sensitivity than required for individual antibiotics when monitoring for MRL non-compliances.
- Confirmation and quantification of screening tests is not performed.
- The dairy plant follows-up positive results and reports them to MAST (see also chapter 5.2.5).

Conclusions

The dairy industry own-control program for surveillance of antibiotics in milk provides additional but selective assurances with regard to the residue status of these commodities.

### *5.2.5 Follow-up of non-compliant results*

Legal requirements

The measures to be taken by the competent authorities in response to the finding of non-compliant residues results are described in Articles 15 to 18 of Directive 96/23/EC.

Findings

According to information provided by Iceland in its reply to the pre-mission document of the Authority, in cases of non-compliant results from residue monitoring, coordination for follow-up actions would be organised at MAST head office in cooperation with the respective District Veterinary Officer from the district where the sample was taken. No written procedures could be provided to the mission team regarding detailed measures to be taken by the competent authorities in response to the finding of non-compliant residues results.

The mission team noted that:

- There were two non-compliant results from NRMP sampling in 2014, both for Group A substances. Urine from a male porcine was found to contain 17-Beta-Nortestosterone - 16µg/l (the standard note provided by the laboratory indicated that the substance can be of endogenous origin in non-castrated pigs, however, no particular explanation pertaining to the actual sample was given by the laboratory). Urine from an ovine was found to contain 17-Alpha-Nortestosterone 2.1µg/l (the standard note provided by the laboratory indicated that the origin could be of endogenous origin due to cryptorchidism and intersex).

- On the sampling forms filled out by the official veterinarian that had taken the non-compliant samples it was not indicated whether the pig was in fact castrated or not nor was the gender of the lamb indicated.
- MAST had accepted the standard explanatory note given by the laboratory regarding the possible interpretation of two non-compliant results from 2014. No evidence of further investigation or follow-up could be provided to the mission team.
- In addition to the NRMP the dairy industry carries out routine analysis of antibiotics in milk samples (see also chapter 5.2.4). Limited evidence was seen of involvement of MAST in positive cases or use of results from this program in planning of residue monitoring.

Conclusions

Investigations and follow-up in cases of non-compliant test results are not in line with Articles 16(2) and 18(1) of Directive 96/23/EC.

## 5.3 Laboratories

Legal requirements

Requirements for designating laboratories are laid down in Articles 12(1) and 33 of Regulation (EC) No 882/2004 and Article 14 of Council Directive 96/23/EC. Requirements pertaining to the capacity laboratories are described in Article 4(2)(c) of Regulation (EC) No 882/2004. Requirements for accreditation of laboratories are laid down in Point 1.2 of the Annex to Commission Decision 98/179/EC and in Article 12(2) and (3) of Regulation (EC) No 882/2004. Requirements for the validation of analytical methods for residues of pharmacologically active substances and certain contaminants are laid down in Articles 3, 4, 5 and 6 of Commission Decision 2002/657/EC. Requirements for analytical methods are also laid down in the annexes to Commission Regulation (EC) No 252/2012 (dioxins and dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

### *5.3.1 General description and organisation*

Findings

According to information provided by Iceland in its reply to the pre-mission document of the Authority, two main laboratories are contracted to perform the analysis of samples collected for the NRMP as follows:

- Laboratory A in Sweden is responsible directly or by subcontracting to other suitable laboratories for A1, A2, A3, A4, A5, A6, B1, B2, B2a, B2b, B2c, B2d, B2e, B2f, B3a, B3b, B3c, B3d and B3e substances[1].
- Laboratory B in Iceland (designated NRL for heavy metals) is responsible directly for analysis of B3c substances.

[1] *Laboratory A in Sweden is responsible for all but B3c (heavy metals) covered by Laboratory B in the second point.*

A written contract for the period September 2015 until February 2016 was presented to the mission team for the Swedish laboratory. The contract included a requirement for compulsory laboratory accreditation from accreditation services linked to the European Cooperation for Accreditation, the use of validated methods according to Commission Decision 2002/657/EC and fixed turnaround times for the reporting of results. The laboratory stated in the contract that a validated method was not available for the analysis of avermectines and benzimidazoles in equines and that they had encountered problems with their analytical method for stilbenes and steroids in equines. The range of veterinary drugs, included in specific methods offered by the laboratory, is stated within the scope of their SWEDAC accreditation. The validation data obtained according to Decision 2002/657/EC, relating to the relevant CCalpha and CCbeta values, for combinations of drug, species and matrix were absent from the contract. However, they are provided when results are reported to MAST for confirmatory analysis.

Within the framework of the NRMP, laboratory B is responsible for the analysis of a portion of the NRMP samples. This laboratory performs the determination of heavy metals (group B3c) in swine, ovine, equine, game and bovine liver and muscle, in aquaculture products and in milk samples with inductively coupled plasma (ICP)/mass spectrometry (MS). A written agreement between MAST and this laboratory was seen, valid for the period November 2015 until February 2016 for the analysis of samples using the ICP/MS technique.

The mission team noted that:

- MAST as the competent authority had not made any assessment to determine any gaps in coverage of the service provided by the laboratories or availability and results from appropriate proficiency tests such as regarding lack of validated methods for the analysis of avermectines and benzimidazoles as noted by the mission team.
- The number of samples, sent in any single shipment to laboratory A, was restricted and suggested that the samples were being batched to meet the workload requirements of the laboratory.
- Turnaround times was prolonged since samples were stored by an Icelandic laboratory, before being sorted and shipped according to the contract with the laboratory (see also chapter 5.3.2).
- The set completion of the analysis for samples was four weeks from the date of delivery to laboratory A.
- A final report was required within a period up to eight weeks. However in the event of samples which, after a screening test, were suspected to contain illegal compounds or veterinary drugs above the MRL, MAST was to be informed immediately. MAST was responsible for requesting a confirmatory test.
- An Icelandic National Reference Laboratory for residues, except for heavy metals, had not been formally designated by the Iceland[2].

[2] *It is not necessary to designate an Icelandic laboratory. Iceland is currently working on a NRL contract with the Swedish laboratory that already analyses most of Iceland´s samples.*

### *5.3.2 Visits to laboratories*

Findings

The mission team visited a contracted laboratory receiving samples in the framework of the NRMP for cold storage until shipped for analysis in other contracted laboratories[3].

The mission team noted:

- All incoming samples were checked for proper condition and complete accompanying documents. In the case of samples in an inappropriate condition or packing for analysis (e.g. sample unfrozen or the plastic bag torn) the official veterinarians were informed orally and asked for additional sampling. If planned samples did not arrive, MAST should be informed according to the contract.
- Written instructions to rectify encountered sampling problems were not in place. The laboratory representative acknowledged that issues with samples were not always recorded.
- Although the individual samples are delivered with a tie seal or adhesive tape (B sample), the transport container, a polystyrene box with adhesive tape, is not tamperproof.
- All samples were stored in suitable devices (refrigerator rooms, freezer rooms). Laboratory staff controlled and recorded the room's temperature within the framework of the Quality Assurance system of the laboratory. However the overview of the temperature monitoring did not provide sufficient assurance of control.
- The freezer room was locked. However, access was available to a range of external official staff and couriers who placed boxes in the freezer, without supervision by the laboratory staff.
- Instructions existed for the packing of samples and transport to the contract laboratories. The laboratory adhered to the timetable of the contract laboratory and contacted the laboratory by e-mail before shipping. They ensured that all documents were available for shipping.
- The B samples were stored in the laboratory freezer room until all samples were analysed. However, there was no evidence that non-compliant B samples were kept for a potential counter analysis.

The mission team visited the designated NRL for heavy metals in the framework of the NRMP.

The mission team noted:

- The laboratory was accredited by the Swedish accreditation body for chemical and microbiological analysis in food (SWEDAC). A method for the determination of

[3] *Contracted laboratory receiving samples stores samples in "freezer storage", not cold storage until samples are shipped. Samples are frozen as soon as they are sampled and stored and shipped frozen, both inside Iceland and when shipped to laboratories outside Iceland.*

trace elements (based on the Nordic Committee on Food Analysis (NMKL) method 186/2007) was included in the accreditation scope.

- Since 2007 the laboratory has had a Quality Manual System in line with ISO17025 standards in place. The quality manual and written instructions were available in paper form and via intranet. Examples of SOPs (method SV-22-02 for heavy metals, in-house verification of methods) were provided. Internal audits and management reviews were done on a regular basis and documented.
- The method used in the laboratory was validated in a method validation study by the NMKL. The laboratory did an in-house verification of the method performance data (accuracy, precision, limit of detection, reporting limit and uncertainty) with different matrices and proved the fitness of purpose of the method that was described in the documentation for accreditation of the laboratory.
- The samples were analysed in batches of at least five samples each. For internal quality control a calibration with standards was done in each sample batch. Each batch contains negative control samples as well as certified reference materials as positive control samples.
- For external quality control the laboratory was participating regularly (4-5 times per year) in proficiency test schemes of Quality Assurance of Information for Marine Environmental Monitoring in Europe (Quasimeme) and of the National Food Agency of Sweden. The participation in the tests was successful for the determination of cadmium, lead and mercury.
- Incoming samples were registered in a Laboratory Information Management System (LIMS), labelled with internal laboratory identification numbers and were stored frozen in the laboratory after registration. The samples arrived at the laboratory in sealed bags, each bag containing samples and counter-samples. Fixed procedures on rejection of samples or on storage of counter-samples were not present. The mission team was informed that there were no non-compliant test results in the last two years.
- Standard compounds (solutions) were stored properly and were labelled with expiry dates. Some of the standard solutions had expired and the laboratory explained that expired solutions were used to do counterchecks against new purchased standards. Standard solutions were prepared gravimetrically. Balances were calibrated once a year.

Conclusions

The designated NRL for heavy metals meets the relevant legal requirements. Iceland has not designated a NRL for other residues in Iceland, as required by Article 33(1) of Regulation (EC) No 882/2004.

It is not ensured that methods offered by a contract laboratory are validated and that the respective laboratories document the validation data they have for combinations of drug and matrix quoting the relevant CCalpha and CCbeta values obtained from their validations, as required by Directive 2002/657/EC.

Long turnaround times of samples have the potential to the decrease effectiveness of follow-up in case of non-compliances.

## 5.4 Veterinary medicinal products (VMPs)

### *5.4.1 Official controls on the authorisation and distribution of VMPs*

Legal requirements

Conditions governing the distribution of VMPs are laid down in Articles 65 to 69 of Directive 2001/82/EC.

Article 67(aa) of Directive 2001/82/EC requires that VMPs for food producing animals are only dispensed to the public under a veterinary prescription unless exempted under the conditions laid down in Article 2 of Commission Directive 2006/130/EC.

Competent authorities have a general obligation under Article 80(1) of Directive 2001/82/EC to carry out inspections throughout the distribution chain of VMPs in order to verify compliance with the provisions of the Directive 2001/82/EC.

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies a non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

Council Directive 96/22/EC prohibits the use of hormones and beta-agonists for use as growth promoters in food producing animals.

Findings

The structure and responsibilities of the relevant competent authorities in Iceland are described in section 2.7 of the Icelandic Country Profile available at www.eftasurv.int. There are no major changes in the system for authorisation and distribution of VMPs since the last mission carried out by the Authority in 2011.

According to information provided by Iceland in its reply to the pre-mission document of the Authority, IMA is responsible for licensing of, and official controls on authorisation and distribution of VMPs to pharmacy level, while MAST is responsible for the control of use of VMPs by veterinary practitioners and on farms (see also chapter 5.4.2). All VMPs in Iceland are imported by licensed wholesalers who are inspected regularly by IMA.

The mission team noted:

- There are two main wholesalers of VMPs in Iceland that supply pharmacies and veterinary practices. The mission team visited one of these wholesalers and noted that the wholesaler was regularly inspected by IMA inspectors and reports were seen issued after each inspection carried out, including documented follow-up when deficiencies had been detected.
- IMA requested a written response from the inspected party including a corrective action plan. The inspection was completed by IMA when the wholesaler had responded to the deficiencies in a satisfactory manner.

- Quarterly reconciliations on narcotics was done in the visited wholesaler but it was noted that IMA did not control if regular reconciliation was carried out for other VMPs.
- Two inspections to veterinary pharmacies had been carried out in 2014, and no inspections had been carried out in 2015, or up until the time of the mission in 2016. It was explained to the mission team by IMA representatives that this had been due to lack of capacity, although the mission team was informed that all veterinary pharmacies had been inspected within the last six years. IMA had a risk-based approach to these controls and had planned 26 inspections to veterinary pharmacies in 2016.
- A list of non-compliances detected in IMA inspections at veterinary pharmacies in 2013 (15 inspections) and 2014 (2 inspections) was provided to the mission team. The overview of findings from these IMA inspections indicated that non-compliances are very common, including non-compliances categorised as being serious by IMA. For example, one of the most common deficiencies detected by IMA was that VMPs were dispensed from the visited veterinary pharmacies without prescriptions (non-compliance in more than half of visited pharmacies).
- Examples of other serious but less common non-compliances seen detected by IMA were that VMPs without marketing authorisation were sold by some pharmacies, labelling on packages of VMPs was found not satisfactory and many expired VMPs were identified.
- Follow-up of identified non-compliances at veterinary pharmacies is done by IMA by way of written report but enforcement was seen weak. Representatives of IMA indicated to the mission team that limited tools were available for enforcement although a recent change in legislation allows for issuing daily fines until the deficiency is rectified (so far not used).
- The mission team noted that in cases of lack of corrective actions being implemented in the inspected veterinary pharmacy, as a response to non-compliances detected in IMA controls, it seemed not fully clear how such cases should be handled. The mission team was informed of an example originating from 2010 that was still open regarding a veterinarian refusing to implement corrective actions requested by IMA such as issuing prescriptions.
- IMA regularly publishes an on-line newsletter on its webpage which is also distributed to veterinarians. This was noted by the mission team to be a good initiative and an effective method to distribute information to veterinary practitioners.

Conclusions

Although distribution of veterinary medicinal products for food producing animals is controlled through official inspections at veterinary pharmacies, lack of recent inspections and non-compliances identified in previous IMA reports indicate that it is not ensured that legislation concerning the distribution of veterinary medicinal products is appropriately enforced and that veterinary medicinal products to food producing animals are frequently distributed in Iceland without a veterinary prescription, which is not in line with Article 67(aa) of Directive 2001/82/EC.

### *5.4.2 Official controls on the use of VMPs*

Legal requirements

Article 8 of Regulation (EC) No 882/2004 requires the competent authority to carry out official controls in accordance with documented procedures and to ensure that corrective action is taken when needed. Article 9 of the said Regulation requires that the competent authority shall draw up reports on the official controls that it has carried out.

The veterinary medicines record keeping requirements for stockowners are laid down in Article 69 of Directive 2001/82/EC, Article 10 of Council Directive 96/23/EC and Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004.

The requirements for food chain information accompanying animals submitted for slaughter for human consumption are laid down in Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004.

Provisions on identification of bovine animals are set out in Regulation (EC) No 1760/2000 and for ovine animals in Regulation (EC) No 21/2004. Legislation for the identification of horses (e.g. Commission Implementing Regulation (EU) 2015/262) is currently not applicable to Iceland under the EEA Agreement.

Rules for the production of medicated feeding stuffs are set out in Council Directive 90/167/EEC, and requirements for the control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive.

Findings

According to information provided by Iceland in its reply to the pre-mission document of the Authority, a control handbook for inspections on cattle farms is included in MAST´s quality manual. Handbooks for poultry, pig, sheep and horse farms are still in draft only. The mission team noted that issues related to use of VMPs are included in the checklist used for official control at farms. The District Veterinary Officers, official veterinarians or special veterinarians at MAST head office carry out controls on the use of VMPs depending on species. The main focus for these controls is on correct storage and labelling of VMPs, to check farm registration of treatment in herd registers and to ensure that withdrawal periods are kept.

According to information provided by Iceland in its reply to the pre-mission document of the Authority, MAST has established an electronic database system (HEILSA) to keep records of use of VMPs on farms in food producing animals, linked to their identification number (see chapter 2.7 in Country Profile). The species-specific electronic herd book systems in Iceland are linked to HEILSA. There is a legal obligation to register all prescriptions for VMPs, including withdrawal times, for cattle and horses in HEILSA but registration for sheep was explained to be required but still not legally binding. The mission team noted that there is no procedure in place regarding nature and frequency of controls on the quality of data inserted into HEILSA and how/if it is used consistently by veterinarians.

The database was demonstrated to the mission team that noted:

- A few examples taken from the database indicated that the legal obligation of registration in HEILSA was not respected in all cases and there was no system in

place to use the information available in HEILSA and control if individual veterinarians fulfilled this legal obligation (one veterinarian picked at random had only two farm visits registered in HEILSA for the year 2015). Evidence of discrepancies were also noted when comparing a list of veterinarians specially authorised by IMA to use a certain product to a list of veterinarians that were registering use of this product in HEILSA.

- In general limited information could be provided to the mission team regarding how/if the quality of the data in HEILSA was checked and limited information could be provided regarding how/if District Veterinary Officers and central MAST staff used the data in HEILSA for official control purposes.

According to information provided by Iceland in its reply to the pre-mission document of the Authority, Regulation IS No. 539/2000 on the authorisation of veterinarians to prescribe medicine states in Article 17 that the Chief Veterinary Officer (CVO) can grant veterinarians a derogation from the requirement to initiate antibiotic treatment themselves in farmed animals where geographical, climate or other external circumstances prevent the veterinarian from initiating the treatment. According to the same information the CVO has issued authorisations to some veterinarians for supply of antibiotics to sheep farmers, particularly for use in the lambing season. These veterinarians shall have a contract with the farmer that they supply antibiotics to and the contract has certain conditions. All supply of antibiotic shall be registered in HEILSA and the farmer shall consult the veterinarian when he needs to use the antibiotic.

The mission team noted:

- A special code (8816) is to be used exclusively by veterinarians for registrations in HEILSA regarding the derogation. It was noted that this code was not consistently used. For example none of the authorised veterinarians in the south district used the code in 2015.
- The code was also, according to data seen in HEILSA, on some occasions used regarding prescriptions for horses and cattle. Authorisations to veterinarians were only applicable to sheep from January 2013, but the mission team was informed by the CVO that older authorisations might still be valid also for other species than sheep.
- The mission team was informed that the system for granting these authorisations to veterinarians had been recently changed from annual to unlimited duration.
- The mission team noted there were limited controls in place regarding this system of granting authorisations to veterinarians. Available data in HEILSA, such as regarding if a veterinarian respected requirements for recording of all use of VMPs in general, was not used before granting authorisation for the same veterinarian under this derogation.

The mission team visited one pig farm, one poultry farm and one farm keeping cattle, sheep and horses. In general, records of VMPs used and withdrawal times were recorded in on-farm herd books, although some examples were seen in the pig farm and the dairy farm where not all treatments with VMPs and withdrawal times were noted in their registers or there was not a clear link between veterinary prescriptions and the treatment records.

The mission team noted:

- On a visited farm, it was seen that some VMPs for cattle were handed out by the veterinarian to the farmer to administer on a later occasion (orbenin / Vitamin ADE, Oxytocin). The mission team noted later when going through registrations in HEILSA at MAST head office, that use of Oxytocin and Vitamin ADE, found in the farm's medicinal cabinet, had not been registered in HEILSA. It was noted that the farmer was not aware of the withdrawal period for the Vitamin ADE (40 days for meat). Also expired VMPs were found on the farm. The last MAST inspection at this farm, regarding cattle, took place in January 2015 and no non-compliances had been identified regarding VMPs on that occasion.
- For sheep it was noted that not all treatments were registered in HEILSA on the visited farm. Use of some products was registered in the farm quality management system register but it was noted that this was not strictly followed (use of avermectine/Veramix not recorded).
- Regarding horses there were no records regarding use of VMPs available on the visited farm and it was explained to the mission team that all VMPs were administered by the veterinarian who recorded the treatments in HEILSA.
- The visited pig farm kept registers of all VMPs used. VMPs were kept at the farm and routinely used by farmer. Withdrawal periods were noted at the medicinal cabinet for each used VMP.
- At a visited broiler farm the storage and use of feed additives (coccidiostats) were found to be in order. The different feed types were kept in clearly identified dedicated silos and the farm representative stated that VMPs were never used at the farm.

According to information provided by Iceland in its reply to the pre-mission document of the Authority, animal welfare officers, which are MAST employees, control sheep and horses regarding use of VMPs. However, the mission team met with an animal welfare officer that stated that his control activities did not include controls on the use of VMPs, that animal welfare officers in general did not have access to HEILSA and that they had not been trained on issues related to VMPs. The mission team was informed that a very limited number of inspections had been carried out by MAST to sheep farms or horse farms regarding the use of VMPs.

According to information provided by Iceland in its reply to the pre-mission document of the Authority, food chain information is required for all farmed animals species brought to slaughter in Iceland. The mission team visited a slaughterhouse approved for slaughtering bovines, ovines, pigs and horses and noted the following:

- The food business operator informed the mission team of measures taken to accept at the slaughterhouse (and place on the market) only animals for which withdrawal times had been respected and did not contain residue levels above MRLs or illegal substances.
- Cattle, horses, sheep and pigs were accompanied by a farmer's declaration containing information on, inter alia, treatments with VMPs and withdrawal periods. The slaughterhouse operator showed the mission team its documented procedures with instructions for checking the food chain information.
- It was noted that respect of withdrawal times was not consistently checked at arrival of food-producing animals either by the food business operator or by the official veterinarian.

- The food business operator explained that MAST sent two or three times a week by e-mail an excel file extracted from HEILSA listing all animals treated with VMPs where the withdrawal period had not passed. However, the food business operator indicated that this information was not used and rather relied on the farmers declaration.
- In relation to slaughtering of horses, the food business operator explained to the mission team that in case the horse arrived at the slaughterhouse without accompanying documents, the horse would be slaughtered and the farmer had 24 hours to provide the required documents. In case no documents were provided or if the withdrawal period had not been respected, the meat would not be used for human consumption.
- Regarding cattle, the food business operator indicated that respect of withdrawal periods and treatments with VMPs might be checked at arrival or after slaughter by accessing information in the central database for cattle, which is linked to HEILSA. In case of a slaughter ban, the relevant carcass would be identified, and the official veterinarian would be informed and the carcass rejected.
- Regarding sheep, slaughter in Iceland is mostly concentrated in the months of September and October. The visited food business operator relied solely on the farmers declarations.
- Regarding pigs, the mission team saw that the farmers' declarations only indicated the farm name (no registration number) and the number of animals.
- The official veterinarian met did not use HEILSA or other electronic databases to retrieve information on possible disrespect of the withdrawal period.

According to information provided by Iceland in its reply to the pre-mission document of the Authority, Regulation IS No 607/2013 and Regulation IS No 608/2013 cover the manufacturing of medicated feed. According to the same information, there is currently no manufacturing of medicated feed in Iceland and no feed mills approved for production of medicated feed.

Conclusions

Instructions are in use by the competent authorities concerning controls of VMPs at farm level, however, a number of deficiencies were observed that had not been detected by the competent authorities and records regarding use of VMPs at farm level are not consistently kept, which is not in line with Article 69 of Directive 2001/82/EC, Article 10 of Council Directive 96/23/EC and Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004.

The provisions of Directive 2001/82/EC are not complied with regarding official controls and use of VMPS on horse and sheep farms.

The official controls on use of VMPs in food producing animals are supported by a central database regarding use of VMPs but the quality of the data in the database and consistency regarding recording of use by veterinarians or farmers is not ensured. As the information in this database plays a role in the set-up in Iceland, concerning food chain information controls in place at food business operator level, this is considered a weakness.

## 6 Final meeting

A final meeting was held on 12 February 2016 at the IMA head office in Reykjavík with representatives from MAST, IMA and representatives from the Ministry of Industry and Innovation and the Ministry of Health. At the meeting, the mission team presented its main findings and the preliminary conclusions of the mission with reference to the relevant EEA legislation. The mission team also explained that, based on a more detailed assessment of the information received during the mission, additional conclusions could be included in the report. The Icelandic representatives were given the opportunity to comment or ask for clarification during the meeting.

## 7 Recommendations

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

| No | Recommendation |
|---|---|
| **1** | Iceland should ensure coordination and cooperation within MAST and between MAST and IMA when drawing up the national residue monitoring plan and when planning official controls on veterinary medicinal products in order to ensure that all relevant information is taken into account in the planning in line with Article 4(3) of Regulation (EC) No 882/2004 and Article 4(2)(b) and (c) of Directive 96/23/EC. |
| **2** | Iceland should ensure that when planning the national residue monitoring plan, selection of substances to be tested within each of the essential subgroups shall be decided based on all relevant risk factors, as required by Article 5(2)(c) and Annex III to Directive 96/23/EC, also including but not limited to, data on use of VMPs in Iceland. |
| **3** | Iceland should ensure that the minimum sampling levels and frequencies, including point of sampling, are respected for all commodities, as required by Article 5 and Annex IV of Directive 96/23/EC, in particular, but not limited to, the minimum sampling frequency for eggs and poultry and sampling at farm level for poultry and aquaculture animals. |
| **4** | Iceland should, where appropriate, include sampling of feed and water in its national residue monitoring plan, as set out in Article 3 of Directive 96/23/EC. |
| **5** | Iceland should ensure that sampling for the national residue monitoring plan is carried out according to requirements of the Annex to Commission Decision 98/179/EC and in particular that sampling shall be carried out in variable intervals spread over the whole year (point 2.1) and that collection of samples is targeted (point 2.3). |
| **6** | Iceland should ensure that investigations and follow-up of non-compliant test results regarding presence of residues are in line with Articles 16(2), 18(1) of Directive 96/23/EC. |
| **7** | Iceland should designate a National Reference Laboratory for residues, other than heavy metals, as required by Article 33(1) of Regulation (EC) No 882/2004. |
| **8** | Iceland should ensure that methods offered by a contract laboratory for analysing samples under the national residue monitoring plan are validated as required by Article 3(c) of Decision 2002/657/EC. |

| | |
|---|---|
| **9** | Iceland should ensure that proper enforcement action towards the relevant operators are taken to ensure that veterinary medicinal products are not dispensed to the public without a veterinary prescription, as required by Article 67(aa) of Directive 2001/82/EC. |
| **10** | Iceland should ensure that all treatments of food producing animals are recorded, as required by Article 10 of Directive 96/23/EC and Article 69 of Directive 2001/82/EC. |
| **11** | Iceland should ensure that inspections are carried out through all links of the distribution chain of veterinary medicinal products in line with Articles 65, 66, 68 and 69 of Directive 2001/82/EC, also regarding, but not limited to, inspections at horse and sheep farms. |

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

| | |
|---|---|
| The Authority | EFTA Surveillance Authority |
| CVO | Chief Veterinary Officer |
| EC | European Community |
| EEA | European Economic Area |
| EEA Agreement | Agreement on the European Economic Area |
| FVO | Food and Veterinary Office of the European Commission |
| ICP | Inductively Couples Plasma |
| IMA | Icelandic Medicines Agency |
| MAST | The Food and Veterinary Authority of Iceland |
| LIMS | Laboratory Information Management System |
| MS | Mass Spectrometry |
| MRL | Maximum Residue Limit |
| NMKL | Nordic Committee on Food Analysis |
| NRMP | National Residue Monitoring Plan |
| NRL | National Reference Laboratory |
| QMS | Quality Management System |
| SOP | Standard Operating Procedures |
| SWEDAC | Swedish accreditation body for chemical and microbiological analysis in food |
| VMP | Veterinary Medicinal Products |

## Annex 2 - Relevant EEA legislation

The main EEA Acts regarding residues, contaminants and veterinary medical products relevant for this mission are:

a. The Act referred to at Point 7.1.13 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

b. The Act referred to at Point 6.1.16 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs*, as corrected and amended;

c. The Act referred to at Point 6.1.17 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin*, as corrected, amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

d. The Act referred to at Point 1.1.11 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as corrected and amended;

e. The Act referred to at Point 1.1.12 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption*, as corrected, amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

f. The Act referred to at Point 1.1.7b of Chapter I of Annex I to the EEA Agreement, *Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC*, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

g. The Act referred to at Point 1.1.7c of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97*, as amended;

h. The Act referred to at Point 1.2.128 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2005/34/EC of 11 January 2005 laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries*;

i. The Act referred to at Point 6.2.39 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/536/EC of 3 September 1998 establishing*

*the list of national laboratories for the detection of residues*, as corrected and amended;

j. The Act referred to at Point 7.1.1 of Chapter I of Annex I to the EEA Agreement, *Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EC*, as amended;

k. The Act referred to at Point 7.1.2 of Chapter I of Annex I to the EEA Agreement, *Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC*, as amended;

l. The Act referred to at Point 7.1.10 of Chapter I of Annex I to the EEA Agreement, *Council Directive 90/167/EEC of 26 March 1990, laying down conditions governing the preparation, placing in the market and use of medicated feedingstuffs in the Community*;

m. The Act referred to at Point 7.2.13 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products*;

n. The Act referred to at Point 7.2.14 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products*, as amended;

o. The Act referred to at Point 7.2.19 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results*, as corrected and amended;

p. The Act referred to at Point 1a of Chapter II of Annex I to the EEA Agreement, *Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

q. The Act referred to at Point 54zz of Chapter XII of Annex II to the EEA Agreement, *Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC*;

r. The act referred to at Point 54zzy of Chapter XII of Annex II to the EEA Agreement, *Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC* as amended;

s. The Act referred to at Point 54zzzl of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) 401/2006 of 23 February 2006 laying*

*down the methods of sampling and analyses for the official control of the levels of mycotoxins in foodstuffs*, as amended;

t. The Act referred to at Point 54zzzp of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analyses for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MPCD and benzo(a)pyrene in foodstuffs*, as amended*;*

u. The Act referred to at Point 54zzzz of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs,* as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement;

v. The Act referred to at Point 87 of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EU) No 589/2014 of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 252/2012*;

w. The Act referred to at Point 12 of Chapter XIII of Annex II to the EEA Agreement, *Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council,* as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement;

x. The Act referred to at Point 13 of Chapter XIII of Annex II to the EEA Agreement, *Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin,* as amended;

y. The Act referred to at Point 15p of Chapter XIII of Annex II to the EEA Agreement, *Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products,* as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement;.

z. The Act referred to at Point 15za of Chapter XIII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae,* as amended*;*

aa. The Act referred to at Point 15zg of Chapter XIII of Annex II to the EEA Agreement, *Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food producing animals from the requirement of a veterinary prescription.*

## Annex 3 - Reply from Iceland to the draft report

| No | Recommendation | Reaction of Icelandic authorities | Date of Compliance | Comment/ attachment |
|---|---|---|---|---|
| **1** | Iceland should ensure coordination and cooperation within MAST and between MAST and IMA when drawing up the national residue monitoring plan and when planning official controls on veterinary medicinal products in order to ensure that all relevant information is taken into account in the planning in line with Article 4(3) of Regulation (EC) No 882/2004 and Article 4(2)(b) and (c) of Directive 96/23/EC. | A request has been sent to IMA for a list of veterinary drugs sold in Iceland and changes of active substances from year to year. Such a request will be sent each year for updated information.<br><br>Cooperation between MAST and IMA has already started by regular meetings sharing of information and field visits to veterinary pharmacies. | Finalised April 2016 | |
| **2** | Iceland should ensure that when planning the national residue monitoring plan, selection of substances to be tested within each of the essential subgroups shall be decided based on all relevant risk factors, as required by Article 5(2)(c) and Annex III to Directive 96/23/EC, also including but not limited to, data on use of VMPs in Iceland. | MAST has requested data from IMA on use of VMPs for different species. During the year the plan is to review the selection of substances to be tested for assurance that the NRMP covers all VMPs used in Iceland in addition to banned substances and other relevant contaminants.<br><br>MAST will look into using data from the database Heilsa in the planning in cooperation with the DVOs to ensure that the right farms are sampled. | March 2017 | |

| No | Recommendation | Reaction of Icelandic authorities | Date of Compliance | Comment/ attachment |
|---|---|---|---|---|
| **3** | Iceland should ensure that the minimum sampling levels and frequencies, including point of sampling, are respected for all commodities, as required by Article 5 and Annex IV of Directive 96/23/EC, in particular, but not limited to, the minimum sampling frequency for eggs and poultry and sampling at farm level for poultry and aquaculture animals. | The sampling plan for 2016 fulfils the minimum sampling levels. Steps have been taken to ensure that sampling will be possible at farm level in poultry (feed) and at different stages of farming in aquaculture. | March 2017 | |
| **4** | Iceland should, where appropriate, include sampling of feed and water in its national residue monitoring plan, as set out in Article 3 of Directive 96/23/EC. | In 2016 feed will be sampled at farm level in poultry farms. In 2017 it will be considered which substances to look for in water and if and where this sampling is most feasible based on risk assessment. See also point 1. | March 2017 | |
| **5** | Iceland should ensure that sampling for the national residue monitoring plan is carried out according to requirements of the Annex to Commission Decision 98/179/EC and in particular that sampling shall be carried out in variable intervals spread over the whole year (point 2.1) and that collection of samples is targeted (point 2.3). | All sampling instructions are being reviewed in order to make it easier to target more suspect animals for sampling. The spreading of sampling throughout the year needs more planning and review of contracts with the laboratories. This will not be possible to fulfil until 2017.<br><br>However, MAST will try in 2016, within the framework of the existing lab contracts, to spread samples as much as practical and possible. | March 2017 | |

| No | Recommendation | Reaction of Icelandic authorities | Date of Compliance | Comment/ attachment |
|---|---|---|---|---|
| **6** | Iceland should ensure that investigations and follow-up of non-compliant test results regarding presence of residues are in line with Articles 16(2), 18(1) of Directive 96/23/EC. | A written procedure is under construction and will include different steps, reports and actions to be taken and persons responsible for each step. | March 2017 | |
| **7** | Iceland should designate a National Reference Laboratory for residues, other than heavy metals, as required by Article 33(1) of Regulation (EC) No 882/2004. | | | |
| **8** | Iceland should ensure that methods offered by a contract laboratory for analysing samples under the national residue monitoring plan are validated as required by Article 3(c) of Decision 2002/657/EC. | The validation documents have already been obtained from the laboratories involved and verified that they are indeed validated as required and accredited. For some few instances we have requested more documentation. These documents are regularly updated by the laboratories and brought to MAST´s attention.<br>This issue will be included in the written procedure on contracting laboratories which is under review. | Action taken. | |
| **9** | Iceland should ensure that proper enforcement action towards the relevant operators are taken to ensure that veterinary medicinal products are not dispensed to the public without a veterinary prescription, as required by Article 67(aa) of Directive 2001/82/EC. | 22 inspections in veterinary pharmacies are on IMAs inspection plan in 2016 IMA now has the resources to follow up on the inspections. | | |

| No | Recommendation | Reaction of Icelandic authorities | Date of Compliance | Comment/ attachment |
|---|---|---|---|---|
| **10** | Iceland should ensure that all treatments of food producing animals are recorded, as required by Article 10 of Directive 96/23/EC and Article 69 of Directive 2001/82/EC. | Veterinarians in private practice (PVPs) have already been reminded of their duty to record all treatments of food producing animals. After reviewing all recordings in the database Heilsa, the District Veterinarians sent information by e-mail to all the veterinarians that have not fulfilled their legal duty of recording treatments of cows and horses in the data base.<br><br>Data concerning exemptions, given by the CVO, to distribute antibiotics to sheep farmers was also analysed and those PVPs that did not fulfil the conditions of the exemption were also sent an e-mail from the DVO in their district. Please find attached examples of the e-mails.<br><br>Veterinarians in private practice have been asked by MAST to give an explanation of their lack of recordings in the database and of their wrong distribution of antibiotics. If they cannot give a full explanation they will receive a reminder from the CVO. The plan is to have this completed by the end of June 2016.<br><br>MAST will continue to monitor recordings in Heilsa. The plan is to increase the inspections of the recordings especially during the lambing season to monitor correct distribution of antibiotics to sheep farmers. | End of June 2016 | Recording in database_letter.do<br><br>VMPs without exemption_letter.do |

| No | Recommendation | Reaction of Icelandic authorities | Date of Compliance | Comment/ attachment |
|---|---|---|---|---|
| | | The long-term plan is to get all veterinarians treating cows, horses and sheep to record their treatments in Heilsa. This should be accomplished by the end of 2017. When that is achieved MAST will increase the scope of its control of the recordings to include comparison of the recordings in Heilsa to sales figures from the Icelandic Medicinal Agency. | End of December 2017 | |
| **11** | Iceland should ensure that inspections are carried out through all links of the distribution chain of veterinary medicinal products in line with Articles 65, 66, 68 and 69 of Directive 2001/82/EC, also regarding, but not limited to, inspections at horse and sheep farms. | New inspection handbooks for sheep and horses were finalized in April 2016. They include a chapter on the performance of VMP inspection on farms. The farmer is responsible for recording all treatments and diagnoses on his farm with help from his/her veterinarian. He/she also has to know and record withdrawal periods for all medicines used on his/her farm.<br><br>The official inspector checks if VMPs are used correctly and if withdrawal periods are recorded and respected. Recordings of diagnoses are checked as well as if medicines on the farm are labelled correctly (incl. use and withdrawal periods). If there are any non-compliances the inspector keeps a record of those and informs the VMP expert at MAST. If expired, unlabelled or illegal VMPs are found at the farm they are confiscated. | | The handbooks will be published on MAST website (soon) and sent to ESA. |