Final report

EFTA Surveillance Authority mission to

ICELAND

21 to 24 January 2008

regarding the application of EEA legislation related to the use of

veterinary medicinal products in animal production, in particular related to

aquaculture

Please note that the comments from the Icelandic competent authorities to the factual content of the report have been included in the body of the report in *underlined italic* print. Additional information from the Icelandic competent authority is given in footnotes in *underlined italic* print. Comments and information on the corrective actions taken are included in Annex 3.
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Introduction

The mission took place in Iceland from 21 to 24 January 2008. The mission team was composed of two inspectors from the EFTA Surveillance Authority (the Authority) and an observer from the Food and Veterinary Office of the European Commission.

The opening meeting was held with representatives of the Icelandic Food and Agricultural Authority (Matvælastofnun) (MAST) and the Icelandic Medicines Control Agency (IMCA) on 21 January 2008 at the IMCA’s office in Reykjavik. At the meeting, the competent authorities added information to the reply to the pre-mission questionnaire. This was the first mission to Iceland focusing on veterinary medicinal products (VMPs).

Throughout the mission, a representative of MAST accompanied the mission team. In addition, representatives of the relevant district offices of MAST participated during meetings at the district offices and the visits to the different farms. Furthermore, representatives of the IMCA participated in the visit to the wholesaler.

A final meeting was held at the IMCA’s office in Reykjavik on 24 January at which the mission team presented its main findings and some preliminary conclusions from the mission.

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

1 Objectives of the mission

The main objective of the mission was to assess the application of EEA legislation related to VMPs and official controls on the production, distribution and use of VMPs in Iceland with emphasis on the controls on aquaculture.

The meetings with the Competent Authorities and the visits to the competent authorities, farms and companies during the mission are listed in Figure 1.

![Figure 1: Competent Authorities, establishments and farms visited during the mission](image)

<table>
<thead>
<tr>
<th>Number</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>An opening and a closing meeting and meetings with representatives of two district offices of MAST</td>
</tr>
<tr>
<td>1</td>
<td>One wholesaler distributing VMPs to pharmacies and veterinarians</td>
</tr>
<tr>
<td>1</td>
<td>One veterinarian running a veterinary pharmacy</td>
</tr>
<tr>
<td>2</td>
<td>Two aquaculture farms.</td>
</tr>
</tbody>
</table>

2 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) The Act referred to at point 1.2.74 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States*.


Other legislation relevant for the mission is listed in Annex 2.

### 3 National legislation

The main Icelandic Acts on official controls on aquaculture and fish diseases are Act No 33/2002 on the aquaculture of sea fish and Act No 57/2006 on fish farming. The main Act concerning VMPs is the Pharmaceutical Act, Act No 93/1994. In addition, and relevant to this mission, are Act No 96/1997 on the raising and health of slaughter animals, slaughtering, processing, health inspection and quality grading of slaughter products and Act No 66/1998 on veterinarians and animal health services.

Based on these Acts, numerous regulations have been issued concerning the wholesale, handling and distribution of VMPs, fish diseases and monitoring, production of products of animal origin, animal husbandry and animal identification which are also relevant for the controls on VMPs.

### 4 Information on production and trade

According to the reply to the pre-mission questionnaire, the production of salmon in Iceland is estimated to have been reduced dramatically in 2007 due to closure of the biggest on-growing farms. Therefore, the total Icelandic aquaculture production was estimated to amount to around 5,700 tonnes in 2007, compared to 9,960 tonnes in 2006.

**Figure 2: Total production in Icelandic aquaculture, 2000 - 2007**

<table>
<thead>
<tr>
<th>Species</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atlantic salmon</td>
<td>2,602</td>
<td>2,645</td>
<td>1,471</td>
<td>3,710</td>
<td>6,020</td>
<td>6,094</td>
<td>6,894</td>
<td>880</td>
</tr>
<tr>
<td>Arctic char</td>
<td>925</td>
<td>1,320</td>
<td>1,540</td>
<td>1,670</td>
<td>1,336</td>
<td>977</td>
<td>1,426</td>
<td>2,700</td>
</tr>
<tr>
<td>Rainbow trout</td>
<td>30</td>
<td>105</td>
<td>248</td>
<td>180</td>
<td>142</td>
<td>50</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Brown trout</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Halibut</td>
<td>34</td>
<td>93</td>
<td>120</td>
<td>95</td>
<td>123</td>
<td>129</td>
<td>141</td>
<td>30</td>
</tr>
<tr>
<td>Turbot</td>
<td>0</td>
<td>2,7</td>
<td>9</td>
<td>32</td>
<td>62</td>
<td>115</td>
<td>47</td>
<td>70</td>
</tr>
<tr>
<td>Sea bass</td>
<td>20</td>
<td>20</td>
<td>40</td>
<td>76</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cod</td>
<td>11.2</td>
<td>70</td>
<td>205</td>
<td>393</td>
<td>595</td>
<td>1,050</td>
<td>1,410</td>
<td>2,000</td>
</tr>
<tr>
<td>Haddock</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>65</td>
<td>0</td>
<td>0</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>Abalone</td>
<td>15.3</td>
<td>22.3</td>
<td>23.6</td>
<td>6.5</td>
<td>1.5</td>
<td>4</td>
<td>0.4</td>
<td>0.4</td>
</tr>
<tr>
<td>Freshwater prawn</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Blue mussel</td>
<td>0</td>
<td>0</td>
<td>0.5</td>
<td>4</td>
<td>5</td>
<td>10</td>
<td>10</td>
<td>20</td>
</tr>
</tbody>
</table>

* Estimate
5 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 93/53/EEC and Council Directive 91/493/EEC. The controls on the distribution and use of VMPs were not addressed during the 2005 mission. The distribution and use of VMPs in Iceland has not been addressed before by the Authority.

6 Main findings

6.1 Transposition and application of relevant legislation


The mission team also noted that Commission Decisions No 2003/390/EC; 2003/466/EC and 2004/453/EC related to aquaculture were not implemented\(^1\).


6.2 Competent Authorities

6.2.1 General information

Two Ministries are responsible for implementation and application of EEA Acts related to official controls on aquaculture and distribution and use of veterinary medicinal products. The Ministry of Fisheries and Agriculture, which started operation as of 1 January 2008 when the Ministry for Fisheries and the Ministry for Agriculture merged, adopts legislation regarding official controls on aquaculture. The Ministry of Health adopts legislation regarding veterinary medicinal products and production, marketing and handling thereof.

The controls on the production, distribution and use of VMPs are divided between two competent authorities, the Icelandic Medicines Control Agency (IMCA) and the Icelandic Food and Veterinary Authority (MAST). The two competent authorities are responsible for the enforcement of legislation adopted by the two Ministries.

The IMCA is responsible for licensing and official controls on manufacture and distribution of VMPs down to pharmacy level, while MAST is responsible for control of VMP usage by the veterinary practitioners and on farms.

\(^1\) While drafting the report the Ministry of Fisheries and Agriculture notified the Authority of the full implementation of the three Commission Decisions.
The IMCA is an independent regulatory and surveillance authority under the Ministry for Health. Its main functions are to issue marketing authorizations for medicines in Iceland in collaboration with regulatory authorities in the European Economic Area (EEA); to ensure control and surveillance of the pharmaceutical industry in Iceland and to contribute to make professional and unbiased information on medicines available to health care professionals and consumers.

In addition, the IMCA is responsible for receiving reports on any adverse reactions to medicines occurring in Iceland. The IMCA also issues permissions for clinical trials, classifies natural products and food supplements as medicines or regular commodities, controls advertisements on medicines and publishes the catalogue of Medicinal Products.

MAST commenced operations on 1 January 2008 as an inspection and administrative body following the merger of the Agricultural Authority, the food sections of the Environment and Food Agency and the Directorate of Fisheries. MAST works under the Ministry of Fisheries and Agriculture and is responsible for administration of tasks which, prior to the merger, were assigned to the Chief Veterinary Officer (CVO), the Feed, Seed and Fertilizers Inspectorate, the plant inspection services of the Agricultural University of Iceland, the meat grading chairman, the Directorate of Freshwater Fisheries, the food division of the Environmental and Food Agency of Iceland, the food division of the Icelandic Directorate of Fisheries and some tasks previously assigned to the Farmers’ Association of Iceland. Therefore, MAST is the Competent Authority with regard to food safety, control of primary production of animal products, including fish products, import and export control of all foodstuffs, supervision of domestic food control by municipal authorities, veterinary services, plant protection services, feed, seed and fertilizer services, meat classification services, services regarding freshwater fisheries and aquaculture, administration of organic production of agricultural products and management, monitoring of supplies and surveillance of animal welfare.

6.3 Organisation and legal powers

The headquarters of MAST are located in Selfoss, about 50 km east of the capital city of Reykjavík. MAST has 14 district offices around Iceland where district veterinarians and official veterinarians render services in accordance with the relevant legislation. MAST is also responsible as of 1 January 2008 for the operation of the veterinary border inspection posts located in Iceland for the control of import of food and live animals from third countries. MAST has the legal powers to enter animal holdings and the premises of food business operators for controls and to perform inspections on holdings and private veterinary practices.

There are two types of District Veterinary Officers (DVOs) in Iceland. Three of the DVOs have official duties only and are not allowed to provide veterinary services. These three are located in the most densely populated agricultural areas of Iceland, i.e. around Reykjavík; in the southern part of Iceland, around Selfoss and Hellá; and in the north around Akureyri. The other eleven DVOs are, in addition to their official duties, also obliged to provide veterinary services to animal owners in the district. According to representatives of MAST, this is to ensure the availability of veterinary services in remote areas of Iceland.

The mission team visited two district offices. One of the DVOs visited was, in addition to his official duties, also obliged to run a private practice. Therefore, the DVO was obliged to act as an official veterinarian towards the customers of his private practice. However, according to the DVO, the central level of MAST had communicated to the DVOs that
private practice services should not be provided to farms when visiting as an official veterinarian. Furthermore, this DVO informed the mission team that he also controlled farms serviced by other private veterinary practitioners. The other DVO visited was not allowed to work as a private veterinary practitioner.

The mission team noted that a limited number of official veterinarians are involved in the aquaculture sector. Therefore, the Official Veterinarian for Fish Diseases (OVFD) had numerous responsibilities regarding fish, including both official duties and services to the aquaculture industry. The mission team noted that, according to the system in place in Iceland, the OVFD is, as a member of the Fish Disease Committee, involved in deciding which veterinarians can prescribe VMPs for aquaculture animals. Furthermore, he is also involved in deciding which medicines may be used and whether they may be mixed with feed. The OVFD carried out almost all official health inspections and inspections related to the handling and use of VMPs in aquaculture farms. Finally, the department responsible for the residue control plan at the central level of MAST based its decisions on where to take samples under the national residue control plan for aquaculture on information provided by the OVFD. The mission team noted that the OVFD was the only veterinarian in Iceland who prescribed VMPs for aquaculture.

The IMCA is located in Seltjarnarnes, in the vicinity of Reykjavík. The IMCA has the legal powers to control wholesalers and retailers of VMPs and to enforce corrective actions. However, representatives of the IMCA stated that the legal powers to enforce corrective actions of practicing veterinarians’ pharmacies were not sufficient.

6.4 Financial and human resources

Representatives of MAST informed the mission team that two persons at central level are involved in official controls of aquaculture farms, the Chief Veterinary Officer (CVO) and the OVFD. At local level, aquaculture farms are under the control of the DVOs and the OVFD.

At central level in MAST the CVO and one veterinary officer are responsible for the coordination of controls on VMPs. At local level the control of VMPs is under the responsibility of the DVOs. However, only a limited part of the total working time is dedicated to the controls on VMPs and the time dedicated to aquaculture is very limited since the district offices have numerous other tasks in the controls on animal husbandry and food production.

In one of the district offices visited, the DVO informed the mission team that the district office was around 30% short of staff according to an internal workload assessment. Therefore, not all inspections on animal holdings assigned to the district office had been conducted in 2006 and 2007. The results of the assessment had been communicated to the head office of MAST.

The representatives of the IMCA informed the mission team that, due to reorganisation and staff changes, the IMCA had been short of inspectors for the last two years. The IMCA representatives also stated that controls on VMPs had not been a priority for the IMCA and that no pharmacies of the veterinary practitioners had been inspected. This was

2 In the comments to the draft report MAST referred to discussions in the final meeting of the mission and stated that the OVFD has nothing to do with the residue control plans and has no opinion on where and how samples are taken.
partly due to uncertainties concerning the legal powers of the IMCA with regard to the
pharmacies of the veterinary practitioners.\(^3\)

6.5 Training of personnel

According to the reply to the pre-mission questionnaire, most of the IMCA’s staff has a
University degree and/or expertise in Pharmaceutics. However, the staff did not have any
special training in veterinary pharmacy, since the IMCA was not responsible for
controlling the end use of the VMPs by the veterinarians.

In January 2008 MAST held a seminar for all official veterinarians on amongst others
contingency plans, new rules related to special licenses, and new rules on registration of
the use of medicines in horses. MAST had also issued some checklists for the official
veterinarians for their controls on farms. The checklist for inspections at dairy farms and
on aquaculture farms contained a section on VMPs. The checklist for inspections on pig
farms did not contain such a section. No other checklists had been made available to the
official veterinarians. The mission team was informed by one of the DVOs met during the
mission that no training had been provided on how to conduct an inspection on the
handling and the use of VMPs on farms.

6.6 Cooperation and coordination with regard to veterinary medicinal products

According to the reply to the pre-mission questionnaire, the two competent authorities
cooperate through the Pharmaceutical Committee, which is the advisory committee of the
IMCA. The Committee is comprised of five persons with a broad expertise in medicine
and pharmaceutics. The Minister of Health appoints the Chairman, and other members in
consultation with the Chairman. When VMPs are dealt with, the CVO and a veterinarian
appointed by the Minister attend the meetings.

In addition, an informal working group was established in October 2007 with members
from the IMCA and MAST. According to the representatives of the competent authorities,
the working group meets at least twice a month. The first tasks of the working group were
to update the rules on granting special dispensations to veterinarians for the purchase of
VMPs without a marketing authorisation in Iceland and to develop rules on the use of
VMPs authorised for horses and the recording of such medication.

The representatives of the IMCA informed the mission team that they had requested
participation of the staff of the CVO, now part of MAST, in inspections of the practicing
veterinarians’ pharmacies. A representative of MAST stated at the final meeting of the
mission that this would be considered in near future.

6.7 Veterinary medicinal products and medicated feedingstuffs

6.7.1 Authorisation of veterinary medicinal products

The IMCA is the competent authority for granting marketing authorisation for VMPs in
Iceland. The IMCA is the competent authority both with regard to human and to
veterinary medicinal products. MAST is the competent authority with regard to specific
provisions for, and the use of, VMPs and supervision of Good Veterinary Practice
(including veterinarians’ use of medicinal products).

According to information provided by the representatives of the IMCA, the production of
VMPs requires a manufacturing license from the IMCA. Wholesalers and retailers of

\(^3\) In the comments to the draft report the IMCA stated that this was mainly due to re-organisation of IMCA’s
inspection unit and training of new inspectors.
VMPs are obliged to have an authorisation issued by the IMCA for their activities. Wholesalers are also required to have a partial manufacturing license in case of, for instance, repackaging and re-labelling of VMPs. All veterinarians, authorised by the Ministry of Fisheries and Agriculture as veterinary practitioners in Iceland are authorised to act as retailers of VMPs.

According to the reply to the pre-mission questionnaire, Iceland participates in the EEA-cooperation in the field of medicinal products and Icelandic national legislation is based on the relevant EEA legislation. Thus, medicinal products may be authorised through the same procedures as in the other EEA States, i.e. through a central procedure and through a mutual recognition authorisation procedure/decentralised procedure in cooperation with other national competent authorities in the EEA States.

The mission team noted that a substantial number of VMPs used for food producing animals in Iceland had not obtained a marketing authorisation, presumably due to the size of the Icelandic market. The IMCA, following consultation with MAST, may give exemptions from the marketing authorisation requirement on an individual basis either for a single treatment of an animal or a herd, or to a veterinarian for use in his/her own practice for a maximum of one year at a time. At the time of the mission these rules had just recently been updated to further ensure proper use of VMPs without marketing authorisations. Therefore, as of September 2007, VMPs can, as a general rule, only be given a special license if they have a marketing authorisation in another EEA State. The competent authorities informed the veterinarians of the changed rules in a letter in November 2007.

A list of VMPs with a marketing authorisation in Iceland is available to the public on the Internet. The list is comprehensive and clearly indicates, inter alia, the route of administration, target species, indications and withdrawal times where appropriate.

The mission team observed that:
- according to Icelandic legislation, the use of Chloramphenicol topically for treatment of infections in eyes and ears of food producing animals was allowed;
- the use of malachite green for food producing species has been banned totally in Iceland;
- in the letter announcing the more restrictive rules on special license VMPs, the competent authorities did not inform of any requirements for keeping of detailed records on the use of the special license VMPs;
- licenses issued before November 2007 not complying with the new procedures had not been withdrawn. The IMCA had informed the wholesalers of the new rules and which VMPs should not be sold on the old licenses as of 1 January 2008. However, the wholesaler visited was not fully aware of the amended procedures;

6.7.2 Distribution of veterinary medicinal products
Wholesalers supply pharmacies and veterinary practitioners with the VMPs. Veterinary practitioners are authorised to sell the VMPs with profit as any other retailer. Only veterinarians are authorised to prescribe VMPs. All VMPs for food producing animals are classified as "prescription only" medicines. However, a derogation allows retailers to sell syringes of anthelmintics for oral use in horses at a time, without a prescription.
The mission team noted that veterinarians get an authorisation for functioning as retailers and that a prior inspection by the IMCA, which is required for other pharmacies, is not required for veterinarians.

### 6.7.3 Medicated feedingstuffs

EEA legislation on medicated feedingstuffs was at the time of the mission not yet applicable to Iceland. It follows from the reply to the pre-mission questionnaire that MAST can authorise, with the acceptance of the CVO, the mixing of VMPs with a single type of feed for a specially defined group of animals.

However, there is no Icelandic legislation concerning the production of medicated feedingstuffs. According to the CVO, no medicated feedingstuffs were produced in feed mills in Iceland. However, the mission team noted that aquaculture farms used medication through feed after a prescription from the OVFD. Furthermore, the mission team observed that the mixing equipment at one of the aquaculture farms visited and the production methods were neither regulated nor inspected by the official services. At the aquaculture farms visited no written guidelines had been issued on the mixing of the medicated feed and the homogeneity of the feed had not been verified.

### 6.8 Official controls of veterinary medicinal products

As mentioned above, the responsibility for the control of VMPs is split between MAST and the IMCA. The IMCA is responsible for the marketing authorisation of VMPs and for the control of production/import and distribution of VMPs until the level of retailers, including the incoming records, the storage facilities and conditions of the VMPs at the veterinary practitioners. An overview of the scheduled and performed inspections by the IMCA is given in Figure 3.

Controls on the proper handling and use of the VMPs by the veterinary practitioners as well as all aspects of VMP controls on animal holdings are the responsibility of MAST. According to information provided to the mission team by the representatives of MAST eight of the fourteen district offices had performed all scheduled inspections in 2006 and seven out of the fourteen in 2007. The remaining district offices had performed from 47 to 94 percent of the planned inspections in 2006 and from 51 to 94 percent in 2007. However, not all the inspections included specific controls on VMPs.

#### Figure 3: IMCA’s planned and performed inspections in 2006 and 2007

<table>
<thead>
<tr>
<th>Type of premises</th>
<th>Number of premises</th>
<th>Number planned to be inspected in 2006</th>
<th>Number actually inspected in 2006</th>
<th>Number planned to be inspected in 2007</th>
<th>Number actually inspected in 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>VMP wholesalers</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>VMP pharmacies</td>
<td>60</td>
<td>12</td>
<td>4</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Veterinary practices</td>
<td>52</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

#### 6.8.1 Wholesalers

Representatives of the IMCA informed the mission team that, according to its internal procedures, large wholesalers should be inspected every three years and smaller ones every three to five years. The mission team noted that a checklist for use during
inspections of wholesalers was available and it also contained checks of the VMPs and purchase by veterinary practitioners.

The mission team noted at the wholesaler visited that;

- the wholesaler had the necessary authorisations in accordance with the activities performed;
- the last complete inspection by the IMCA was in 2002. Since then some partial inspections had been performed, however, not related to VMPs;
- the company had got a renewal of the authorisation in 2005 without an inspection by the IMCA;
- on a limited number of occasions prescription only VMPs were sold to medical doctors, although not permitted by the national legislation;
- a system was in place to ensure that special license VMPs were only provided to veterinary practitioners which held the necessary license. However, the copies of the licenses granted to private practitioners observed by the mission team were not always clearly filled out and not always easily readable;
- 96 percent of the VMPs sold were purchased by veterinary practices.

6.8.2 Retailers

According to the reply to the pre-mission questionnaire, VMPs are distributed mainly via practicing veterinarians who purchase VMPs from the wholesalers for use in own practice and run veterinary pharmacies where they sell VMPs to animal owners. Small quantities of VMPs are distributed through other pharmacies.

According to internal rules of the IMCA, retailers should be inspected every four to ten years. Out of 60 VMP pharmacies 12 were planned to be inspected in 2006 and 2007. However, four had been inspected each year. Out of 52 practicing veterinarians authorised to run a veterinary pharmacy no inspections were planned in 2006 and 2007 nor had any been carried out. The representatives of the IMCA stated that this was partly because of lack of personnel and reorganisation of the IMCA, but also because of lack of legal tools for demanding corrective actions. Checklists to be used during inspection of retailers and of veterinary practitioners running veterinary pharmacies were available for the use of the inspectors of the IMCA.

Representatives of the IMCA provided documentation for follow-up of one inspection at a veterinary practice in 2003. Severe remarks were made on the record keeping, storage and handling of VMPs. The veterinary practitioner informed the IMCA promptly on corrective actions taken for most of the issues raised by the IMCA inspector. The IMCA stated that it would verify the corrective actions by inspection. However, at the time of the mission no follow-up inspection had yet been performed. The IMCA had informed the CVO of the deficiencies but no action had been taken by the CVO.

The mission team noted that no private veterinary practices had been inspected by MAST, although controls on the outgoing transactions from the veterinary pharmacies are the responsibility of MAST. Furthermore, the mission team noted that no guidelines were provided at the central level, nor had procedures been established for the district offices’ inspections of veterinary practitioners and their handling and use of VMPs, although the representatives of the central level of MAST stated that the controls on veterinary practitioners were the responsibility of the district offices.
6.8.3 Animal holdings

MAST (the DVOs) has the responsibility to ensure the proper use and storage of medicines at farms. According to information provided by representatives of MAST to the mission team, persons responsible for food producing animals, i.e. equidae, bovines, ovines, caprines, porcines, poultry and farmed fish, are obliged to keep records on the health status of the animals, including any treatment, and keep the records for at least 10 years. The mission team noted that official inspections by DVOs were not planned neither in sheep farms nor horse holdings.

MAST has developed a special form for the private veterinary practitioners to fill out at each visit, where the identification of the animal, the diagnosis, the treatment and the VMPs used, and the withdrawal times are registered. However, representatives of the MAST informed the mission team that the use of this form by the veterinary practitioners was not consistent. The mission team noted that one of the veterinarians visited was not aware of the existence of this form.

According to information provided to the mission team by representatives of MAST, all VMP treatments on food producing animals should be initiated by a veterinarian. However, the representatives also stated that the CVO could grant a dispensation to veterinary practitioners for treatments on farms in remote areas where weather conditions are likely to be harsh making it difficult for the veterinarian to reach the farm in time. According to more detailed rules of the CVO, this was applicable only to injectable antibiotics, preferably penicillin, prescribed to sheep, and only if the farmer had a special contract with a veterinary practitioner for supplying the antibiotics. The farmer is obliged to have a contract with only one veterinary practitioner and purchase VMPs from that veterinarian only, to keep detailed records on the purchase and the use of the VMPs and have these records available for inspection by the official veterinarian.

One of the DVOs visited had such a dispensation from the CVO. However, this DVO informed the mission team that not all farmers kept the required records and that not all farmers sent reports on a yearly basis to the DVO as required. Furthermore, the district office did not have an overview of the number of farmers in the district that had such contracts. The mission team noted in one report available at the district office that the farmer had purchased VMPs from more than one veterinary practitioner. The DVO stated that the derogation was not functioning properly and that no guidelines were given on how to control compliance with the requirements. The DVO furthermore stated that actions to be taken in the event of non-compliances found had not been formalised. The mission team noted that no relevant official inspections had been carried out or were planned on the sheep farms having this dispensation.

The mission team noted that dairy farms were to be inspected once per year. In one of the district visited around 66 percent of the dairy farms had been inspected in 2007, while in the other district visited all dairy holdings had been inspected. The mission team noted that a checklist for use during inspections was available which included checks on VMPs. However, no guidelines had been issued on how the use and the records of VMPs should be checked. Furthermore, the DVOs stated that the records kept on dairy farms usually only include the milking cows and not calves and young animals. The DVOs stated that the records differed extensively from farm to farm. No cross checks on the purchase and the use of VMPs had been conducted.

According to information provided by MAST, holdings keeping bovines for beef production, pig farms and poultry farms were also to be inspected once per year. The
mission team noted that a limited number of holdings keeping bovines only for beef production had been inspected in the districts visited. A checklist to be used at inspections on pig farms did not include any checks on the VMPs. The pig farms had not been inspected in 2007 in one of the districts visited. Representatives of MAST informed the mission team that for poultry farms no checklist existed and that no guidelines on how to inspect the VMP usage were available.

At the time of the mission, no official inspections were carried out regarding the use of VMPs in horses. In addition, a representative of MAST stated that not all horse owners kept treatment records. Furthermore, the EU legislation on the horse passports is not applicable to Iceland. However, an existing database, the stud book for the Icelandic horse, "World Fengur", which is accessible on the Internet, has been extended to include treatment records. This extension had at the time of the mission just been launched. The veterinary practitioners were informed by the head office of MAST in a letter dated late January 2008 of obligations to record treatments in the database. The requirements so far comprised three VMPs, one containing acepromazine and another one containing permethrin, both to be registered in the database with a withdrawal time of six months pre-programmed in the system and a third VMP, containing heparin and 2-hydroxyethyl-salicylate, where treated horses were to be permanently excluded from the food chain.

The mission team took note that permethrin was listed for use in horses with six months withdrawal time although it does not appear on the list to the Annex to Commission Regulation (EC) No 1950/2006. The mission team also noted that the date of entry into force of the new system was not included in the letter.

According to these new procedures, every horse treated has to be micro chipped or freeze branded so the horse can be scanned at slaughter to check whether or not it has been treated. The representatives of MAST stated that it would be possible to extend the registration to all treatments of horses. At the time of the mission, the slaughterhouses did not yet have scanners to read the micro chips and the slaughterhouses were not yet connected to the database. The representatives of MAST stated that it was expected that the system would be up and running before summer 2008. They further stated that the new system would be introduced to the slaughterhouses by a letter and by visits to the slaughterhouses in April and May 2008.

The mission team noted that neither were the farmers legally obliged to declare that withdrawal times had been respected for animals brought to slaughter, nor were the slaughterhouses obliged to ensure that the withdrawal times had been respected. However, the representatives of MAST informed the mission team at the final meeting that MAST had already informed the slaughterhouses of their duty to obtain farmers declaration on the use of VMPs when animals are brought to slaughter. Furthermore, the MAST representatives also stated that this would be followed up during planned visits to the slaughterhouses in April and May 2008.

A representative of MAST informed the mission team that from 1 January 2008 it is no longer possible to get phenylbutazone on a special license and that it is illegal to use the substance in horses in Iceland. However, a VMP with this active substance in a preparation suitable for horses was observed at the wholesaler visited.

According to information provided at the final meeting by representatives of MAST, a new computerised register was being developed, and when operational, it would facilitate
the supervision of the use of VMPs in the farming industry. However, a date for when the system would be operational was not yet decided on.

Finally, representatives of MAST stated at the final meeting that the on-farm inspections in 2008 would be targeted on the handling and use of VMPs.

6.8.4 Aquaculture farms
All aquaculture farms in Iceland are approved by MAST. The controls on the farms are divided between the DVOs and the OVFD. The DVOs take samples both for disease controls and within the residue control programme, while the OVFD inspects the farms. The mission team noted that the OVFD had a checklist for his inspections and that the OVFD controlled the VMP records, the storage and use on all aquaculture farms in Iceland.

A contingency plan for animal diseases including fish diseases had been updated in January 2008 with relevant amendments related to the establishment of MAST.

The farms visited during the mission had been inspected yearly as scheduled and samples had been taken according to the plan. In the fish farms visited, records of purchase of VMPs and treatment records were kept and were easily accessible to the mission team. In one of the farms, inventory of the VMP storage was checked every month. In one farm leftovers from a treatment in 2006 had not been disposed of and no routines were in place for disposal of outdated VMPs. However, VMP records were in accordance with the amount of VMPs observed on the farm. In the other farm visited feed in small quantities used for feeding trials was stored in the same storage as the VMPs, some of which had expired.

7 Final meeting

A final meeting was held on 24 January at the IMCA’s office in Reykjavik with representatives from the IMCA and MAST. At this meeting, the mission team presented its main findings and some preliminary conclusions of the mission. The representatives of the competent authorities did not indicate any disagreement with the observations of the mission team.

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.

8 Conclusions

8.1 General conclusion
A system is in place in Iceland for authorising VMPs and controlling wholesale, distribution and use of VMPs. However, the mission team observed several aspects which can impair the functionality of the system.

8.2 Implementation of Acts incorporated into the EEA Agreement
There was an extensive delay in implementing legislation already included in the EEA Agreement. This influences the functionality of the EEA Agreement and the effectiveness of the official controls.
8.3 Authorisation of veterinary medicinal products
Compliance with Article 5 of Council Regulation (EEC) No 2377/90 and Annex IV thereto, could not be ensured since Chloramphenicol was authorised for topical treatment of infections in eyes and ears in food producing animals.

8.4 Distribution of veterinary medicinal products
Compliance with Article 65(4) of Directive 2001/82/EC could not be fully ensured since medical doctors had repeatedly been able to purchase VMPs from a wholesaler.

8.5 Official controls on veterinary medicinal products
8.5.1 Compliance with Article 11(4) of Directive 2001/82/EC could not be fully ensured since the veterinarians were not required to keep adequate records when they had recourse to the provisions in Article 11(1) and (2).

8.5.2 Compliance with Article 80 of Directive 2001/82/EC could not be fully ensured since the Competent Authority had not, by repeated inspections and if necessary unannounced inspections, ensured that all legal requirements related to VMPs were complied with, at all stages of production and distribution.

8.5.3 Compliance with Article 66 of Directive 2001/82/EC could not be fully ensured since the incoming transactions and the facilities at the veterinary practitioners’ pharmacies had not been inspected as set out by the competent authorities in, at least, the last two years. Furthermore, the outgoing transactions of veterinary practitioners’ pharmacies, the proper use in own-practice and the distribution to end users had never been inspected by the competent authorities.

8.5.4 One of the DVOs visited informed the mission team that not all owners or keepers of food producing animals could provide proof of purchase, possession and administration of VMPs; specifically the date of administration, the name of the VMP, the quantity administered, the name and address of the supplier and the identity of the animals treated. The competent authority had not included all types of animal holdings in its inspection plans and not all planned inspections of animal holdings were performed. Furthermore, the storage, handling and record keeping of the VMPs were not controlled in all types of holdings inspected by MAST. Therefore, Iceland could not ensure that all owners or keepers of animals for food production complied with the provisions in Article 69 of Directive 2001/82/EC.

9 Recommendations to the Icelandic competent authority
Notification of corrective action and a plan for completion of measures
Iceland should inform the Authority in its reply to the draft 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 conclusions under Chapter 8 of this report. This information will be annexed to the final report. The Authority should also be kept informed of the completion of the measures included in the timetable.
### Annex 1 - List of abbreviations and terms used in the report

<table>
<thead>
<tr>
<th>Authority</th>
<th>EFTA Surveillance Authority</th>
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<tbody>
<tr>
<td>CVO</td>
<td>Chief Veterinary Officer</td>
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<tr>
<td>DVO</td>
<td>District Veterinary Officer</td>
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<tr>
<td>EC</td>
<td>European Community</td>
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<tr>
<td>EEA</td>
<td>European Economic Area</td>
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<tr>
<td>EEA Agreement</td>
<td>Agreement on the European Economic Area</td>
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<tr>
<td>FVO</td>
<td>Food and Veterinary Office of the European Commission</td>
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<tr>
<td>IMCA</td>
<td>The Icelandic Medicinal Control Agency</td>
</tr>
<tr>
<td>MAST</td>
<td>The Food and Agricultural Authority of Iceland</td>
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<tr>
<td>OVFD</td>
<td>Official Veterinarian for Fish Diseases</td>
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Annex 2 - Other relevant legislation

The main EEA Acts regarding VMPs and aquaculture and relevant for this mission are:


c) The Act referred to at point 4.2.72 of Chapter I of Annex I to the EEA Agreement, Commission Decision 2003/390/EC of 23 May 2003 establishing special conditions for placing on the market of aquaculture animals species considered not susceptible to certain diseases and the products thereof.

d) The Act referred to at point 4.2.73 of Chapter I of Annex I to the EEA Agreement, Commission Decision 2003/466/EC of 13 June 2003 establishing criteria for zoning and official surveillance following suspicion or confirmation of the presence of infectious salmon anaemia (ISA).


Annex 3 - Comments from Iceland to the draft report

Selfoss, 5th of June 2008

Subject: Draft mission report from ESA on the application of EEA legislation related to the use of veterinary medicinal products in animal production, in particular related to aquaculture.

Reference is made to a letter from ESA, including a draft report (Case no. 63249, event no. 46023) from a mission to Iceland from 20 to 24 January 2008. The mission was concerning the application of EEA legislation related to the use of veterinary medicinal products in animal production, in particular related to aquaculture.

The central competent authorities are the Icelandic Food and Veterinary Authority (MAST) and the Icelandic Medicines Control Agency (IMCA), supervision of the mission was with MAST.

Enclosed are the comments made by MAST and IMCA to the main findings in Chapter 6 and conclusions in Chapter 8 of the draft report from the mentioned mission.

For the purpose of clarity the comments made by the CA in the enclosed document have been written in italics after each of the relevant conclusions in Chapter 8 and see comments in as track changes in Chapter 6.

Please be in contact if you need additional information or clarification.
ESA mission in Iceland 20 to 24 January 2008
Regarding the application of EEA legislation related to the use of
veterinary medicinal products in animal production, in particular
related to aquaculture

Comments form Iceland with respect to
the conclusions in Chapter 8 of the draft report

10 8 Conclusions

8.1 General conclusion
A system is in place in Iceland for authorising VMPs and controlling wholesale,
distribution and use of VMPs. However, the mission team observed several aspects which
can impair the functionality of the system.

8.2 Implementation of Acts incorporated into the EEA Agreement
There was an extensive delay in implementing legislation already included in the EEA
Agreement. This influences the functionality of the EEA Agreement and the effectiveness
of the official controls.

Delays in implementing EEA legislation are mainly due to delays in translation. The
Translation Centre of the Ministry for Foreign Affairs is responsible for translation of
Acts.

8.3 Authorisation of veterinary medicinal products
Compliance with Article 5 of Council Regulation (EEC) No 2377/90 and Annex IV
thereto, could not be ensured since Chloramphenicol was authorised for topical treatment
of infections in eyes and ears in food producing animals.

As stated in art. 5 in Regulation no. 539/2000 on MP for Veterinarians, Chloramphenicol
is authorised for topical treatment of infections in eyes and ears in food producing
animals. A request will be sent to the ministry of Health regarding changes to the
regulation, so that all use of Chloramphenicol in food producing animals will be
prohibited.

8.4 Distribution of veterinary medicinal products
Compliance with Article 65(4) of Directive 2001/82/EC could not be fully ensured since
medical doctors had repeatedly been able to purchase VMPs from a wholesaler.

According to Article 33(5) of the Medicinal Products Act No 93/1994, Medicinal product
wholesalers may sell medicinal products to physicians for use in their own offices or on
house calls and furthermore according to Article 33(6) Medicinal Product wholesalers
may sell VMPs to veterinarians for use in their own offices or for house calls and for sale
from their offices. The legislation does not foresee that medical doctors can purchase
VMPs from wholesalers. The wholesaler in question has been contacted and advised in
the matter. Furthermore IMCA has distributed a note to all wholesalers with guidance, i.e.
that according to the Medicinal Product Act only veterinarians can purchase VMPs from
wholesalers.
8.5 Official controls on veterinary medicinal products

8.5.1 Compliance with Article 11(4) of Directive 2001/82/EC could not be fully ensured since the veterinarians were not required to keep adequate records when they had recourse to the provisions in Article 11(1) and (2).

8.5.2 Compliance with Article 80 of Directive 2001/82/EC could not be fully ensured since the Competent Authority had not, by repeated inspections and if necessary unannounced inspections, ensured that all legal requirements related to VMPs were complied with, at all stages of production and distribution.

Due to reorganisation IMCA has not been able to fulfil all planned inspections Regarding the above mentioned compliance with Article 80 of Directive 2001/82/EC IMCA has inspected one facility on 9th April which will be followed by 3 planned inspections next fall. Therefore, work is already in process to comply with Article 80 of Directive 2001/82. The wholesaler in question did receive a wholesalers licence in the year 2002 after routine inspection and a renewal in 2005 without routine inspection. In the meantime however, three inspections dedicated for certain topics had been conducted. An inspection is scheduled in week 25 this year.

8.5.3 Compliance with Article 66 of Directive 2001/82/EC could not be fully ensured since the incoming transactions and the facilities at the veterinary practitioners’ pharmacies had not been inspected as set out by the competent authorities in, at least, the last two years. Furthermore, the outgoing transactions of veterinary practitioners’ pharmacies, the proper use in own-practice and the distribution to end users had never been inspected by the competent authorities.

The conclusion that “Compliance with Article 66 of Directive 2001/82/EC could not be fully ensured since the incoming transactions and the facilities at the veterinary practitioners’ pharmacies had not been inspected as set out by the competent authorities in the last two years.” refers to IMCA’s answer under point 8.5.2.

With reference to the conclusion that "the outgoing transactions of veterinary practitioners’ pharmacies, the proper use in own-practice and the distribution to end users had never been inspected by the competent authorities", it can be stated that this can be explained by lack of resources and manpower in the past. However, the implementation of the EU Food law and the Hygiene and Control package is now ongoing in Iceland. MAST has already sent the Ministry of Fisheries and Agriculture the recommendation that the text in the law nr. 66/1998 on the veterinary service should be amended in order to implement special provisions where the DVO’s would be required to enforce the requirements of the storage, handling and record keeping of the VMPs, in their districts.

8.5.4 One of the DVOs visited informed the mission team that not all owners or keepers of food producing animals could provide proof of purchase, possession and administration of VMPs; specifically the date of administration, the name of the VMP, the quantity administered, the name and address of the supplier and the identity of the animals treated. The competent authority had not included all types of animal holdings in its inspection plans and not all planned inspections of animal holdings were performed. Furthermore, the storage, handling and record keeping of the VMPs were not controlled in all types of
holdings inspected by MAST. Therefore, Iceland could not ensure that all owners or keepers of animals for food production complied with the provisions in Article 69 of Directive 2001/82/EC.

Article 8 in the Regulation nr. 289/2005 on the identification of farming animals, requires the owners of farmed animals to keep records of diseases in the animals under his care and the handling of these diseases and the measures to prevent diseases. It has been foreseen that these records, that should comply with the provisions in Article 69 of Directive 2001/82/EC, would be entered into a central database, that is being programmed by the Farmers Union, according to an agreement with the Ministry for Agriculture. However, this programming has been delayed now for a couple of years. Therefore the enforcement of the provisions of Article 8 in the Regulation nr. 289/2005 has been delayed.

With reference to the conclusion that "the competent authority had not included all types of animal holdings in its inspection plans", it can be stated that the Icelandic regulations on the keeping and welfare of farmed animals only provide for regular inspections by the District Veterinary Officers (DVO’s) for farms with cattle, horses, farmed birds and pigs.

Referring to the conclusion that "the storage, handling and record keeping of the VMPs were not controlled in all types of holdings inspected by MAST", it can be stated that due to lack of resources and manpower in the past, this type of enforcement has not been prioritized in the past by the DVO’s and the CVO.

Referring to the conclusion that "not all planned inspections of animal holdings were performed" this can be explained by lack of resources and manpower in the past.

However, the implementation of the EU Food law and the Hygiene and Control package is now ongoing in Iceland. MAST has already sent the Ministry of Fisheries and Agriculture the recommendation that the text in the law nr. 66/1998 on the veterinary service should be amended in order to implement special provisions where the DVO’s would be required to inspect regularly all farm holdings with food producing animals in order to enforce the requirements of the storage, handling and record keeping of the VMPs.