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Final report

EFTA Surveillance Authority mission to

Iceland

6 to 14 December 2011

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 and information from the Icelandic competent authorities on the corrective actions already taken and planned by the Icelandic competent authorities are included in Annex 3 in the report and referred to in foodnotes in *underlined italic print* in the body of the report.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority (the Authority) in Iceland from 6 to 14 December 2011 regarding application of EEA legislation related to control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.

Council Directive 96/23/EC regarding national residue control programmes have been applicable to Iceland since 1 November 2011. Iceland had an 18 month transitional period to comply with the provisions of this Directive. Prior to that date, Iceland has put in place a National Residue Control Plan (NRCP) as a third country for commodities exported to the European Union.

The mission team found that the main legal framework for the National Residue Control Plan, i.e. Council Directive 96/23/EC and associated legislation (including Commission Decision 2002/657/EC concerning validation of analytical methods for residues and Council Directive 90/167/EEC on use of medicated feedingstuffs) had not been made part of the Icelandic legal order.

Competent authorities had been designated, however, a possible conflict of interest was identified since veterinarians responsible for official controls at farm level concerning use of veterinary medicinal products at the same time were prescribing medicine to the same farms as private practitioners. In addition, gaps were seen in the organisation of official controls for veterinary medicinal products i.e. so far no inspections concerning use and distribution of veterinary medicinal products had been carried out to sheep and horse farms of which there are substantial numbers in Iceland.

The residue monitoring plan for cattle, sheep, pigs, horses and aquaculture is generally in line with the minimum requirements of Directive 96/23/EC. However, the narrow scope of testing, in particular for steroids in cattle, sheep, pigs and horses, weakens the effectiveness of the plan. Concerning implementation of the plan the main problem observed was a clustering of the sampling in the late autumn of the year. Moreover, a lack of supervision of the implementation of the plan was noted.

There has not yet been appointed a National Reference Laboratory for residues in Iceland. Two laboratories in Iceland are involved in residue testing (and both were visited) and other samples are sent abroad. In one of the laboratories visited the methods used were not validated so there were doubts about their accuracy. The other laboratory visited performed with satisfactory accuracy.

Veterinarians in Iceland do not write prescriptions at all in spite of a clear national legal basis. At the same time gaps were seen in the implementation of a system for food chain information, and consequently the slaughterhouses did not have routines in place to ensure that animals are not slaughtered within the withdrawal times for veterinary medicinal products used. Combined with findings of large numbers of farms and veterinarians not being controlled at all by the competent authorities, the mission team concluded that there is a risk of meat and milk containing residues of veterinary medicine.

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

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1 Introduction

The mission took place in Iceland from 6 to 14 December 2011. The mission team comprised one inspector from the EFTA Surveillance Authority (the Authority), a national expert from the Community Reference Laboratory (CRL) for residues in Berlin, Germany, and an observer from the European Commission's Food and Veterinary Office (FVO).

The opening meeting was held with representatives of the Icelandic Food and Veterinary Authority (MAST) on 6 December at the MAST head office in Selfoss. At the meeting the competent authorities added information to the reply to the pre-mission questionnaire.

Throughout the mission a representative of the head office of MAST accompanied the mission team. In addition, representatives of the relevant district offices of MAST participated during meetings at the district offices and at the visits to the different farms, laboratories and establishments. Furthermore, representatives of the Icelandic Medicines Agency (IMA) participated in the additional meeting in IMA concerning authorisation of veterinary medicinal products (VMPs) as well as the visit to the wholesaler of VMPs.

A final meeting was held on 14 December at the IMA's 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 96/23/EC") 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 VMPs and feed additives, the use of which may give rise to residues in such 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 aspects of the Authority's mission on control of VMPs carried out in 2008.

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

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

	Number	Comments
Competent Authorities	**5**	An opening meeting at the MAST head office and a closing meeting at the IMA head office, one meeting at the IMA head office concerning authorisation and VMPs and meetings with representatives of two district offices of MAST.
Laboratories	**3**	Two laboratories analysing samples for the National reissue Control Plan (NRCP) and one laboratory in a dairy plant analysing milk for antibiotics (own control)
Slaughterhouse	**1**	A slaughterhouse slaughtering horses, cattle, pigs and sheep/lamb
Wholesaler	**1**	One wholesaler distributing VMPs to pharmacies and veterinarians
Retailer	**1**	One veterinary clinic
Farms	**3**	One pig farm, one turkey farm and one dairy farm (cattle)

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

4.1. Previous missions

In 2005 the Authority carried out one mission to Iceland regarding controls of certain fish diseases and health conditions for placing fishery products on the market. During that mission, the Authority assessed the competent authorities' application of Council Directive 96/23/EEC and Council Directive 91/493/EEC.

In 2008 the Authority carried out a mission to Iceland regarding the distribution and use of VMPs in particular in relation to aquaculture. During that mission the Authority assessed the competent authorities' application of Directive 2001/82/EC, Regulation (EC) No 1831/2003, Commission Regulation (EC) No 1950/2006 and Council Regulation (EEC) No 2377/90.

Council Directive 96/23/EC regarding national residue control programmes (NRCP) entered into force on in the EEA on 1 January 1999, however, the Directive was initially not applicable to Iceland. By Decision No 133/2007 of the EEA Joint Committee of 26 October 2007 it was decided that several acts in the veterinary field which had not previously been applicable to Iceland, or had only applied to aquaculture animals and products, were to apply in full to Iceland. The Decision entered into force on 1 May 2010. Iceland was given a transitional period of 18 months, until 1 November 2011, to comply with the provisions of the relevant acts. Accordingly, from 1 November 2011, Directive 96/23/EC has been fully applicable for all the relevant commodities produced in Iceland.

Prior to 1 November 2011, Iceland has put in place a National Residue Control Plan (NRCP) as a third country for commodities exported to the European Union, which has been approved by the European Commission. Although not enforceable under the EEA

Agreement, references to previous Icelandic NRCPs and control and enforcement results are included in this report where relevant to describe findings.

However, findings related to the situation prior to the full applicability of the relevant EEA legislation will not be subject to any formal follow-up by the Authority. Recommendations made on the basis of such findings are included in the report, but are only intended as guidance for the competent authorities to be used in their preparation, implementation and enforcement of future NRCPs.

From 1 November 2011, Iceland is obliged to forward the NRCPs to the Authority.

4.2. Production information

Information on the quantities of food commodities of animal origin produced in Iceland in 2009 and 2010 was provided by MAST as follows:

Commodity	**Animal population**		**National production (metric tonnes)**	
	2009	**2010**	**2009**	**2010**
Bovine	72,012	73,781	3,761	3,895
Ovine	457,861	479,605	8,841	9,166
Swine	4,265	3,615	6,375	6,158
Equine	77,502	77,196	1,018	799
Poultry	294,886	219,012	7,146	6,905
Goats	563	729	0	0

Commodity	**National production (metric tonnes)**	
	2009	**2010**
Milk collected by dairies	125,569	123,178
Eggs	3,024	2,747
Aquaculture products	5,165	5,050

5 Main findings

5.1. Transposition and application of relevant legislation

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

The Ministry of Welfare is responsible for implementation of legislation on veterinary medicinal products (VMPs). The main Icelandic Act concerning VMPs is the Pharmaceutical Act No 93/1994 and relevant secondary legislation.

The Ministry of Fisheries and Agriculture is responsible for the implementation of legislation on residues, contaminants and certain substances in animals and animal

products. The main Acts relevant for this mission are Act No 97/98 on slaughtering and slaughtering products and Act No 66/1998 on veterinarians and animal health services. These Acts and Regulations provide the legal powers for the competent authorities (MAST and IMA) to carry out controls and to enforce legislation.

Legislation on residues monitoring and sampling

The mission team noted that:

- The legal framework for the National Residue Control Plan (NRCP), i.e. Council Directive 96/23/EC, Commission Decision 97/747/EC and Commission Decision 98/179/EC (all three concerning the NRCP) have not yet been made part of the Icelandic legal order. According to information received from the Ministry of Fisheries and Agriculture a national order implementing the above-mentioned legislation is in the process of being prepared and should enter into force before the end of 2011.
- According to the information received from the Ministry of Fisheries and Agriculture, Commission Decision 2002/657/EC (concerning validation of analytical methods for residues) has not yet been transposed but it is in the process of transposition and a national regulation transposing it is expected in beginning of 2012.

Legislation on MRLs, forbidden substances, pesticides, contaminants etc.

The mission team noted that:

- According to information received from the Ministry of Fisheries and Agriculture Council Directive 96/22/EC has been made part of the Icelandic legal order by national Regulation No 539/2000. However, the two amending Directives from 2003 (Directive 2003/74/EC) and 2008 (Directive 2008/97/EC) have not been transposed yet. The Ministry was aware of this and mentioned that a draft regulation was in the process of transposing the two amending Directives[1].

Legislation on medicated feedingstuffs and additives

The mission team noted that:

- According to the information received from MAST that is responsible for medicated feedingstuffs Council Directive 90/167/EEC (regarding medicated feedingstuffs) has not yet been made part of the national legal order. However, MAST informed that there was a process of drafting a national regulation to transpose Council Directive 90/167/EEC but a timeframe for transposition could not be provided[2].

Legislation on VMPs

The mission team noted that:

- The relevant EEA legislation on VMPs has been made part of the Icelandic legal order. However, it was noted that Commission Regulation (EC) No 1950/2006 (regarding a list of substances essential for the treatment of horses), which entered into force in the EEA in December 2009, was not made part of the legal order until September 2010.

[1] *See Annex 3 for additional comments on transposition of Commission Regulation (EC) No 178/2010 from MAST.*
[2] *See Annex 3 for additional comments on transposition of Commission Regulations No (EC) 386/2009 and No (EC) 767/2009 from MAST.*

Conclusions

The main legal framework for the NRCP, i.e. Council Directive 96/23/EC, and other relevant legislation including Commission Decision 2002/657/EC concerning validation of analytical methods for residues and Council Directive 90/167/EEC on use of medicated feedingstuffs have not yet been made part of the Icelandic legal order. Moreover, updating of national regulations does not take effect in line with the deadlines set in the EEA Agreement.

5.2. Competent authorities

5.2.1. Designation of competent authorities and cooperation and coordination between competent authorities

Legal requirements

Article 4(1) and (2) of Regulation (EC) No 882/2004 require 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 and require that staff carrying out official controls are free from any conflict of interest.

Findings

Controls on the production, distribution and use of VMPs are divided between two competent authorities: IMA under the Ministry of Welfare and MAST under the Ministry of Fisheries and Agriculture.

MAST is responsible for residue monitoring in live animals and animal products. In particular, MAST is responsible for drawing up the NRCP for Iceland according to Directive 96/23/EC and for the implementation and supervision of the plan. According to the information received from both MAST and IMA for several years IMA has not had an input to the NRCP e.g. based on their data of VMP use on substances and amounts used in Iceland. MAST is also responsible for the application of Council Regulation (EEC) No 2377/90 on MRLs.

The IMA is responsible for licensing and official controls on manufacture and distribution of VMPs down to pharmacy level including veterinary practitioners, while MAST is responsible for official controls of VMP usage on farms (see also the Authority's report on VMPs from 2008). In addition, a representative from MAST is participating as an observer in the IMA inspections to veterinary practitioners/pharmacies.

The mission team noted that:

- Since 1 November 2011 the districts of MAST has been reduced from 14 to 6 districts, where each district is led by a District Veterinary Officer that has one to three official veterinarians to perform official controls related to animal health and food safety. The six District Veterinary Officers are not allowed to carry out private practice work. However, it is still allowed for the Veterinary Officers to carry out practice work beside their official duties. In one district visited it was found that an official veterinarian was carrying out both private practice work (prescribing VMPs) and official controls in the same cattle farms (including controls on VMPs and taking samples on the cattle farm according to the NRCP).

- The situation described in the Authority's report on VMPs from 2008 remained the same concerning a centrally employed (in MAST) official veterinarian for fish diseases. The official veterinarian has still numerous responsibilities regarding aquaculture: he runs a private practice including prescribing use of VMPs in all the aquaculture farms and at the same time he is responsible for official controls on the aquaculture farms (concerning animal health and use of VMPs). The sampling for residues according to the NRCP in the aquaculture farms has been delegated to one private veterinarian.

Conclusions

Iceland has designated competent authorities responsible for the official controls of residues and contaminants in live animals and animal products including controls on VMPs in line with the requirements laid down in Article 4 of Regulation (EC) No 882/2004. However, the cooperation and coordination between the two involved competent authorities, as required by Article 4(3) of that Regulation, in the area of drawing up the NRCP and planning of official controls of VMPs in order to use all relevant knowledge were limited.

Moreover, a possible conflict of interest was identified by the mission team for staff at central as well as on district level which is not in line with Article 4(2)(b) of Regulation (EC) No 882/2004.

5.2.2. Adequacy of personnel involved in the control system

Legal requirements

Article 4(2)(c) of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff. 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.

Findings

According to the information received from MAST three staff at central level and 16 staff at district level have responsibilities in relation to official controls and sampling of residues and contaminants in live animals and animal products including controls on VMPs. However, these have other duties as well and only part of their working time is specifically used for the NRCP and VMPs.

The mission team noted that:

- According to information received from MAST at both central and district level the number of planned inspections on farms in relation to controls of VMPs had not been carried out due to lack of resources. All farms with cattle (both dairy and beef cattle), pigs, poultry (both for eggs and broilers) and aquaculture farms are planned to be inspected on a yearly basis to check the use of VMPs. However, for cattle farms less than 50 % of the planned inspections had been carried out in 2010. Nevertheless, in spite of the planned high frequency for control visits to the above mentioned farms no inspections had been planned or carried out on horse farms and sheep farms regarding official controls of the use of VMPs in spite of high numbers of these farms (see also section 5.5. on VMPs) according to MAST due to lack of staff.

- Concerning IMA and their planned controls of wholesalers of VMPs the frequency of inspections was set to once every three years to wholesalers (that has been carried out as planned) and there is no set frequency for the veterinary pharmacies However all new premises or if there is a new owner of a veterinary pharmacy will be inspected. According to the information received from IMA, due to budget restraints and lack of competent staff only 15 veterinary pharmacies out of 60 had been inspected since 2009 (in 2011 no inspections were carried out in the first ten months of the year).
- Official veterinarians responsible for official controls and sampling of residues and contaminants in live animals and animal products including controls on VMPs had not received any training on sampling procedures, targeting of sampling or other issues related to implementation of the NRCP of VMP controls. The knowledge of the responsible official veterinarians concerning e.g. targeting of samples for residues (see also section 5.3. on NRCP) was in some cases seen not sufficient. Nevertheless, MAST informed that meetings had been organised with participation of official veterinarians responsible where procedures for sampling had been discussed.

Conclusions

The MAST staff had not received training and were not kept up-to-date in their competencies concerning official controls and sampling of residues and contaminants in live animals and animal products including controls on veterinary medicinal products in line with the requirements laid down in Article 6 of Regulation (EC) No 882/2004.

As regards official controls carried out by IMA for veterinary pharmacies, inspections had not been carried out with the planned frequency in recent due to lack of competent staff, which is not in line with Article 4(2)(c) of Regulation (EC) No 882/2004.

5.2.3. Procedures, corrective action and enforcement

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.

Findings

According to the information received from MAST checklists have been issued from central level to cover the planned inspections from the districts to farms with production animals on controls on the use of VMPs. In addition, a new database (BUSTOFN) introduced in 2010 requires that all livestock in Iceland is registered. The district official veterinarians are obliged to enter their reports from official controls into this database. At the time of the mission 90 % of the official reports were in the database according to information received from MAST.

The mission team noted that:

- In one district visited it was confirmed that checklists were available (also on the homepage of MAST) for the following species: cattle (including checks on VMP storage, labelling of VMPs, marking of treated animals, registers for treatment) and pigs (including checks on VMPs).

- As regards sampling for residues including targeting of samples and follow-up procedures in case of non-compliances there have not been issued detailed instructions on how to sample and target the sampling from the central level to the districts of MAST.
- In one district visited, the competent authorities expressed uncertainty of the legal powers for the enforcement of legislation on VMPs (see also section 5.5) and limited evidence could be provided of enforcing the legislation.

Conclusions

Instructions had been issued by MAST concerning controls on VMPs for the planned inspections in bovine and pig farms and reports were written by official veterinarians after performed inspections that covered controls on VMPs in line with Articles 8 and 9 of Regulation (EC) No 882/2004. However, as regards official controls and sampling of residues and contaminants in live animals and animal products there are no detailed guidelines on how to sample and target the sampling in line with Directive 96/23/EC as required by Article 8 of Regulation (EC) No 882/2004.

5.3. National Residue Control Plan (NRCP)

5.3.1. Planning of the residue monitoring plan

Legal requirements

Article 5 of Directive 96/23/EC provides that the EEA EFTA 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. The following EEA legislation has a direct bearing on the elaboration/updating of the residue monitoring plan:

- Article 3 of Regulation (EC) No 882/2004 deals with the general obligations with regard to the organisation of official controls;
- Articles 3 to 7 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans;
- Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues;

Findings

For the NRCP drawn up by MAST for 2011, the mission team noted that:

- There was no involvement of relevant stakeholders, for example laboratories and the IMA, in the planning process.
- According to MAST expert knowledge of usage patterns of VMPs was taken into account when drawing up the plan. However, it could not be demonstrated what information was taken into consideration in the planning process for the 2011 or 2010 plan. Data on sales volumes (IMA) or treatments (HEILSA, see also section 5.5) respectively, have not been used.
- Eggs, wild game (reindeer, puffins) and honey have not been included in the 2011 residue monitoring plan although these commodities are produced in Iceland.

- The sample numbers scheduled in the 2011 plan met the minimum numbers required under Annex IV to Directive 96/23/EC and Decision 97/747/EC, except for sheep (267 versus 278) and poultry (9 versus 800).
- The relevant substance groups as specified in Annex II to Directive 96/23/EC were covered for all commodities, except for poultry which was only tested for *anticoccidials* (B2b).
- Of the steroids with androgenic, estragenic or progestagenic activity (group A3) only *oestradiol* was tested for in cattle, horses, sheep and pigs. No samples from pigs tested for group A substances were scheduled to be taken on farm. *Nitrofurans* and *nitroimidazoles* (group A6), which are considered essential for residues monitoring in swine, were not included in the plan, nor were *nitroimidazoles* for horses.
- Corticosteroids (group B2f) were not covered, although *dexamethason* and *prednisolon im*ported under special license is used in cattle and horses.
- *Flunixin* was the only non-steroidal anti-inflammatory drug (NSAID, group B2e) tested for in cattle, horses, sheep and pigs. However, other NSAIDs are also used in Iceland, including *meloxicam* and *metamizole* in cattle, horses and pigs.
- The scope of antibiotic testing (group B1) did not include some of the antibiotics used in Iceland, for example: *neomycin* and *trimethoprim* in calves and pigs, *streptomycin*, *oxacillin* and *cloxacillin* for cattle.
- The antibiotic screening test for milk was not capable of detecting residues at or below the maximum residue limit (MRL) for *erythromycin*, *spiramycin* and *trimethoprim*.

Conclusions

The mission team found that the National Residue Control Plan for cattle, sheep, pigs horses and aquaculture 2011 was generally in line with the minimum requirements of Directive 96/23/EC. However, the narrow scope of testing, in particular for steroids in cattle, sheep, pigs and horses, weakened the effectiveness of the plan. The residues status of eggs, poultry, wild game and honey is unknown in the absence of monitoring in these commodities.

Please see section 4 for background information on Iceland's status regarding the NRCP prior to 1 November 2011. From 1 November 2011, Iceland is obliged to fulfil all requirements of Directive 96/23/EC and forward the NRCPs to the Authority.

5.3.2. Implementation of the residue monitoring plan

Legal requirements

Articles 3, 4 and 12 of Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. 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. Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues and Commission Decision 98/179/EC lays down the rules for official sampling under the residue monitoring plan.

Findings

For the NRCPs drawn up by MAST prior to 1 November 2011, the mission team noted that:

- The central office of MAST distributes the samples to be taken in the districts according to production volume and sends sampling orders to district offices. Sampling is carried out by official veterinarians in the districts. All samples are sent to a laboratory, which in this regard only functions as a physical storage facility for MAST, with the exception of milk samples which are analysed at the laboratory. Received samples are recorded by MAST central office and are sent for analysis to foreign laboratories. MAST central office is responsible for supervision of the implementation.
- MAST central office sent the first sample orders to the districts for the 2011 plan in November 2011. The mission team also noted that the sample orders for the 2010 plan had been sent in September 2010. Districts were requested to take samples within a two week period. Sampling orders for live animals had not been sent out yet.
- In 2011 the samples to be taken from live cattle were scheduled in one region only. The mission team noted that the 2010 samples from live animals were also taken in only one region.
- In one district visited samples were taken from emergency slaughtered animals throughout the year, and kept in the freezer in order to be sent upon arrival the residue monitoring plan sampling requests. Certain analytes may, however, deplete when the sample is stored for an extended time period.
- Not all samples had been taken yet in 2011, despite the two week sampling period having elapsed. Sampling orders for on-farm sampling of cattle for steroids had not been sent out.
- In one district visited aquaculture sampling was contracted to a private veterinarian.
- Sampling is unannounced and samples were traceable from the farm or animal of origin. Appropriate sampling material was used and samples were adequately sealed.
- Sampling staff interviewed had limited knowledge of targeting criteria. Nevertheless, the sample order forms contained limited sampling instructions.

Conclusions

Undersampling and severe clustering of samples in time undermine the effectiveness of the residues monitoring and is not in line with point 2.1 of the Annex to Commission Decision 98/179/EC requiring that sampling shall be carried out in variable intervals spread over the year. Private veterinarians taking official samples in the framework of the NRCP is not in line with point 1.1 of the Annex to Decision 98/179/EC.

5.3.3. Other residue control programmes

Legal requirements

In addition to the residue monitoring plan required by Article 5 of Council Directive 96/23/EC, Article 11 of the said Directive gives Member States the option of conducting other residues testing, particularly in relation to the detection of illegal treatment of food

producing animals. Article 9 of the Directive foresees the application of own-checks by food business operators.

Findings

The dairy plant visited carried out tests for antimicrobials on each truck delivery of milk, as well as on a milk sample from a single farm's milk tank once a month.

The mission team noted that:

- The truck delivering the milk to the dairy had three compartments, containing milk from multiple farms. A mixed sample of the three compartments was tested. Testing on mixed milk reduces the likelihood of finding residue violations by individual farms. Nevertheless, a sample taken from the tank from each farm is kept by the diary plant, so that the farm of origin can be traced in case the test on the mixed milk is non-compliant.
- Milk samples from individual farms are tested every month by the dairy plant.
- The tests used are not sensitive enough to detect maximum residue limits (MRL) violations for all antibiotics which may be used in Iceland.

Conclusions

The visited dairy plant's testing program provided additional information and guarantees in relation to the presence of antibiotics in milk.

5.3.4. 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 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Council Directive 96/23/EC. In addition Article 54 of Regulation (EC) No 882/2004 lays down the principles to be followed in the application of national enforcement measures and actions to be taken in cases of non-compliances.

Findings

The mission team noted that:

- MAST is responsible for follow-up on non-compliant test results in the residue monitoring plan. The industry is primarily responsible for following up on non-compliant test results in own controls, but are obliged to inform MAST which can carry out its own follow-up investigation. There are no written procedures or checklists for follow-up actions in case on non-compliances.

5.3.5. Non-compliant results

5.3.5.1. Non-compliant results in the NRCPs for 2010 and 2011

At the time of the mission, the results of the residue monitoring for 2011 were not yet available.

However, the mission team noted that the results of the 2010 residue monitoring, as reported to the European Commission in March 2011, indicated one non-compliant test result, a finding of *oestradiol* in a horse.

In this regard, the mission team noted that:

- In relation to the finding of *oestradiol* follow-up actions were not documented. The case was closed by MAST on the assumption that the finding was caused by an ovarian cyst.
- There was a screening test positive of antibiotics in milk in the 2010 residue monitoring plan. No confirmatory test was performed on the sample and there was no documented evidence of follow-up. MAST informed the mission team that the finding was found compliant based on the fact that the dairy plant's own test (on the mixed sample of truck milk) had been compliant on that day, and on the assumption that remains of disinfectants in the milk tank could have interfered in the official test.

5.3.5.2. Non-compliant results in other residue control programmes

The mission team noted that:

- The contract between the plant and farmers indicated financial penalties for delivery of milk contaminated with antibiotics.
- There had been several non-compliant findings in 2010 and 2011. The dairy plant carried out investigations, and it was observed that in some cases the origin of the cause of the non-compliance could be established. Findings had been communicated with the district office of MAST. Evidence was seen that MAST had sent a warning letter to a farm where a residue violation was detected.

Conclusions

In relation to previous years' residues monitoring, and to the provisions of Directive 96/23/EC, the combination of not sending official screening tests, non-compliant test results for confirmation, relying on industry's own tests, the absence of written procedures for follow-up and not documenting actions and decisions taken undermined the effectiveness of the residues controls.

5.4. 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 and capability of 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 1883/2006 (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).

5.4.1. General description

Findings

Within the framework of the NRCP only two laboratories in Iceland perform the analysis

of samples. One of the laboratories analyses milk samples for antibiotic residues (group B1) and for *chloramphenicol* (A6) with screening test kits, the other laboratory performs the analysis of heavy metals (group B3c) in swine, ovine and bovine liver, in aquaculture products and in milk samples with inductively couples plasma (ICP)/mass spectrometry (MS).

The mission team noted that:

- A National Reference Laboratory (NRL) for residues had not been designated by the Icelandic competent authorities.
- There was a written agreement on the analysis of samples with one of the laboratories e.g. the analysis of 160 heavy metal determination in 40 samples using the ICP/MS technique was agreed upon for 2011.
- MAST has outsourced all other testing to external laboratories outside of Iceland (in Sweden, Denmark and Norway).
- There is no common contract template for the analysis of the Icelandic NRCP samples. Written contracts were not present for all laboratories (and consequently no official designation as an official laboratory) which were selected to do the analysis of Icelandic NRCP samples. The contracts did not all include requirements for the compulsory laboratory accreditation, the use of validated methods according to Commission Decision 2002/657/EC and the fixed turnaround times of results.
- All incoming samples were checked one of the two laboratories (see also section 5.3.2) for proper conditions and complete accompanying documents. In case of samples in inappropriate conditions for analysis (e.g. frozen blood samples targeted for the preparation of serum) the official veterinarians are informed orally and asked for additional sampling. Written instructions to rectify encountered sampling problems are not in place.
- All samples were stored in suitable devices (refrigerator rooms, freezer rooms). The rooms are controlled for adequate temperatures within the framework of the Quality Assurance system of the laboratory.

Conclusions

There is no designation of a NRL for residues as it is required by Article 33(1) of Regulation (EC) 882/2004 in Iceland. In addition, not all of the laboratories operating in the area of the NRCP were officially designated by the competent authorities as required by Article 12(1) of Regulation (EC) No 882/2004.

5.4.2. On-the-spot visits in the laboratories

The mission team visited both laboratories in Iceland dealing with testing of samples taken in the framework of the NRCP.

5.4.2.1. Laboratory A

Findings

Laboratory A is responsible for the analysis of milk samples for B1 compounds and for *chloramphenicol*. In addition, the laboratory functions as a storage facility for samples taken in the framework of the NRCP to be sent for testing abroad (see also section 5.4.1).

The mission team noted that:

- The laboratory is accredited by Swedish accreditation body for microbiological analysis. The method “Delvo test” was included in the accreditation after a recent surveillance visit of the accreditation body in February 2011. The ELISA test for *chloramphenicol* as well as the “Tetra Sensor” for *tetracyclines* were not accredited. The laboratory informed that these NRCP samples are the only samples that are analysed in this laboratory in the framework of residues. The laboratory considered it difficult to maintain competence when so few sample analyses were carried out.
- The laboratory had a Quality Management System in line with ISO 17025 standards. A quality manual and written instructions are available via an intranet based information system. Examples of Standard Operating Procedures (SOPs) (for Delvo test, validation) and records of training of staff were provided.
- None of the methods applied for NRCP samples were validated or verified in-house. The laboratory used validation data of the producers without own internal verification of the "fitness for purpose" as it is required by ISO 17025.
- For internal quality control negative and positive control samples were included only for the Delvo Test in each batch. Even though two incurred samples were used as positive control samples these samples are due to their high analyte content (*benzylpenicillin* 10 and 34 ng/g respectively) only partly suitable to prove the proper functioning of the test (i.e. the ability to control for different antibiotics at and above the MRL). For the Tetra Sensor and the ELISA-screening for *chloramphenicol* no positive control samples were included at all.
- For external quality control the laboratory participated successfully in the last two years in two proficiency tests organised by a private laboratory in Finland. In the test from 2011 the Delvo Test as well as the Tetra Sensor were applied for the samples. Even though the participation was successful, the number of analytes (only *oxytetracyklin* and *benzylpenicillin*) and the analyte content in the tests (*oxytetracyklin* at levels 3 to 5 times as high as the MRL) is only partly suitable to verify the ability of the laboratory to control samples with levels of analytes around the set MRL value.
- Incoming milk samples were separated from the other samples of the NRCP, transferred in the laboratory section and registered in a Laboratory Information Management System (LIMS) system. The samples are stored frozen in the laboratory after registration. Even though the samples were not labelled with the internal number of the laboratory directly after registration, the sample identification was guaranteed, since the sample number provided by MAST was unique. The samples arrived at the laboratory in sealed bags, each bag containing samples and counter-samples. Procedures on storage of counter-samples were not given and they were discarded after the analysis of the samples. The mission team was informed that there were no non-compliant test results in the last two years with the exception of one positive milk sample for antibiotics (see also section 5.3.5.1).
- The necessary test kits for the analysis were available in the laboratory and stored under suitable conditions. No standard substances except those supplied with the test kits were available in the laboratory. The test kits were out of date, however, the laboratory was well aware of this problem. The mission team was informed that the laboratory is going to purchase new test kits after the arrival of all samples for 2011 in the laboratory and after the number of required test kits is clear.

- All samples of the NRCP for the whole year were collected before the analysis was started. The laboratory informed that this practice is applied in order to do the analysis economically efficient, since these tests are used only once per year in the laboratory for the NRCP samples. Consequently samples from 2011 had not been analysed yet. Samples of the NRCP 2010 arrived e.g. on 19 January 2011 in the laboratory and were only analysed on 14 March 2011, i.e. the turn-around time being two months. Some samples of the NRCP 2011 arrived e.g. on 16 November 2011 (sample taken on 9 November 2011) and were not yet analysed at the time of the mission.

Conclusions

There is no clear evidence that the screening methods used in this laboratory for the analysis of antibiotic residues in milk are effective in order to control the compliance with MRL values or to detect the presence of a banned substance (*chloramphenicol*) since the methods used were not validated as required by Commission Decision 2002/657/EC.

In addition, the methods used for samples tested in the framework of the NRCP were not part of the accreditation of the laboratory as required by 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.

5.4.2.2. Laboratory B

Findings

Laboratory B is responsible for the analysis of liver samples from different animals and of milk samples for group B3c compounds (lead, cadmium and mercury).

The mission team noted that:

- The laboratory is accredited by a Swedish accreditation body for chemical and microbiological analysis in food. A method for the determination of trace elements (based on the Nordic Committee on Food Analysis (NMKL) method 186/2007) was included in the accreditation scope after a recent visit of the accreditation body in March 2011. The method was finally approved in July 2011.
- Since 2007 the laboratory had a QMS in line with ISO 17025 standards in place. 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. In October 2011 a comprehensive re-evaluation of the QMS was done by Swedish accreditation in order to prolong the accreditation for another four years. A report of this visit and the findings was available in the laboratory.
- 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 from fish and proved the fitness of purpose of the method. An additional verification for the matrix milk was planned.
- In 2010 and in 2011 tests on heavy metals in 40 samples each were ordered by MAST, 44 samples had arrived in the laboratory to date. The analysis of samples from 2011 had recently started. The tests are performed using the accredited

method, i.e. 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 is 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, except for one case where a follow-up could not be documented.
- Incoming samples are registered in a Laboratory Information Management System (LIMS) system, labelled with internal laboratory identification numbers and are stored frozen in the laboratory after registration. The samples arrive 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) are stored properly and are labelled with expiry dates. Some of the standard solutions had expired and the laboratory explained that expired solutions are used to do counterchecks against new purchased standards. Standard solutions are prepared gravimetrically. Balances are calibrated once a year.

Conclusions

The laboratory visited used validated methods in line with Commission Decision 2002/657/EC and was able to provide satisfactory evidence that the screening methods used for the analysis of heavy metals in milk and liver are effective. The methods used for samples tested in the framework of the NRCP were accredited as required by 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.

5.5. Veterinary medicinal products (VMPs) and medicated feeding stuffs

5.5.1. Authorisation, distribution and use of VMPs

Legal requirements

Conditions governing the marketing authorisation of VMPs are laid down in Articles 5 to 15, 21 to 30, 58 to 62 and 83 of Directive 2001/82/EC. VMPs which are authorised for use in food producing animals may only contain pharmacologically active substances which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Council Directive 96/22/EC prohibits the authorisation of hormones and beta-agonists for use as growth promoters in food producing animals. Conditions governing the distribution and use of VMPs are laid down in Articles 65 to 71 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.

Findings

The mission team noted that:

- There are no major changes in the system since the mission was carried out by the Authority in 2008 on VMPs: Two licensed (by IMA) wholesalers of VMP supply pharmacies (60 licensed by IMA) and veterinary practices that at the same time run a veterinary pharmacy (50 veterinary practices where a license from IMA is not required).
- Only veterinarians are authorised to prescribe VMPs for animals. However, according to IMA a common finding on their inspections to veterinary pharmacies/practices was that the veterinarians in Iceland rarely write a prescription including information on withdrawal times (the same finding was made by the mission team in two farms visited, see section 5.5.2.) even though there has been a clear legal national basis for a prescription in national Regulation 289/2005. This national regulation requires that when a veterinarian provides VMPs to a farmer a prescription must be made including written withdrawal times and in addition, that the farmer is obliged to register their use of VMPs e.g. in herd books. According to IMA the reason for the lack of prescriptions from veterinarians in Iceland is due to lack of a clear legal basis in the existing national legislation to enforce the legislation. According to IMA one solution could be to require veterinary pharmacies/practices to have a license from IMA to operate, then if there were irregularities from the veterinarian the license to prescribe VMPs could be withdrawn by IMA.
- One pig farm and one dairy farm were visited where treatment records were available and the treatments, VMPs used and withdrawal times were appropriately recorded.

Conclusions

Compliance with Article 67(aa) of Directive 2001/82/EC could not be ensured since veterinarians distribute VMPs to farmers without prescription including written instructions on withdrawal times.

5.5.2. Official Controls on the distribution and use of VMPs

Legal requirements

Competent authorities have a general obligation under Article 80(1) of the Community code relating to VMPs (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. Specific obligations for competent authorities are laid down in Articles 65, 66, 68, 69 of this Directive. With regard to ensuring that the production of medicated feeding stuffs is in accordance with Council Directive 90/167/EEC, the rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive. 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 requirement 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.

Findings

Different databases for veterinarians, official veterinarians and farmers that could be used for the official controls on use of VMPs were presented to the mission team. The database (HEILSA) is a new instrument (launched in the summer 2011) for veterinarians only, where all farms with production animals must be registered including register of animals, health records and prescriptions for VMPs used including withdrawal times. However, according to the information received there is not yet access for official veterinarians at slaughterhouses. In addition, there are a number of databases including herd information for different species: HUPPA (cattle), FJARVIS (sheep) and FENGUR (horses). Today there is no link between the different databases, however, according to the information received from the competent authorities the intention is to link all these in a central database in the future.

The mission team noted that:

- In one veterinary clinic visited it was confirmed that information on animals treated with VMPs was entered into HEILSA in most cases (only one case found of a cow treated with VMPs that was not entered).
- According to MAST there has been a system in place for many years for food chain information in Iceland covering all species of production animals. However, in one turkey farm and one pig farm visited the farmers had never sent the required documents with the animals to the slaughterhouse and there had been no reaction from the slaughterhouses in this regard.
- In one dairy farm visited the farmer had declared that a cow had not been treated 60 days before being sent to slaughter, nevertheless he had noted in the herd register that the cow had been treated 15 days before slaughter and later it was confirmed that the treatment was with an antibiotic that has a withdrawal period of 30 days, i.e. the cow was sent to slaughter within the withdrawal period. Later the mission team received a declaration from the veterinarian responsible that the VMP had been administered intravenously and therefore the withdrawal time was shorter (in spite of different information to the farmer and noted in his herd book that the VMP had been administered intramuscularly with a set withdrawal time of 30 days).
- The district offices of MAST carry out controls on the use of VMPs to farms with pigs and cattle on storage and labelling of VMPs and to check the farmers registration of treatment in herd registers to ensure that withdrawal periods are kept. In the three farms visited reports were seen for these controls, however, the shortcomings noticed by the mission team were not mentioned regarding the lack of food chain information and/or lack of prescriptions from veterinarians.
- So far no inspections have been carried out by MAST to sheep farms or horse farms on the distribution and use of VMPs.
- The IMA carries out controls on the use of VMPs to wholesalers of VMPs (two licensed), pharmacies selling VMPs and veterinary pharmacies/veterinarians. However, according to the information received from IMA due to budget restraints and lack of competent staff only 15 veterinary pharmacies out of the 60 had been inspected since 2009 (see also section 5.2.2).

Conclusions

There is a system in place for food chain information in Iceland, however, it is not in all cases implemented by the farmers and slaughterhouses which is not in line with Section III of Annex II to Regulation (EC) No 853/2004.

The official controls on the distribution and use of VMPs in farms are not in all cases efficient since deficiencies detected by the mission team were not detected in MAST controls. Regarding official controls in veterinary clinics and pharmacies inspections carried out had been very limited and no controls regarding VMPs on horse and sheep farms have been carried out so the provisions of Directive 2001/82/EC are not complied with.

6 Final meeting

A final meeting was held on 14 December 2011 at the head office of the IMA in Reykjavik with representatives from the MAST, IMA, etc. 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 Icelandic representatives were given the opportunity to comment or ask for clarification during the meeting. The Icelandic representatives did not indicate any disagreement with the main findings and the preliminary conclusions presented. Nevertheless, there was some discussion on the issue of possible conflict of interest for competent authorities and how to avoid it.

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

7 Recommendations

No	Recommendation
1	Iceland should ensure that all the relevant legislation concerning residues and veterinary medicinal products is made part of its legal order.
2	Iceland should improve coordination and cooperation between MAST and IMA when drawing up the National Residue Control Plan and when planning official controls on veterinary medicinal products in order to ensure that all relevant information is included in the planning in line with Article 4(3) of Regulation (EC) No 882/2004.
3	Iceland should ensure that official veterinarians who carry out official sampling for the National Residue Control Plan or perform official controls on use of veterinary medicinal products are free from any conflict of interest when simultaneously carrying out private practice work as required by Article 4 (2.b) of Regulation (EC) No 882/2004.
4	Iceland should ensure that there is a sufficient number of suitably experienced and qualified staff to carry out official controls on the National Residue Control Plan and on the use of veterinary medicinal products efficiently and effectively in line with Article 4 (2.c) of Regulation (EC) No 882/2004.
6	Iceland should ensure that necessary training is provided to responsible staff for official controls and sampling of residues and contaminants in live animals and animal products including controls on veterinary medicinal products in line with the requirements of Article 6 of Regulation (EC) No 882/2004.
7	Iceland should ensure that legislation concerning the use of veterinary medicinal

	products is appropriately enforced in line with Article 54 to Regulation (EC) No 882/2004.
8	Iceland should ensure that when planning the National Residue Control Plan all relevant substances, including steroids, should be included in the scope of testing and that relevant commodities, including eggs, poultry, wild game and honey, should be included in the monitoring as set out in Directive 96/23/EC.
9	Iceland should ensure that the correct measures are applied when finding non-compliant residues results in the implementation of the National Residue Control Plan in line with Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Council Directive 96/23/EC, and that when non-compliances are detected including on the use and distribution of VMPs, proper action must be taken to ensure that the operator remedies the situation in line with Article 54 to Regulation (EC) No 882/2004.
10	Iceland should designate a National Reference Laboratory for residues as required by Article 33(1) of Regulation (EC) No 882/2004.
11	Iceland should ensure that all laboratories performing residue testing also in other countries are officially designated by the competent authorities as required by Article 12(1) of Regulation (EC) No 882/2004.
12	Iceland should ensure that all decisions regarding compliance/non-compliance of samples are based on confirmatory analysis using an analytical method validated to the requirements of Commission Decision 2002/657/EC and that methods used for samples tested in the framework of the NRCP are accredited as required by 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.
13	Iceland should ensure that veterinary medicinal products for food producing animals are only dispensed to the public under a veterinary prescription as required by Article 67(aa) of Directive 2001/82/EC.
14	Iceland should ensure that food business operators operating slaughterhouses do not accept animals (other than wild game) for slaughter unless they have been provided with the relevant food chain information as set out in Section III of Annex II to Regulation (EC) No 853/2004.
15	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.

The following recommendations are intended as guidance to the competent authorities only:

No	**Recommendation**
1	Iceland should ensure that procedures are in place when non-compliances are detected during official controls that documented corrective actions are taken in line with Article 8 (3.b) of Regulation (EC) No 882/2004.
2	Iceland should ensure that sampling for the National Residue Control Plan is carried out in variable intervals spread over the whole year and that a sufficient number of samples are taken as required by Commission Decision 98/179/EC.

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

The Authority	EFTA Surveillance Authority
CRL	Community Reference Laboratory
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
NRCP	National Residue Control Plan
NRL	National Reference Laboratory
QMS	Quality Management System
SOP	Standard Operating Procedures
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 6.2.15 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 93/257/EEC of 15 April 1993 laying down the reference methods and the list of national reference laboratories for detecting residues,* 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 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;

h. 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;

i. The Act referred to at Point 7,.1.2, *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;

j. 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*;

k. 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*;

l. 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;

m. 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;

n. 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;

o. 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*;

p. 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;

q. 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;

r. The Act referred to at Point 54zzzn of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs*;

s. 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;*

t. 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;

u. The Act referred to at Point 14 of Chapter XIII of Annex II to the EEA Agreement, *Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin,* as amended*;*

v. 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;.

w. 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;*

x. 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 the MAST and IMA to the draft report

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

December 6 to 14 2011

Subject: Control of residues and contaminants in live animals and animal products including control on VMPs.

General remarks

The competent authority, MAST does not make any additional remarks to the report of the abovementioned mission, other than already stated in a letter to the Authority dated 13 February 2012. Due to the fact that only minor amendments were made to the initial draft report from the Authority, MAST would like to reiterate the following:

In the draft report there are several observations, conclusions and recommendations that are based on the legislation in force, official controls and national residue control plans (NRCP) in Iceland prior to November 2011. The Icelandic Food and Veterinary Authority (MAST) considers these findings, conclusions and recommendations unacceptable as they are based on observations relevant to the legalisation and practices that were in force prior to the EEA obligations on implementing and enforcing the legislation that forms the basis for the ESA mission. Even though this is commented in the draft report, the mission team can not conclude and make recommendations on corrective actions based on prior obligations and practices.

For further clarification and as an example, the Icelandic NRCP was issued and sent annually to the EC Food and Veterinary Authority (FVO) only, not to ESA, since Iceland was a third country with respect to export of animal products to the EC (other than fish and fish products). Consequently, the NRCP covered products that were being exported and was not relevant for other products like eggs, wild game and honey. In addition, Iceland has not been exporting pork meat or poultry. The obligation for Iceland to send a NRCP to ESA according to the EEA-legislation is first valid now and with a time limit of 31 March 2012. Therefore all observations, conclusions and recommendations in this respect in the draft report are not relevant or EEA enforceable, except as a part of a learning process.

The following statements regarding implementation of legislation need to be corrected:

- In the report it is noted that Regulation No 178/2010 has not been implemented into Icelandic legislation. This is not the case as the regulation was implemented with Regulation No 112/2011 which entered into force January 31, 2011.

- In the report it is noted that Regulations 386/2009 and 767/2009 have not been implemented into Icelandic legislation. This is not the case as the regulations were implemented with Regulation No 312/2010 (386/2009) and Regulation No 744/2010 (767/2009).

The proposed actions of IMA and MAST to the Recommendations of the Authority are set foward in Annex 2. The general remarks made by the Icelandic Medicine Agency to the draft report are attached as Annex 3.

Response of the Competent Authorities of Iceland to the recommendations of report of an ESA mission carried out in Iceland December 6 to 14 2011 related to control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products.

Recommendations

No	Recommendation	Reaction of the Competent Authority	Date of compliance	Comment/ attachment
1	Iceland should ensure that all the relevant legislation concerning residues and veterinary medicinal products is made part of its legal order.	Several relevant EU-acts have been implemented since the mission took place. Council Directive 92/23, commission Decisions 97/747 and 98/179 have been made part of the Icelandic legal order, with Regulation No 30/2012 which entered into force January 3, 2012. Commission Decision 2002/657 is being translated at the Translations centre with the Ministry of FA. The Ministry of Fishery and Agriculture has already insisted for the translation to be prioritized. Work is ongoing within the Ministry of Welfare and the Icelandic Medicinal Agency to fully implement Regulation 92/22 with amending Directives 2003/74 and 2003/97 and Council Directive 90/167.	Ongoing.	

No	Recommendation	Reaction of the Competent Authority	Date of compliance	Comment/ attachment
2	Iceland should improve coordination and cooperation between MAST and IMA when drawing up the National Residue Control Plan and when planning official controls on veterinary medicinal products in order to ensure that all relevant information is included in the planning in line with Article 4(3) of Regulation (EC) No 882/2004.	MAST will make an agreement with IMA regarding cooperation on providing information on the use patterns of veterinary medicines. A written procedure on the drawing up of the NRCP will be prepared.	01.03.2012 01.04.2012	
3	Iceland should ensure that official veterinarians who carry out official sampling for the National Residue Control Plan or perform official controls on use of veterinary medicinal products are free from any conflict of interest when simultaneously carrying out private practice work as required by Article 4 (2.b) of Regulation (EC) No 882/2004.	A letter has been sent to all District Veterinary Officers, with instructions to ensure that official veterinarians are free from any conflict of interests. Further actions will be taken in order to hinder any conflict of interest in the work of all Official Veterinarians.	01.05.2012	 Letter to DVOs.pdf

No	Recommendation	Reaction of the Competent Authority	Date of compliance	Comment/ attachment
4	Iceland should ensure that there is a sufficient number of suitably experienced and qualified staff to carry out official controls on the National Residue Control Plan and on the use of veterinary medicinal products efficiently and effectively in line with Article 4 (2.c) of Regulation (EC) No 882/2004.	Actions have already been taken in order to improve the matter. An expert within MAST has taken up increased responsibility in designing the NRCP and preparing the sampling process. It is being considered for 2013 to outsource the preparation and sending of sampling equipment to a laboratory to further decrease the work load at MAST. The evaluation of results and follow-up procedure would however be carried out by experts at MAST.		
6	Iceland should ensure that necessary training is provided to responsible staff for official controls and sampling of residues and contaminants in live animals and animal products including controls on veterinary medicinal products in line with the requirements of Article 6 of Regulation (EC) No 882/2004.	MAST has for many years organized annual one or two day seminars for DVOs and OVs where training on official sampling has been part of the agenda. A seminar was held in the middle of November 2011 (DVOs) and another in middle of February 2012 (DVOs & OVs).		DVOs seminar 2012_agenda.doc OVs Seminar material.ppt DVOs seminar 2011_agenda.pdf

No	Recommendation	Reaction of the Competent Authority	Date of compliance	Comment/ attachment
7	Iceland should ensure that legislation concerning the use of veterinary medicinal products is appropriately enforced in line with Article 54 to Regulation (EC) No 882/2004.	A new regulation on the electronic recording of the prescription and use of VMPs by all veterinarians has been published. It enters into force 1 November 2012.		Regulation_Registration VMPs.pdf
8	Iceland should ensure that when planning the National Residue Control Plan all relevant substances, including steroids, should be included in the scope of testing and that relevant commodities, including eggs, poultry, wild game and honey, should be included in the monitoring as set out in Directive 96/23/EC.	Substances in the NRCP will be reviewed in a meeting with the IMA. Eggs, poultry and reindeer will be added to the monitoring in 2012. An updated plan will be sent before March 31. Honey is not produced for marketing in Iceland.	31.03.2012	
9	Iceland should ensure that the correct measures are applied when finding non-compliant residues results in the implementation of the National Residue Control Plan in line with Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Council Directive 96/23/EC, and that when non-compliances are detected including on the use and distribution of VMPs, proper action must be taken to ensure that the operator remedies the situation in line with Article 54 to Regulation (EC) No 882/2004.	Written procedures will be prepared	01.04.2012	
10	Iceland should designate a National Reference Laboratory for residues as required by Article 33(1) of Regulation (EC) No 882/2004.	Nominations for a NRL will be sent from MAST to the Ministry.	01.06.2012	

No	Recommendation	Reaction of the Competent Authority	Date of compliance	Comment/ attachment
11	Iceland should ensure that all laboratories performing residue testing also in other countries are officially designated by the competent authorities as required by Article 12(1) of Regulation (EC) No 882/2004.	Laboratory contracts are to be renewed for 2012. Designations will be documented accordingly and presented on the internet.	01.06.2012	
12	Iceland should ensure that all decisions regarding compliance/non-compliance of samples are based on confirmatory analysis using an analytical method validated to the requirements of Commission Decision 2002/657/EC and that methods used for samples tested in the framework of the NRCP are accredited as required by 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.	MAST will take notice of this when contracting laboratories. A work procedure will be designed in cooperation with Inspectors who are responsible for official control and follow-up. The work procedure will be a part of MAST´s quality manual which will be issues later this year.	01.12.2012	
13	Iceland should ensure that veterinary medicinal products for food producing animals are only dispensed to the public under a veterinary prescription as required by Article 67(aa) of Directive 2001/82/EC.	So far IMA has not had sufficient tools to enforce this. However, the Ministry of Welfare has drafted, in cooperation with IMA, a regulation		

No	Recommendation	Reaction of the Competent Authority	Date of compliance	Comment/ attachment
14	Iceland should ensure that food business operators operating slaughterhouses do not accept animals (other than wild game) for slaughter unless they have been provided with the relevant food chain information as set out in Section III of Annex II to Regulation (EC) No 853/2004.	A letter has been submitted to all slaughterhouse operators and DVOs/OVs to reiterate the requirements regarding food chain information. A letter was also sent to the same parties in February 2009 to inform them about the provisions of the legislation and how to proceed regarding slaughtering of horses and export of horse meat. Also attached is an e-mail sent in August 2010 to all DVOs regarding work procedures in slaughterhouses for receipt of animals for slaughtering.	Completed	 Letter FBOs_DVOs 27022012_rec 14.doc  Letter FBOs 2009.doc  E mail to DVOs 2010.pdf

No	Recommendation	Reaction of the Competent Authority	Date of compliance	Comment/ attachment
15	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.	IMA carries out regular inspections at wholesalers for veterinary medicines at least every third year. Public pharmacies that sell both human and veterinary medicines are also inspected at regular intervals. However the EFTA Surveillance Authority mission commented on low number of inspections of pharmacies run by veterinarians and this was a comment raised during previous inspection as well in 2008. IMA pointed out during the inspection that since the previous inspection, IMA had carried out 15 inspections (as compared to zero in the previous years) at dedicated veterinarian‘s pharmacies. Due to the fact that the only trained inspector was no longer working at IMA and because of lack of resources those inspections had only been four in the year 2011 at the time of the inspection.		

The following recommendations are intended as guidance to the competent authorities only:

No	Recommendation	Ábyrgð	Date of compliance	Comment/attachment
1 (7)	Iceland should ensure that procedures are in place when non-compliances are detected during official controls that documented corrective actions are taken in line with Article 8 (3.b) of Regulation (EC) No 882/2004.	A work procedure for follow-up of non-compliances has been drafted and will be published in 2012 as a part of MAST´s Quality Manual. Guidelines for actions related to control of residues will be prepared as a part of the procedure.	1.1.2013	
2 (10)	Iceland should ensure that sampling for the National Residue Control Plan is carried out in variable intervals spread over the whole year and that a sufficient number of samples are taken as required by Commission Decision 98/179/EC.	Notice has been taken of this recommendation		