Brussels, 7 September 2021
Case No: 86189
Document No: 1224905

Final report

EFTA Surveillance Authority's remote audit of

Iceland

from 31 May to 14 June 2021 to evaluate official controls on residues and contaminants in live animals and animal products

In response to information provided by Iceland, any factual error noted in the draft report has been corrected. Information on the corrective actions already taken and planned are included in Annex 3 to the report.

Executive Summary

This report describes the outcome of a remote audit carried out by the EFTA Surveillance Authority in Iceland from 31 May to 14 June 2021.

The objective of the audit was to evaluate the effectiveness of official controls related to residues of veterinary medicinal products (VMPs), pesticides and contaminants in live animals and animal products.

The planning process for the residue monitoring control plan is well established and a comprehensive selection of data, from several official sources, contributes to this process. The plan is generally implemented on time with sampling spread throughout the year in most cases. Final targeting of animals for sampling on farm and in slaughterhouses is left to the discretion of district staff.

Surveillance for detection of illegal administration of prohibited substances and the abusive administration of approved substances and controlling compliance with maximum residue limits (MRLs) could be further strengthened in certain instances by reviewing the sampling strategy e.g. the possibility of sampling suspect animals delivered to slaughterhouses and ensuring on farm sampling is performed throughout the winter period.

Follow up action in the case of non-compliant test results is taken and this includes on-site inspections, sampling of additional animals or products and the prohibition of placing relevant products on the market. These follow up actions are generally satisfactory. However, in the case of some non-compliant results, there were long delays before the competent authorities (CAs) verified corrective action was taken and product was placed on the market before re-sampling results were available to the CA.

A network of official laboratories has been established for the analysis of samples from live animals and animal products for residues and contaminants. Most analyses are carried out in other countries of the European Economic Area (EEA) and the relevant laboratories are appropriately designated and accredited. Sampling instructions are in place though the time between taking a sample and receipt of laboratory results can be prolonged. This has the potential to delay follow-up actions in the event a non-compliant result is detected.

All sectors responsible for distribution and use of VMPs are subject to official controls and the respective responsibilities of the Icelandic Food and Veterinary Authority (MAST) and the Icelandic Medicines Agency (IMA) are well defined. Collaboration between the two organisations facilitates planning of the residue monitoring control plan and the authorisation of VMPs in Iceland.

The report includes a number of recommendations addressed to the Icelandic CA aimed at rectifying identified shortcomings and enhancing the official controls system in place.

ESA | EFTA Surveillance Authority

Table of Contents

1 Introduction

The remote audit took place in Iceland from 31 May to 14 June 2021. The audit team comprised two auditors from the EFTA Surveillance Authority ('the Authority').

A pre-audit questionnaire was sent by the Authority to the Icelandic Ministry of Industries and Innovation ('the Ministry') on 31 March 2021. A reply ('the pre-audit document') was provided on 14 May 2021.

The opening meeting was held remotely with representatives of the Ministry, the Icelandic Medicines Agency (IMA) and the Icelandic Food and Veterinary Authority (MAST) on 31 May 2021. At the meeting, the audit team confirmed the objectives and scope of the audit and the Icelandic representatives provided additional information to that set out in the pre-audit document.

Throughout the audit, representatives from the head office of MAST participated in all meetings.

A final remote meeting was held with the relevant competent authorities (CAs) on 14 June 2021. At this meeting, the audit team presented its main findings and preliminary conclusions from the audit.

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

2 Objective and scope of the audit

The objective of the audit was to evaluate:

- The effectiveness of official controls related to residues of veterinary medicinal products, pesticides and contaminants in live animals and animal products.

The scope of the audit included:

- Terrestrial and aquatic animals;
- The planning process and implementation (at central and district level) of the annual residue monitoring control plan (RMP) for live animals and animal products;
- Follow up actions taken after non-compliances have been detected, including communication between the different CAs involved;
- The capacity and analytical capability of the laboratory network; and
- The distribution and use of veterinary medicinal products.

The assessment was carried out based on the legislation referred to in Annex 2 to this report. The assessment was further based on the competent authorities ('CAs') response to the pre-audit document.

The evaluation included the gathering of relevant information and appropriate verifications. This was undertaken by means of interviews/discussions and the review of relevant documents and records in order to ascertain both the normal control procedures adopted and the measures in place to ensure that necessary corrective actions are taken when necessary.

The remote meetings with the CAs selected for documentary review of official controls during the audit are listed in Table 1.

Table 1: Competent authorities and establishments/sites reviewed during the mission

Relevant CA, establishment or site	Number of meetings	Comments
Central competent authorities (CCAs)	3	An initial, a clarification and a final meeting between the audit team and the Icelandic CAs
District Competent Authorities	2	
Slaughterhouse	1	
Laboratory	1	
IMA	1	

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;

c) Article 116 of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products ('OCR'), as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement.

Legislation relevant to this audit is listed in Annex 2.

4 Background - Previous missions

4.1 Background information

This audit was performed remotely due to the Covid-19 pandemic and consequential restrictions on travel. A programme of remote meetings and interviews was arranged with staff of the Central and District CAs. The findings and conclusions of this remote audit of CA performance are limited in certain aspects where the audit team was, for example, unable to verify fully CA activities at establishment level. Such verification may be necessary at a future date when travel is again permitted.

Each year the Authority conducts an assessment of the Icelandic RMP against the requirements of the relevant European Economic Area ('EEA') legislation[1]. This includes an evaluation of the number of samples planned against the minimum number of samples required by relevant EEA legislation.

4.2 Previous missions

The Authority carried out a mission to Iceland from 8 to 12 February 2016 regarding the application of EEA legislation related to control of residues and contaminants in live animals

[1] Directive 96/23/EC, Commission Decision 98/179/EC and Commission Decision 97/747/EC. The Official Controls Regulation (EU) 2017/625, implemented in Iceland on 20 March 2020, repeals Directive 96/23 (Article 146(1) of the OCR) but includes a transitional period during which States of the EEA must continue monitoring residues in accordance with the requirements of Directive 96/23/EC (Article 150 of the OCR).

and animal products, including controls on veterinary medicinal products (VMPs). The final report can be found on the Authority's website (www.eftasurv.int).

5 Findings and conclusions

5.1 Competent Authorities

Legal Requirements

Articles 4, 5 and 6 of Regulation (EU) 2017/625

Findings

5.1.1 *Personnel and staff training*

1. Training in relation to residues and official sampling is mainly based on new employees accompanying more experienced staff on sampling duties. More recently, on-line training on residues sampling in aquaculture was delivered to a small number of MAST staff.

2. Staff guidance on sampling is available and all sample submission forms include guidance on sampling. Staff interviewed were generally knowledgeable on procedures and how to target animals for sampling.

5.1.2 *Audits and verification / supervisory activities*

3. According to the pre-audit document, an internal audit on official controls related to the use and registration of VMPs in primary production and slaughterhouses was carried out in 2018. However, the internal audit did not focus on implementation of the RMP. The CA confirmed that this topic would be considered when programming future internal audits.

4. Planning and supervision of the RMP is mainly the responsibility of the senior veterinary officer of residues (SVOR) at MAST. SVOR sends out monthly sample requests (including sample submission forms and packaging), issues a veterinary certificate for shipment of laboratory samples from Iceland to the designated laboratories in other EEA countries and receives all residue laboratory results.

Conclusions

5. Implementation of the RMP is regularly monitored by SVOR which helps ensure all sampling is completed.

5.2 Planning of residue monitoring

Legal Requirements

Article 5 of Directive 96/23/EC

Findings

6. MAST is responsible for preparing the annual RMP, collecting related samples and following up non-compliant analytical results. SVOR acts as programme co-ordinator for terrestrial and aquatic animals and animal products on behalf of the CCA. SVOR

drafts the national RMP and then distributes it to the districts. Direction on procedures for planning the RMP is available in a guidance document on the control of residues in animal products (Document LBE-010).

7. MAST confirmed that a selection of official data is used during the planning process. SVOR calculates the number of samples to be collected for each relevant substance listed in Annex I of Directive 96/23/EC, based on production figures for each category of animal or product from the previous year. Data on the number and distribution of livestock in the districts is obtained from the Ministry's Bústofn Database.

8. Other sources of information used for planning includes:

    - Details of on farm use of VMPs in cattle and horses recorded by private veterinary surgeons in the Búfjárheilsa database;
    - Annual sales of VMPs to wholesalers provided by IMA;
    - Throughput data from all slaughterhouses from the previous year;
    - Production data for aquaculture obtained from the annual report on veterinary fish diseases;[2] and
    - Milk production data.

9. In addition, European Union Reference Laboratories (EURLs) for residues evaluate RMPs of EEA countries on an annual basis. This involves, *inter alia*, recommending the minimum number of analytes for the relevant substances listed in Annex I of Directive 96/23/EC, the screening and confirmatory method to be used and the recommend matrices for the different substances by species or product.

10. Following the EURLs' evaluation of Iceland's 2020 RMP, the CA confirmed they had followed some of the EURLs' advice e.g. poultry samples were added in the 2021 RMP for nitrofurans and nitroimidazoles while for cattle, horses, pigs and sheep, aminoglycoside and nitroimidazole samples were added.

11. The CA confirmed that, based on the above information, SVOR divides the farm and aquaculture sampling between districts. The RMP includes details on the specific slaughterhouses and egg packing stations where samples should be taken. It is the responsibility of districts to determine which farms are selected for sampling based on their risk assessment of the farms and local knowledge.

12. The CA confirmed that the RMP is usually circulated to districts in February of the sampling year. The audit team confirmed that the 2019 RMP was distributed in March of that year whilst the 2020 RMP was distributed in February of that year. E-mail correspondence from SVOR to districts was presented to the audit team which confirmed that slaughterhouse samples were allocated for collection in January 2020 to compensate for late circulation of the RMP.

13. According to information provided in the pre-audit document, samples for VMP residue analysis in cattle and horses are collected throughout the year, with the choice of residues sampled being dependent on trends in VMP sales. Samples from hen eggs and raw milk (bovine) are collected over three sampling periods each year. More recently, collection of farmed fish samples has changed from three to five sampling periods per year. The CA confirmed that the timing of the sampling periods during the year, for example for milk samples, vary from one year to the next.

[2] https://www.mast.is/static/files/skyrslur/arsskyrsla-dyralaeknis-fisksjukdoma-2020.pdf

Conclusions

14. The planning process for the RMP is well established, undertaken in a timely manner and a comprehensive selection of data, from several official sources, contributes to this process.

5.3 Implementation of residue monitoring control plan

Legal Requirements

Article 5(2)(c) and Annexes III and IV of Directive 96/23/EC, Annex to Decision 97/747/EC and Annex to Decision 98/179/EC

Findings

15. Each month, based on RMP requirements, SVOR sends sampling requests to the districts concerning farm and aquaculture samples and directly to official staff in slaughterhouses where samples must be collected. These requests consist of a summary of all samples required for the month and a partially completed sample submission form for each sample required. The sample submission forms are pre-populated with the sampling period and a deadline for return of the samples. In addition, the required sampling material and packaging material for shipment of samples is supplied.

16. Different sample submission forms are available for each species sampled. All submission forms include guidance related to collection, packaging, sample security (use of a tamperproof seal with a unique identification number), storage conditions and details of where the sample must be sent. In addition, a guidance document on control of residues in animal products (LBE-010) provides more detailed information on sampling and sample preparation. The CA confirmed that there is generally no public access to those areas of MAST's premises where samples are stored.

17. Official staff in the districts select holdings for sampling based on risk factors and local knowledge. District staff confirmed that they also attempt to rotate farms so that the same farms are not repeatedly targeted for sampling. Collection of samples is performed by official veterinarians (OVs) and official employees of MAST.

18. OVs interviewed confirmed that it was their decision when to take samples during a given sampling period. Reasons provided by OVs for selecting which animals to sample included targeting adult cows for Group B(1) substances and male animals for Group A substances, the age of the animal (for example, sampling of both adult sows and younger fattening pigs) and ensuring sampling from a cross section of both large and small producers.

19. Documentation relating to milk samples taken for the monitoring of certain substances and residues in one district were reviewed by the audit team. This confirmed that the requirement that 70% of bovine milk samples be analysed for at least four analytes from at least three of the substance groups A6, B1, B2(a) and B2(e) was not met, contrary to Section B. (a) of Part 1. of Chapter 1of the Annex to Decision 97/747/EC.

20. According to the pre-audit document, in some cases sampling is carried out with prior notice. This may occur if samples are collected far away from the district offices or due to unpredictable weather at the sampling location. One OV interviewed confirmed that official control visits to fish slaughterhouses are announced on the same day that

sampling is due to take place. However, if there is no slaughter taking place on the day of the announcement, this may result in the food business operator (FBO) receiving several days notice of an official control taking place. Notwithstanding, guidance document LBE-010 on the control of residues in animal products states that sampling should be carried out without prior notice.

21. The CA confirmed that no casualty animals (animals with an injury which does not prevent their transport to a slaughterhouse for welfare reasons) had been targeted for residue sampling in at least the previous three years. This type of animal is not expected to be slaughtered and is therefore more likely to be undergoing treatment with legal substances (where the withdrawal period is not met) or prohibited substances when presented at a slaughterhouse. Furthermore, there are no arrangements in place to facilitate the sampling of such animals – for example, a financial mechanism to pay for such sampling and no arrangements with the relevant laboratories to process such samples.

22. The CA recognises the seasonality of lamb slaughter in Iceland when targeting sampling for this species. Consequently, the CA confirmed that all residue samples from sheep are collected during the short slaughter season between September and October each year.

23. According to the pre-audit document, sampling at terrestrial or aquatic farm level is not usually performed during the winter months and this was further confirmed by the CA during the remote audit.

24. MAST staff interviewed were generally knowledgeable concerning sampling instructions and could competently describe procedures for sampling, sample preparation and dispatch.

25. According to information provided by MAST, two Icelandic laboratories receive and store samples prior to shipment to the relevant designated laboratories in other countries (see paragraph 29). These two Icelandic laboratories record sample arrival and shipment dates. This information, together with a certificate of shipment and all sample analysis results being sent to SVOR, is relied on by SVOR to monitor implementation of the RMP.

Conclusions

26. Implementation of the RMP is structured at district level with very clear guidance on sampling requirements provided to staff throughout the year. The RMP is generally implemented on time, with sampling spread throughout the year in most cases.

27. Certain aspects of surveillance for detection of illegal administration of prohibited substances or the abusive administration of approved substances and of controlling compliance with maximum residue limits (MRLs) could be further strengthened by reviewing the residues sampling strategy. In particular, the exclusion of casualty animals from targeted sampling weakens the surveillance strategy. Slaughter of these animals is not anticipated and there is consequently an increased likelihood that they may be undergoing treatment with legal (where the withdrawal period is not met) or prohibited substances when presented at a slaughterhouse. In addition, on farm sampling should be spread over the whole year and bovine milk samples should be analysed consistently.

5.4 Official sampling and laboratory analysis

Legal Requirements

Articles 5, 39 and100 of Regulation (EU) 2017/625 and Annex to Decision 98/179/EC

Findings

28. The analysis of samples from live animals and animal products in order to detect residues and contaminants is, with the exception of samples analysed to detect heavy metals, performed in laboratories situated in other EEA countries.

29. According to information provided by MAST, the Swedish Food Agency (SFA) and Matis are the designated national reference laboratories (NRLs) for residues in terrestrial animals and heavy metals respectively. The Danish Veterinary and Food Administration (Foedevarestyrelsen) acts as an official laboratory for residues in aquaculture samples.

30. In accordance with Article 100(1) of Regulation (EU) 2017/625, the Ministry has designated SFA as NRL for the detection of residues and Matis as NRL for, *inter alia*, heavy metals in feed and food. The SFA designation is valid until 31 December 2023 and outlines, *inter alia*, responsibilities and mechanisms for dispute resolution. In addition, there is an annual agreement between MAST and SFA which details, *inter alia*, the total number of samples to be analysed by SFA during the year, analytes to be tested for and when samples are scheduled to arrive at SFA.

31. SFA operates in accordance with EN ISO/IEC 17025 and is accredited[3] in accordance with that standard by the Swedish national accreditation body (SWEDAC). Accreditation includes the methods of laboratory analysis. The laboratory methods used by SFA, on a selection of reports reviewed by the audit team, were included in the current SFA accreditation document issued on 30 October 2020.

32. In accordance with Articles 39(1) and 100(2) of Regulation (EU) 2017/625, MAST has not organised audits of SFA, relying instead on its accreditation status.

33. The CA provided evidence that SFA provide scientific and technical advice to MAST. Examples included e-mail correspondence between the two parties related to non-compliant results and advice included in non-compliant test reports.

34. The Ministry has designated Matis as NRL for, *inter alia*, heavy metals in food. In addition, Matis is accredited by SWEDAC and the scope of the accreditation includes heavy metals and methods used for chemical analysis.

35. According to information provided in the pre-audit document, once samples have been collected at district level, they are sent to one of two Icelandic laboratories for storage prior to shipment to the relevant designated laboratory for analysis. Samples should be sent to the relevant designated laboratory in the second or third week of the month following the sampling period.

36. The audit team reviewed turnaround times for samples taken as part of the 2020 RMP which were stored and then shipped via the two Icelandic laboratories. Samples were regularly kept in the two Icelandic laboratories for four to five weeks prior to shipment.

[3] https://swedacsearchfiles.blob.core.windows.net/omfattning/A000034-001%20omfattning%201457%20201030.pdf

37. A sample of non-compliant results reviewed included examples where it took between sixty to seventy days from initial sampling to analysis results being made available to CA.

38. The annual agreement between MAST and SFA (see paragraph 30) permits an unspecified extension to the normal four week deadline, from the date of receipt of the sample by the designated laboratory until completion of the relevant sample analyses, during a three month summer period and in December.

39. The CA confirmed that SFA participates in workshops and proficiency tests (PTs) organised by relevant EURLs. MAST do not routinely receive results of PTs and last requested results in September 2019.

40. The official veterinary certificate issued by SVOR which accompanies each consignment of samples leaving Iceland includes details of the number of samples sent for analysis, animal health attestations and sample storage instructions.

41. All laboratory results are sent to SVOR. Results are filed in the official electronic filing system "One-CRM." The CA demonstrated separate folders for the results received from each laboratory and a separate folder for each non-compliant result and associated correspondence/documentation.

Conclusions

42. A network of official laboratories has been established for the analysis of samples from live animals and animal products to detect residues and contaminants. Most analysis is carried out by laboratories in other EEA countries which are appropriately designated and accredited. Sampling instructions are in place, although the time between taking a sample and the receipt by SVOR of the analysis results is sometimes prolonged. This can be due to delays in shipping the samples to designated laboratories or in delays in analysis of the samples by the designated laboratories. This has the potential to delay follow-up actions by the CAs in the event that a non-compliant result is detected.

5.5 Follow up of non-compliant results

Legal Requirements

Article 138 of Regulation (EU) 2017/625

Article 4 of Delegated Regulation (EU) 2019/2090

Findings

43. MAST publishes an annual report on fish diseases which includes a statement on VMP use in Icelandic aquaculture production. The most recent report for 2020[4] confirms that no samples analysed during 2020 (as for the years before) contained VMP residues (antibiotics) or other contaminants.

44. According to information provided by MAST, there were a number of non-compliant results in terrestrial animals during the period 2018 - 2020. A summary of non-compliant results during this period is available on MAST's homepage[5]. These were detected in a range of species and consisted mainly of detection of thiouracil, 17α-Nor-testosterone

[4] https://www.mast.is/static/files/skyrslur/arsskyrsla-dyralaeknis-fisksjukdoma-2020.pdf
[5] https://www.mast.is/is/um-mast/eftirlitsnidurstodur/efnaleifar-i-dyraafurdum

and 17 β-Nor-testosterone, dioxins in eggs, anticoccidials exceeding statutory MRLs in finishing feed for broilers and anthelmintics.

45. The audit team reviewed a selection of non-compliant results with a focus on those detected in districts where staff were interviewed. For these cases, follow up actions generally included a combination of on-site inspections, sampling of additional animals or products and prohibiting relevant products being placed on the market.

46. A guidance document on control of residues in animal products (LBE-010) is available and outlines how non-compliant results should be followed up. Further guidance is available in the MAST Quality Manual. Specifically, Document VLY-102 ("How to deal with suspicion of illegal treatment with VMPs") and Document VLY-104 ("How to deal with samples exceeding the MRL").

47. In one non-compliant case involving anthelmintics, there was a seven week delay between sampling and the SVOR receiving a positive laboratory result. Documentation was available to confirm that the slaughterhouse had been contacted in relation to recall of the product. However, there was no visit to the farm of origin. Rather, a telephone interview was conducted between district staff and the farmer. In addition, food chain information presented with the animal from which the positive sample was taken was misleading (there was no record of VMPs administered) and the Búfjárheilsa database did not, at the time, record any use of VMPs on the relevant farm.

48. The audit team reviewed another non-compliant case involving detection of a coccidiostat in finisher poultry feed above the MRL. Follow up actions included taking additional feed samples and also liver samples at slaughter. An official control report required the FBO to immediately ensure that all slaughter flocks were given a final feed which did not contain the relevant coccidiostat above the MRL. Correspondence was provided to the audit team which confirmed that the CA had also contacted all poultry companies in writing highlighting this incident.

49. Notwithstanding, there was an interval of approximately nine months between issue of the non-compliance for coccidiostat being present in finisher feed and verification that corrective action had been taken. Also, at the time of slaughter of the poultry and the sampling of offal for presence of the relevant coccidiostat, the slaughtered poultry and offal were placed on the market without a test result being available.

Conclusions

50. Follow up action is taken in the case of non-compliant test results. This may include on-site inspections, sampling of additional animals or products and prohibiting the placing on the market of relevant products. These follow up actions are generally satisfactory, although in some cases reviewed there were significant delays in verification by the CA of remedial action taken by the relevant FBO and products were placed on the market before test results were available to confirm their fitness for human consumption.

5.6 Distribution and use of Veterinary Medicinal Products

Legal Requirements

Articles 65 to 70 and 80 of Directive 2001/82/EC

Article 10 of Council Directive 96/23/EC

Findings

51. Part 1 of the Country Profile[6] for Iceland describes the organisation of control systems for VMPs and residues. In summary, IMA is responsible for licensing and official controls related to the manufacture and distribution of VMPs to pharmacy level and for official controls over medicated feedstuffs. MAST is responsible for the control of VMPs use by veterinary practitioners and on farms.

52. The CA confirmed that the use of VMPs in aquaculture is under the supervision of MAST. Aquaculture must not be treated with antibiotics unless there is a veterinary diagnosis or results from an accredited laboratory indicate a requirement for antibiotic use.

53. According to the pre-audit document, inspection manuals are available for CA staff performing official controls on farms. These manuals include a section on VMPs which outline areas for verification e.g. correct recording of VMP use, withdrawal periods and product expiry dates. The CA confirmed that these official controls are carried out regularly i.e. on pig and poultry farms annually, on dairy farms every second year and on sheep farms every third year. The audit team were provided with examples of non-compliances detected during these official controls.

54. All pharmacies dispensing VMPs (mainly private veterinary practices) were subject to a desktop official control by IMA during 2019. Approximately 20% of these pharmacies received a further control in 2020. No non-compliances were recorded during these controls.

55. A list of VMPs with marketing authorisation in Iceland is publicly available on the IMA website[7]. IMA confirmed that all VMPs with a marketing authorisation in Iceland originate in the European Union ('EU'). Furthermore, private veterinarians must apply to IMA for approval if they wish to use VMPs with no marketing authorisation in Iceland. An example of communications between IMA and MAST concerning one such application was provided to the audit team.

56. Information on annual sales of VMPs to wholesalers is provided to MAST by IMA (see paragraph 8) and the CA confirmed that MAST and IMA intend to reinstate regular meetings between the two organisations.

57. The CA confirmed that all FBOs operating slaughterhouses receive a daily list of animals which have been treated with VMPs and where the withdrawal period has not been met. The list includes animals permanently excluded from the food chain due to treatment with certain VMPs. The list is derived from the Búfjárheilsa database.

58. The audit team reviewed the case of one horse treated with a non-steroidal anti-inflammatory drug (NSAID) in early 2021. A daily list of animals sent to FBOs, reviewed during the audit, confirmed that the horse had been permanently excluded from the food chain as required.

Conclusions

59. All sectors responsible for distribution and use of VMPs are under official control and responsibilities are well defined between MAST and IMA. Collaboration between the two organisations is in place which facilitates planning of the RMP and authorisation of VMPs in Iceland.

[6] https://www.eftasurv.int/cms/sites/default/files/documents/gopro/Icelandic%20Country%20Profile%20-%20Part%201%20-%20for%20web%20publishing.pdf
[7] https://www.lyfjastofnun.is/wp-content/uploads/2021/06/dyralyf-med-markadsleyfi-x.xls

6 Final meeting

A final remote meeting was held on 14 June 2021 with representatives from the relevant ministries and CAs present. At this meeting, the audit team presented its main findings and preliminary conclusions. During this meeting, the CCA did not express any disagreement with the findings and preliminary conclusions of the audit team.

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Iceland should notify the Authority no later than 5 November 2021 of additional corrective actions planned or already taken other than those already indicated in the reply to the draft report of the Authority. In case no additional corrective actions have been planned, the Authority should be informed of this. The Authority should be kept continuously informed of such changes made to the already notified corrective actions and measures, including changes to the deadlines indicated for completion and also the completion of the measures included in the timetable.

No	Recommendation
1	MAST should ensure that there is no undue delay between collecting residue monitoring samples and receipt of laboratory analysis results as required by Article 5(1)(a) of Regulation (EU) 2017/625. Recommendation based on conclusion at paragraph 42. Associated findings: paragraphs 35, 36, 37, 38 and 47.
2	MAST should ensure that the residues sampling strategy is designed to maximise the detection of illegal treatments and the control of compliance with the maximum residue limits for residues of veterinary medicinal products as required by Point 2.2 of the Annex to Decision 98/179/EC. Recommendation based on conclusions at paragraph 27. Associated findings: paragraphs 21 and 23.

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

Authority	EFTA Surveillance Authority
CA	Competent authority
CCA	Central competent authority
DG SANTE	Directorate-General for Health and Food Safety of the European Commission
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EU	European Union
EURL	European Union reference laboratory
FBO	Food business operator
IMA	Icelandic Medicines Agency
MAST	Icelandic Food and Veterinary Authority
MRL	Maximum residue limit
NRL	National reference laboratory
NSAID	Non-steroidal anti-inflammatory drug
OCR	Official Controls Regulation (EU) 2017/625
OV	Official veterinarian
PT	Proficiency Test
RMP	Residue monitoring control plan
SFA	Swedish Food Agency
SVOR	Senior Veterinary Officer of Residues
SWEDAC	Swedish national accreditation body
VMP	Veterinary medicinal product

Annex 2 - Relevant legislation

The following EEA legislation was taken into account in the context of the audit:

a) The Act referred to at Point 11b. of Part 1.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EU) No 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC, as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement;

b) The Act referred to at Point 13 of Part 7.1. 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 specific and sectoral adaptations referred to in Annex I to that Agreement;

c) The Act previously referred to at Point 2 of Part 7.1. of Chapter I of Annex I to the EEA Agreement, *Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC,* as amended (repealed by Regulation (EU) No 2017/625 but remains relevant as per Article 150 of that Regulation);

d) The Act referred to at Point 13 of Part 7.2. 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*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

e) The Act referred to at Point 14 of Part 7.2. 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 and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

f) 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 as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex II to that Agreement;

g) The Act referred to at Point 11bu. of Part 1.1 of Chapter I and Point 31qu. of Chapter II of Annex I and at point 164u. of Chapter XII of Annex II to the EEA Agreement,

Commission Delegated Regulation (EU) 2019/2090 of 19 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and Council regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substance, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

Annex 3 - Plan for corrective measures and actions

Table of corrective actions ESA mission 2021/ICE/1 to evaluate official controls on residues and contaminants in live animals and animal products

No	Recommendation	Corrective action	Date of compliance
1	MAST should ensure that there is no undue delay between collecting residue monitoring samples and receipt of laboratory analysis results as required by Article 5(1)(a) of Regulation (EU) 2017/625. Recommendation based on conclusion at paragraph 42. Associated findings: paragraphs 35, 36, 37, 38 and 47.	MAST will try to ensure shorter turn-around-time for future NRCP, by shipping the samples as soon as possible to the designated laboratories and possibly by shortening the sampling period each month. An updated SOP (LBE-010) will be presented to all employees of MAST collecting official residue samples, with a shorter turn-around time. Also, the annual contracts with each designated laboratory will be reviewed were the main focus will be on shorter turn-around time of official samples from Iceland.	Updated SOP (LBE-010) and introduction thereof to employees of MAST collecting official residue samples: The end of January 2022. Reviewed annual contracts: End of May 2022.
2	MAST should ensure that the residues sampling strategy is designed to maximise the detection of illegal treatments and the control of compliance with the maximum residue limits for residues of veterinary medicinal products as required by Point 2.2 of the Annex to Decision 98/179/EC. Recommendation based on conclusions at paragraph 27. Associated findings: paragraphs 21 and 23.	MAST will make a request to designated laboratories regarding sending suspect samples whenever needed, and in addition request that suspect samples will be analysed without unnecessary delay. Also, the relevant SOPs will be updated accordingly and a sampling form for suspect samples will be designed and introduced to employees of Mast collecting official residue samples. MAST will ensure that on-farm sampling will be distributed further over the sampling year. Also, MAST will look in to the possibility to sample milk over more than 3 sampling periods.	Updated SOPs/ sampling form for suspect samples and introduction thereof to employees of MAST, collecting official residue samples: End of January 2022. Updated NRCP with further distribution of both on-farm level samples and possibly milk samples: End of May 2022.