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Brussels, 23 January 2009

Final report

EFTA Surveillance Authority mission to

ICELAND

23 to 30 September 2008

regarding the application of EEA legislation related to

health conditions for the production and the placing on the market of fishery products

Comments to the draft report are referred to in the report in *underlined italic*. Information on the corrective actions already taken and planned by the Icelandic competent authority are also included in Annex 4 to the final report.

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1 Introduction

The mission took place in Iceland from 23 to 30 September 2008. The mission team was composed of three inspectors from the EFTA Surveillance Authority (the Authority) and one observer from the Food and Veterinary Office (FVO) of the European Commission. For most of the mission the team was split in two sub-teams, each visiting different parts of the country.

The opening meeting was held with representatives of the Icelandic competent authorities *Matvælastofnun* (MAST)/Icelandic Food and Veterinary Authority and representatives of *Heilbrigðiseftirlit Suðurlands/*the Environmental and Public Health Authority (LPHA) of South Iceland on 23 September 2008 at MAST's headquarters in Selfoss. At this meeting the representatives of the competent authorities provided additional information to the Icelandic reply to the Authority's pre-mission questionnaire.

The previous mission in the field of health conditions for the production and the placing on the market of fishery products was carried out in Iceland in 2005.

Throughout the mission, representatives of the MAST headquarters accompanied the two sub-teams. In addition, representatives of the relevant Inspection Bodies (IBs) and the LPHA accompanied the mission teams during the visits to the establishments.

A final meeting was held at the MAST headquarters in Selfoss on 30 September 2008, at which the mission team presented its main findings and some preliminary conclusions to representatives from the Ministry of Fisheries and Agriculture, MAST and two LPHAs.

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

2 Mission objectives and proceeding

The main objective of the mission was to assess the application by the Icelandic competent authorities of Council Directive 91/493/EEC on health conditions for the production and the placing on the market of fishery products, and related legislation (see Chapter 3 and Annex 2 to this report). In particular, emphasis was put on the performance of the competent authority in relation to the approval of fishery products establishments (including vessels), the carrying out of official controls (including the level of assessment of documentation and facilities, reports from visits, follow-up of findings and enforcement of legislation), and, finally, training of staff.

The meetings with the competent authorities and the visits to laboratories, aquaculture farms, vessels, landing sites, auction markets and establishments during the mission are listed in Figure 1. None of the vessels visited were on the itinerary agreed before the start of the mission. Additionally, one establishment and one ice production plant were added to the itinerary after the opening meeting.

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Figure 1: Competent authorities, laboratories and food business undertakings visited

	Number	Comments
Competent authorities	5	Opening and final meeting, two meetings with different Local Public Health Authorities and one with MAST
Laboratories	2	One private and one public
Landing sites	3	Two during landing/unloading of fish/fishery products
Auction markets	2	
Ice processing plants	2	Only the external facilities checked in one
Aquaculture farm	1	
Vessels	6	Five fishing vessels and one factory vessel. All visited at the quayside
Establishments	13	Producing different types of fishery products

3 Legal basis for the mission

The legal basis for the mission was:

a) Point 4 of the Introductory Part of Chapter I of Annex I to the EEA Agreement.

b) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (Surveillance and Court Agreement).

c) 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.*

d) The Act referred to at point 6.1.8 of Chapter I of Annex I to the EEA Agreement, *Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement, and in particular Article 8 of that Act.

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

4 Information on production and trade

Annex 3 contains information on the number of aquaculture farms, factory vessels, freezer vessels, listed fishing vessels, landing sites, auction markets and establishments in Iceland. Furthermore, information is given about the production volume of the main species produced in Iceland, as well as the main countries importing Icelandic fishery products, both EEA countries and third countries. Finally, information about countries exporting fishery products to Iceland is also included in the above mentioned Annex.

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5 Previous missions

The last mission to Iceland was carried out in September 2005. That mission was a follow-up mission to the one carried out in September 2004. The reports from the previous missions are available at http://www.eftasurv.int/.

In the report from the mission carried out in 2005 the Authority concluded, *inter alia*, that the competent authority could not ensure that the persons responsible for establishments had taken all necessary measures so that, at all stages of the production of fishery products, the specifications of Council Directive 91/493/EEC were complied with. The Authority also had conclusions related to the establishments' HACCP systems, the facilities and equipment, to hygiene and production, to labelling and to storage of products.

6 Main findings

6.1 National legislation

The general framework for the functioning of MAST is laid down in Act No 80/2005, with amendments made by the Icelandic Parliament by Act No 167/2007 of 14 December 2007. The latter lays foundation for the merger of control and administrative authorities and services dedicated to agriculture, fisheries and food into a single inspection and administrative body, MAST. For the LPHAs the general legal framework is Act No 7/1998 and later amendments.

A number of regulations have been adopted by the relevant Ministries in order to incorporate EEA Acts relevant for the handling, processing and distribution of fishery products. The Icelandic legislation that provides the legal basis for MAST's application of Council Directive 91/493/EEC is implemented in Act No 55/1998 regarding handling, processing and distribution of fishery products, and Regulation No 233/1999 on fishing, handling, processing and distribution of fishery products. The latter entered into force on 30 March 1999.

The Food Act No 93/1995 defines duties and responsibilities of the LPHA. However, according to information provided by MAST representatives this act does not implement Council Directive 91/493/EEC.

6.2 Follow-up of previous missions

In the reports from the missions in 2004 and 2005 the Authority pointed out, amongst others, that it was not in compliance with Council Directive 91/493/EEC that one establishment could have more than one approval number. As part of the general review mission carried out early 2006 the Icelandic competent authority informed the Authority that it was in the process of amending the procedures so that approved establishments only received one approval number. However, during this mission MAST representatives informed the mission team that these procedures were still not finalised and that establishments still receive approval numbers according to the different types of production.

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In order to improve the HACCP competence among staff of the fishing industry the competent authority informed the Authority that courses of 1½ to two weeks duration involving the Icelandic Polytechnic School were scheduled. During this mission, MAST representatives informed the mission team that this had not been established. However, representatives of the competent authority had participated in several courses arranged by DG SANCO.

During the general review mission the competent authority informed the mission team that issues related to production of ice, including competent authority responsibility and inspection of such production were in the process of being assessed. The Authority was also informed that all such establishments would be registered. During this mission, representatives of MAST and one of the LPHAs informed the mission team that issues such as competent authority responsibility had still not been finalised.

6.3 Competent authorities

6.3.1 General information

The Ministry of Fisheries and Agriculture is, *inter alia*, responsible for the implementation and application of the European Community (EC) acts incorporated into the EEA Agreement and falling within the scope of this mission.

MAST is the competent authority related to application of the relevant EC acts incorporated into Annexes I and II of the EEA Agreement and applicable to Iceland.

6.3.2 Organisation and budgetary allocations

MAST is also responsible for inspections and administrative work for matters concerning the handling, transport, storage and processing of fishery products and for most other objects within the scope of this mission. Act No 80/2005, with amendments made by the Icelandic Parliament's Act No 167/2007 of 14 December 2007, provides the legal background for the establishment of MAST. With the entry into force of the latter Act, the Icelandic Food and Veterinary Authority has, *inter alia*, taken over the tasks and duties of the Agricultural Authority of Iceland and the food safety and food control tasks and duties of the Environmental and Food Agency of Iceland and the Icelandic Directorate of Fisheries.

The headquarters of MAST are situated in Selfoss, about 50 km east of the capital city of Reykjavík. MAST has 14 District Offices covering all parts of the country where District Veterinarians and Official Veterinarians render services in accordance with the relevant legislation. At the District Office in the capital area, MAST runs an import/export unit rendering services to individuals and businesses engaged in import and export. MAST is also responsible for the operation of border inspection posts (BIPs) for the control of import of foods from third countries. The ten LPHAs are organised under the respective municipalities. However, their work is coordinated by MAST.

All staff within MAST carrying out official food control has a university degree in natural sciences, mainly food science, biology or veterinary medicine. The Division of Food Safety and Consumer Affairs in MAST is responsible for official control related to production of fish products intended for export to other countries. The official inspections are carried out by the staff of the two IBs. The LPHAs are responsible for official control of fishery products establishments regarding environmental issues and for food control at retail level.

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The Ministry of Fisheries and Agriculture is responsible for the budgetary allocations to MAST. Costs related to inspections carried out by the IBs are paid directly to the IBs by the fishery products establishments. Costs related to the inspections carried out by the LPHAs' are covered by payments from the establishments inspected.

6.3.3 Inspection bodies

Two accredited IBs, acting on behalf of MAST, perform inspections of factory vessels, certain fishing vessels, auction markets and fishery processing establishments. The legal basis for the work of the IBs is article 16 of Act No 55/1998.

The IBs shall undertake inspections of health conditions for the production of fishery products for human consumption intended for export to other countries. Such inspections comprises checking hygienic conditions, premises, equipment and own-checks. The IBs regularly submit the results of their inspections to MAST, which handles actions that need to be taken on the basis of their results. MAST has developed an inspection manual for fishery products, inspection reports etc. in order to harmonise and facilitate inspections and regular reporting of findings to MAST.

The IBs shall operate in accordance with the standard of ÍST EN 45004; 1995 and are defined according to Article 4.2.1 of this standard as a type A inspection bodies. Both IBs are accredited by the Icelandic Metrology and Accreditation Service, in accordance with the provisions of Regulation No 450/1997 on surveillance framework and working methods of accredited inspection bodies in the fish industry.[1]

An inspection body shall be operated as a private company that charges an inspection fee to its clients, i.e. the licensed producers,. At the opening meeting MAST representatives informed the mission team that MAST does not consider the fees to be paid to the inspection bodies to be its concern. The actual fees paid are therefore not known to MAST.

6.3.4 Human resources

MAST has seven senior staff members and two inspectors involved in monitoring and follow-up of the inspections carried out by the IBs. The IBs have a total of 6,5 man labour years divided into two directors and 2,5 man labour years in one of the IBs and two man labour years in the other.

At the time of the mission, information about the number of fishery products establishments approved by the LPHA and the man labour years spent on inspections etc. of such establishments was not available to the mission team.

6.3.5 Training of personnel

According to information received from MAST it appears that the staff of one of the IBs regularly participates in different training courses, including in training courses on HACCP and own-checks systems. However, one staff member in one of the IB had not received formal HACCP training despite having been involved in inspections of fishery products establishments for almost one year. For the LPHAs relevant training on HACCP and own-checks has not been offered to the staff recently.

[1] *See comment from Mast on page 28 of the report.*

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6.3.6 Approval and suspension/withdrawal of approval of vessels and fishery products establishments

Before sending an application to MAST for approval of a fishery product establishment, the LPHA must have confirmed that the facilities are in compliance with a number of environmental requirements. In the application it must also be documented that at least one person in the establishment has satisfactory knowledge about own-checks systems including HACCP. Documentation of participation in a one or two day's course organised in Iceland is considered sufficient. In addition, the applicant must have signed a contract for regular inspections with an accredited IB.

Relevant information in the establishment's quality manual must also be enclosed with the application. MAST carries out an inspection of the facilities only if the information submitted is sufficient. If corrective action is not necessary MAST issues a temporary approval and the establishment receives an "IS number". This approval is valid for three months and in this period the own-checks system must be finalised in order to receive a permanent approval. MAST carries out an inspection at the end of the three months period in order to verify that the quality system is functioning. However, the step concerning the final approval was still pending because MAST has yet to revise the inspection manual where this approval will probably influence the frequency of IBs inspections. A date was not set at the time of the mission. For factory vessels the procedure is the same apart from the approval by the LPHA.

Approvals can be suspended or withdrawn following a notice from the IB, because of a serious deficiency, following findings during an inspection by MAST or after a notification by the establishment. MAST representatives informed the mission team that withdrawals of approvals following inspections by MAST are exceptional.

Approval of an establishment at retail level starts with an application from the establishment's representative to the LPHA. After a positive assessment of the documentation and an inspection with favourable result the approval is issued by the board of the LPHA. The criteria for the approval is included in the application in addition to the date of expiry and other information such as the risk class (indicating the number of inspections by the LPHA per year).

The mission team observed that some of the establishments visited were not approved for some of the activities taking place although they were in full activity.

In one establishment the mission team observed that following relocation of production from one facility to another and changing activity so that it only produced for the Icelandic market, the official control had been transferred from the old competent authority to the LPHA. The LPHA had issued an approval document without having inspected the establishment. Moreover, at the time of the mission the establishment had not been inspected although ten months had elapsed since issuing of the approval. Furthermore, eight months had elapsed from the change introduced by Act No 167/2007 which stipulates that from 1 January 2008 the LPHAs should only inspect establishments at retail level.

Another establishment producing, *inter alia*, fish balls and smoked fish fillets was not approved by the competent authority according to Council Directive 91/493/EEC.

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In another establishment visited, the establishment's representative informed the mission team that 3-4 years ago the company started production of ready to eat salted, frozen sushi and that soon production of smoked, pasteurized cod roe for export to the EU would commence. The establishment had not been approved by MAST for any of these products. Moreover, a representative from the IB had informed the establishment that no additional approval was required for these productions.

Furthermore, one establishment had acquired new facilities for a cold store and had requested an approval from MAST. However, although the cold store had been in operation for one year MAST had not issued any approval.

Finally, the mission team observed that an establishment smoking fishery products had received an approval number without having a HACCP system for such production in place.

6.3.7 Harmonisation of official control

According to information received from MAST in the reply to the pre-mission questionnaire and during the mission, procedures are established and applied for harmonising the work of the inspectors of the IBs. However, information about any harmonisation of the inspections carried out by the IBs and by the LPHA was not available.

The harmonisation is done based on the inspection manual issued by MAST. In addition to the manual the inspectors of MAST carry out inspections together with the inspectors of the IBs. During these inspections the inspector of the IB is the leader and the MAST inspector observes and comments on the performance. The inspectors from MAST also sometimes inspect establishments shortly after inspections by the IBs. Non-conformity reports are written and discussed in meetings with all inspectors from the IBs. Once a year MAST is also comparing the performance of all inspectors from MAST and the IBs based on statistical information from the inspection reports. A seminar is arranged with the IBs where the results are presented and some of the findings in the evaluation are discussed.

According to representatives from two LPHAs, harmonisation of inspections between the different LPHAs is mainly ensured through applying the inspection handbook prepared for the LPHAs by the former central competent authority (the Environmental and Food Agency of Iceland).

6.3.8 Carrying out of official controls

Approved establishments with all year production and factory vessels should be inspected four times per year. For other vessels, including freezer vessels, the number of inspections is two times per year for vessels bigger than 15 GRT (Gross Register Tonnage). Smaller fishing vessels are inspected by inspectors from MAST on an irregular basis, usually only when deficiencies are reported. MAST representatives informed the mission team that such inspections are very rare carried out.

An inspector of one of the IBs informed the mission team that he follows the same checklist for almost all inspections of establishments. The inspections can last for three to six hours depending on how detailed he is looking into the different points in the checklist.

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A copy of the checklist with the observations made is left at the establishment after each visit.

Representatives of two LPHAs informed the mission team that establishments producing fishery products under their control are in general inspected once per year. The inspections normally last for two to four hours. Both these LPHAs issue reports on-the-spot and the representatives of the establishments must sign to acknowledge that the report has been received. Additionally, one of the LPHAs also sends the inspection reports to the establishments afterwards for the representative to comment on the content. In another LPHA letters are only sent to the establishments when corrective action is required.

In one of the LPHA visited a bill is sent to the establishment after each inspection. The amount goes directly into the LPHA's account. A representative from another LPHA informed the mission team that after calculation of the number of inspections to be carried out each year and the time anticipated to be used, a bill is sent to all establishments at the beginning of the year.

A representative of one of the IBs informed the mission team that one of the accredited IBs is offering employees of establishments a discount on official checks of their cars if the establishment is signing a contract with that IB.

One LPHA representative informed the mission team that checks of retail sale of fish is the responsibility of the LPHAs. However, according to information provided by MAST and LPHA representatives, official control of the production of dried fish is only done in establishments producing for export. Official control of production of dried fish for the Icelandic market is not carried out.[2]

In general, the mission team revealed serious deficiencies in the HACCP systems in all the establishments visited. None of these had been addressed in the latest reports of official inspections carried out in these establishments. Moreover, in two of the establishments visited the representatives of the IB and of MAST confirmed to the mission team that the establishment's own-checks systems had not been checked so detailed that it could be revealed that relevant hazards had not been identified.

In one establishment visited the mission team observed that during the previous missions carried out by the IB only very few minor non-compliances had been registered in the reports and normally only one or two serious deficiencies. During this visit the IB noted almost three times as many non-compliances as the average non-compliances registered in the last nine reports. The mission team registered almost seven times as many deficiencies as the average reported by the IB.

In one of the ice production plants visited, the mission team observed that neither MAST nor the LPHA had approved the plant. Representatives of the two competent authorities informed the mission team that it had not been decided between them who should have the responsibility. The representatives also informed the mission team that they had not inspected the plant for the purpose of checking compliance with the legislation covered by the scope of the mission. The representatives also informed the mission team that no official samples had been taken.

[2] *See comment from MAST on page 28 of the report..*

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During the visit to an establishment approved for ready to eat fishery products, several non-compliances noted by the mission team had not been reported by the IB, which had carried out a complete inspection of the establishment one week earlier. Flaking paint in a corner in the high risk area was the only remark made by the IB. In another establishment a severe potential risk of cross contamination was observed by the mission team. This had not been registered by the IB.

A MAST representative informed the mission team that it had been decided that vessels should only be visited at the quayside. The representative also informed the mission team that quota inspectors from the Directorate of Fisheries check some hygienic issues when inspecting factory vessels in the open sea. Findings are reported to MAST. It is the intention that such checks will be formalised in an agreement between the two competent authorities.

6.3.9 Enforcement

According to the reply to the pre-mission questionnaire any infringements by stakeholders will be resolved in accordance with articles 28 to 31 of Act No 93/1995 on foodstuffs. Where there is deemed to be a risk that foodstuffs may cause severe damage to public health, the Minister of Fisheries and Agriculture may order necessary precautionary and preventive measures. Before any action, the Minister shall consult the Chief Epidemiologist and the Director General of MAST.

MAST may also suspend or limit the production and distribution of foodstuffs and impound the same if there is reason to suspect that foodstuffs do not fulfil the provisions of the Foodstuffs Act or other related acts or regulations.

Anyone convicted of a violation against the provisions of the Foodstuffs Act shall pay the entire cost incurred in obtaining samples, their testing and other costs resulting from the violation. In other respects, the provisions of the Act No 7/1998 on hygiene and pollution control shall apply concerning procedures, rulings and penalties. According to the latter, if violations of the food laws or regulations are considered serious, penalties can be given either in the form of fines or the relevant person can also be sentenced to prison for a maximum of four years.

MAST has similar procedures in place regarding fishery products and similar provisions can be found in articles 19, 20 and 32 in Act No 55/1998 regarding handling, processing and distribution of fishery products. Violations of the Act or implementing regulations can result in penalties, either in for form of fines or imprisonment.

Representatives from two LPHAs informed the mission team that normally enforcement starts with the actions to be taken following an inspection. If relevant action is not taken the LPHA can issue a warning. The next step will be a fine. However, issuing of fines are normally not done. The last option is to stop the production temporarily or withdrawal of approval. According to a representative of one LPHA, imposed stops in production or withdrawal of approvals happen only on rare occasions.

Due to some severe unhygienic observations made outside one establishment not intended to be visited during the mission, MAST representatives decided to make an inspection the following day. A representative of the establishment was notified of the intended visit.

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However, the day after the production facilities were without power supply and a representative from the establishment was not present. A proper inspection could therefore not be carried out. Information about any follow-up by MAST was not provided during the drafting of the report.[3]

The mission team observed that the approach to its observations varied between the food business operators. For example, in one establishment the management acknowledged the comments made and took immediate actions to correct deficiencies identified. In another establishment, despite the unhygienic conditions and the serious risk for cross-contamination observed, *inter alia*, tubs containing fish in stagnant water at a temperature higher than that of melting ice, cross-contamination between two sections of the processing areas and severe conditions in the cold store, no corrective action were taken on-the-spot.[4]

6.3.10 Official sampling

Although the inspection manual prepared by MAST contains details on official sampling, representatives of both MAST and the IBs normally do not take any samples. In one of the establishments visited a LPHA representative informed the mission team that official samples are not taken when inspecting establishments. However, the LPHAs are taking samples of the municipal water according to the relevant Icelandic legislation related to potable water.[5]

6.4 Laboratories

6.4.1 General information

In the reply to the pre-mission questionnaire, MAST stated that laboratories performing analyses required in the fishery legislation must be accredited. However, no formal procedures for approval of laboratories by the competent authority is in place in Iceland.

6.4.2 Laboratories

In one of the laboratories visited a letter of approval for analyses of fishery products was presented to the mission team. The letter was issued in 2003 by the competent authority and was related to the, at that time, accredited methods in the laboratory. The mission team observed that the competent authority had not inspected any of the two laboratories visited, nor had there been any exchange of information related to the accreditation status of the two laboratories visited since 2003.

During the visits, representatives of the two laboratories informed the mission team that not all methods of analyses performed in the context of control of fishery products were accredited. In one of the laboratories visited this concerned histamine, heavy metals, *Clostridium perfringens*, and parasites in fishery products and physical parameters in water. In the other laboratory visited this concerned methods for analysing Total Volatile Basic Nitrogen (TVB-N) and Trimethylamine Nitrogen (TMA-N). In the last laboratory, the methods were also not validated.

[3] *See comment from MAST on page 28 of the report..*
[4] *See comment from MAST on page 28 of the report.*
[5] *See comment from MAST on page 28 of the report.*

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Moreover, during the visit, representatives of one of the laboratories and of MAST informed the mission team that, for analyses related to the establishments' own-checks, accreditation of the methods was not required.

One of the laboratories visited is the only one in Iceland performing histamine analyses. However, histamine analyses were currently only carried out on samples taken of fish meal and in case of suspected outbreaks of histamine (2-3 cases in the last few years). Consequently, analyses for histamine in fishery products are not performed in Iceland despite the fact that Iceland is exporting extensive amounts of, for example, mackerel and herring.

The mission team visited one public laboratory analysing samples taken based on Council Directive 91/493/EEC. Methods for analysing samples of fishery products for, *inter alia*, *Salmonella* sp., *Listeria monocytogenes*, *Staphylococcus aureus*, thermotolerant *E. coli*, total viable count (TVC) at 30°C and TVB-N were accredited by the Swedish accreditation body, SWEDAC.

For potable water and ice methods for analysing for *E. coli*, *Entercocci*, coliform bacteria and mesophilic TVC at 30°C were accredited. However, the method used for analysing samples for *Clostridium perfringens* was accredited for food but not for water.[6] For chemical analyses of water and for certain contaminants (dioxins, PCB's and organochlorinated substances) samples are sent to accredited laboratories abroad.

Representatives of the laboratory informed the mission team that samples analysed at the laboratory are mainly received from food business operators in the context of their own-checks. Samples are normally not received from the competent authorities or the IBs. However, official samples of fishery products taken at retail level are received from the LPHAs. In addition to these samples, analyses are carried out of samples taken for special monitoring programs funded by MAST. These samples are related, *inter alia*, to programmes for undesirable substances in seafood, pesticides, heavy metals etc. A report of a survey carried out in 2006 on several parameters, including Cadmium in flesh of fishery products, was provided to the inspection team. The inspection team was informed that annual surveys of this kind have been carried out since 2003.

As regards parameters listed in Council Directive 95/2/EC and used in the fish processing establishments, a survey on phosphates had been carried out several years ago. However, any survey on the use of polyphosphates, metabisulphites etc. has not been carried out.

In the event of notifiable diseases (*Listeria monocytogenes* and *Salmonella*) results of analyses carried out by the laboratory are sent to the owner of the sample and to the CA.

Costs of analyses are covered by the food business operators for own-checks, by the LPHAs for samples taken at retail level, and by MAST for other special services. The costs of analyses are negotiable and are influenced by the parameters to be analysed, the number of samples, the amount of samples etc.

During the visit to the laboratory facilities, the inspection team observed that analyses were being performed for TVB-N and TMA-N by an extraction method which was not

[6] *See comment from Mast on page 28 of the report..*

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accredited, instead of using their accredited method for TVB-N. Very few analyses for freshness are performed in this laboratory.

To the knowledge of the management of this laboratory and of MAST representatives, none of the Icelandic fishery products establishments have internal laboratories. The mission team observed that several samples are received at the laboratory from different establishments as part of their daily and weekly own-checks. However, inconsistencies in the food business operators' use of the sampling forms provided by the laboratory were observed, in particular related to the indication of matrix.

A laboratory representative informed the mission team that no samples of smoked salmon for analyses of *Listeria monocytogenes* had been tested in the laboratory.

In the other laboratory visited good management, adequate facilities and technical knowledge and traceability were observed. This was a private laboratory and consultancy and it had maintained an accreditation SWEDAC since 1999. Accredited methods are for all the microbiological parameters referred to in Commission Decision 93/51/EEC and all microbiological methods for water unless *Clostridium perfringens*. However, the methods used for checking the freshness, TVB-N and TMA, were neither accredited nor validated. The laboratory receives a small amount of samples from the LPHAs, mainly water samples. Furthermore, sulphites are analysed at the laboratory, but only for the lobster industry. Three lobster companies have been sending 20-40 samples per year for sulphite testing. About ten companies in Iceland are approved for lobster processing and they mainly export their products. Samples have not been analysed for polyphosphates at this laboratory.

Representatives of the laboratory informed the mission team that the food business operator's choice of laboratory is mainly a question of price.

In one of the establishments visited, the mission team observed that a sample of roe to be analysed for *Listeria* spp. had been sent to this laboratory. However, although positive for *Listeria* spp. the positive finding had not been followed up. Representative of MAST informed the mission team that it is only obligatory to notify findings of *Listeria monocytogenes*. Furthermore, the consignment was rejected by the company but in the absence of notification to the competent authority it was not possible to trace this product further.[7]

The laboratory participates in proficiency tests organised by Statens Livsmedelsverk (SLV) in Sweden for microbiology and Association of Analytical Communities (AOAC) for chemicals in fish meal.

The mission team observed that forms for sampling were in place but the producers did not always use them. The reports with the results of analyses carried out in this laboratory only contain the value of the parameter tested. In case of values exceeding the limits fixed by the legislation, no further information is provided.

[7] *See comment from MAST on page 28 of the report...*

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Laboratory representatives informed the mission team that training of staff was difficult due to funding and the possibility to find relevant courses. However, internal and external training were properly documented.

6.5 Establishments

6.5.1 Own-checks systems

6.5.1.1 Pre-requisites

All establishments had to some extent established the necessary pre-requisites. However, it was observed in at least two establishments that the relevant samples were not always taken.

In one establishment visited some pre-requisites had been established. However, it could not be verified that these had been followed by the management. For example, according to the pre-requisites one sample of potable water should have been taken every year in May, but the sample had not been taken in 2008. Furthermore, samples for checking the quality of cleaning had not been taken in 2008.

A representative of one of the establishments visited informed the mission team that during one year only one sample was taken of potable water and one of ice. The number of samples equals the official minimum requirements.

In one establishment visited cleaning of the ice machine had not been considered in the own-checks system despite repeated non-conformity with the microbiological requirements.

6.5.1.2 HACCP plans

A complete HACCP plan was not observed in any of the establishments visited. In general, in most of the establishments visited staff involved in own-checks documented limited knowledge about basic HACCP principles.

In one of the establishments visited, the mission team observed that a multidisciplinary team dealing with establishing the own-checks system had not been established. Furthermore, not all potential biological, chemical or physical hazards that could be reasonably expected to occur, had been listed at each step of the process, and no critical control points had been identified. Finally, in this establishment no samples were taken of the end product.

In another establishment visited producing both pelagic and white fish products no critical control points had been identified. Not all relevant biological hazards had been identified and the establishment representative was not familiar with possible histamine risks in the relevant fish species.

In one of the establishments approved by the LPHA, the mission team observed an own-checks system only consisting of pre-requisites. This establishment was producing a number of ready to eat products, the majority containing fish. A HACCP system had not been established although it was a legal requirement. However, it was not evident from the Icelandic legislation whether a HACCP system should have been established before

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approving the establishment. Finally, according to the Icelandic legislation, the HACCP requirement was not absolute for some small size establishments.[8]

In two establishments approved for production for the Icelandic market only, the mission team observed that the relevant hazards had not been identified and it could not be documented that risk analyses had been carried out. These establishments, producing several different types of fishery products both fresh and frozen, had not identified any critical control points. Moreover, end product testing in these two establishments was either absent or very rare.

In one establishment a HACCP plan for a new product (smoked cod roe) had not been prepared. However, the product was already in test production and a consignment had been sent to France. Moreover, the HACCP plan for sushi and for caviar contained 15 CCP for each of the products. It was also observed that the establishment had mixed control points with critical control points.

In one establishment producing smoked and marinated salmon the mission team observed that for example *Listeria* spp. had not been related to a CCP in the production process. The reason was, according to the establishment's representative, that *Listeria* spp. could not be eliminated if present. Moreover, only three samples had been taken and analysed for *Listeria* spp. the last three years and a monitoring programme for checking possible presence of *Listeria* spp. in the environment had not been established.

6.5.2 Hygiene and production

A clear separation between clean and contaminated parts of the production facilities was not observed in any of the establishments visited. Staff outside the working facilities in working clothes was observed to walk directly into the processing area in several establishments. Doors to the outside not closing tightly were observed in most of the establishments visited. In one establishment the mission team observed that two doors to the outside from the processing area were kept open for a long period during processing of fishery products. Furthermore, in all establishments visited the same fork lifts were used both outside and in the presumed clean parts of the processing areas. Outside all establishments some presumably clean and some very dirty tubs were stored exposed to all kinds of possible contamination.

In all establishments visited fish was kept in tubs not ensuring adequate drainage of melt water.

In some of the establishments visited a general absence of necessary hand washing facilities in the processing areas was observed together with insufficient procedures for washing hands. However, this serious shortcoming had not been registered in the reports from the IB or from MAST.

By-products were treated as waste in several establishments visited although the products were sent to other establishments for further processing before being exported to third countries where they were intended for human consumption.

[8] *See comment from MAST on page 28 of the report..*

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In one establishment approved by the LPHA without being inspected and not inspected since April 2007, waste and large amounts of waste water were accumulating on the floor in the processing area. Waste was kept in tubs without lids in the production area during a half hour break. In addition, large amounts of fish fillets were kept on the working tables and in crates during the break. The competent authority measured the temperature in several of the fish fillets to be above 4°C, some as high as 8 and 9°C. A door to one of the refrigerated rooms was not functioning and therefore kept open at all times. Unpacked, wrapped and packed products were observed in the refrigerated room together with several other types of products from another establishment. None of the fishery products in that room were labelled. Furthermore, a machine for washing crates was located close to the ice machine where ice was kept in a tub without protection. Tubs were washed in a corner of the processing area close to where heading and filleting took place, and the floor around the filleting tables was hosed while filleting took place.

In another establishment serious deficiencies with regard to respecting hygienic procedures were observed. In the reception area fish fillets intended for further processing were temporarily stored in closed tubs together with contaminated salt intended for use in the production. Staff was handling mechanically recovered fish using dirty gloves without hand washing facilities available. Exposed packaging materials in an open area ready for use with a high risk of contamination by staff with dirty working clothes used in the reception area for raw material. In the processing area the mission team registered temperature between 8 and 9,5°C in fishery products.

In one establishment the mission team observed that the blueprint of the production facilities and the facilities did not correspond. A wall had been removed between the processing area and the area for packaging of exposed final products, considerably increasing the risk of cross contamination of these products. This important modification had neither been addressed by the IB nor by MAST.

In the same establishment salt was reused and kept in open tubs and cleaning of metal plates with a high pressure hose were taking place near the fillets for human consumption. The cold store was not well maintained and fishery products fit for human consumption were found together with a big quantity of fishery products unfit for human consumption.

In several of the establishments' reception areas different types of handling and transport of fish and fishery products took place at the same time increasing the risk of cross contamination of products. Fish fillets were observed on the processing tables during breaks in at least two establishments visited.

In one establishment the mission team observed that smoking of fish fillets took place in a small smokehouse placed outside the processing facilities. The fillets were taken out of the production area for smoking and in, again, without any cover or protection.

6.5.3 Premises and equipment

In general, there were no clear separation between clean and contaminated parts of the facilities in any of the establishments visited. Untidy and dusty mezzanines were observed in at least three of the establishments visited. The use of stand alone freezer containers for storage of, *inter alia*, final products was observed in several of the establishments visited. As a consequence, doors to the outside are open during processing of fishery products in order to transport final products out of the processing area.

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In several of the establishments visited the production areas, and in particular in the processing areas and in the storage rooms, the mission team observed condensation on the walls and the ceiling, flaking paint on the floors and walls, damaged doors and accumulation of waste water on the floors.

6.5.4 Packaging, storage and transport

In all establishments visited wrapping and packaging materials were not stored protected from dust and contamination, and often also stored together with other production equipment, machinery or spare parts. Wrapping and packaging materials were often stored in different parts of the production area in an amount exceeding the actual need.

MAST representatives informed the mission team that no formal procedures are in place for approval and control of transport vehicles used for carrying fishery products.

6.6 Vessels

In one port the mission team visited five fishing vessels, mainly fresh fish trawlers, all Icelandic. Two of the vessels were built in the 1970ies while three others were only a few years old. The maintenance in the two oldest ones was limited although the processing equipment was in an acceptable state of repair. However, all cutting boards in all the vessels visited were not well maintained and in one of the older boats the mission team observed a wooden working table. The newest vessels were in a good state of repair.

All vessels were either keeping ice in tubs or in parts of the holds. However, the ice kept in parts of the holds was often contaminated. The mission team also observed that dirty tubs were sometimes taken into the holds contrary to how this was described in the established procedures. Some staff was also walking in presumably clean tubs intended for storage of fish.

The mission team also visited a factory vessel at the quayside. The vessel was built in the late 1980ies but was in an acceptable state of repair. During the visit parts of the processing equipment was under maintenance. However, the equipment observed was in an acceptable state of repair. The owner of the vessel was in the process of updating the HACCP system. The mission team observed that not all relevant hazards had been identified. The vessel did not have any critical control points. A blueprint of the processing area was not available. Wrapping materials were not always kept protected from dust and contamination.

In all the vessels visited the working clothes were in an acceptable state of cleanliness. However, they were not always kept hygienically when not used.

6.7 Ice production plants

Representatives of both the LPHA and of MAST informed the mission team that neither of the competent authorities had approved any of the ice processing plants with regard to the legislation within the scope of the mission. Moreover, neither of the competent authorities are controlling ice production plants in Iceland.

One of the ice production plants visited was producing approximately 15.000 tons of ice per year. A representative of the plant informed the mission team that one sample was taken of the water and one of the ice per year.

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The mission team observed that some equipment in one of the storage rooms for ice was being repaired. However, the ice around the equipment had been contaminated since it had not been protected. The mission team also observed that parts of the walls in the room were dirty and that a lot of rust had accumulated in parts of the ceiling. This rust was falling down and contaminating the ice.

Outside another ice processing plant the inspection team observed that ice was filled in contaminated tubs in an unsheltered area outside the plant.

6.8 Traceability

During the visit to an establishment approved for ready to eat fishery products the mission team observed that traceability could not always be assured. One consignment of shrimps originating in Russia with a Spanish certificate was possible to be traced back to the boat. However a consignment of more than 110.000 kg of shrimps from a third country with an EU veterinary certificate upon entering the EU could not be traced forward to the papers for the shrimp shipment.

In the reception area of another establishment visited the mission team was able to trace back to the origin only one of three tubs checked.

6.9 Aquaculture farms

The mission team visited one aquaculture farm for artic char and Atlantic salmon. It was found in very good condition, necessary bio security measures had been implemented. The rearing tanks were clean and well maintained.

6.10 Landing sites and auction markets

The mission team visited one landing site during unloading of fresh fish. The unloading appeared to be well organised and took place rapidly. The fish was normally unloaded in tubs on ice and placed in refrigerated containers for export to mainland Europe. However, the mission team observed that small amounts of fish was kept on the quayside for a long period, some of it with very little ice. The mission team also observed that the forklift, when placing one tub on top of another, contaminated the ice and the fish in the lower tub.

Another port was also visited which had three main landing sites, one for fishery products coming with vessels from other countries, one area for small fishing vessels and another area for domestic trawlers. In the latter, fish was unloaded and transported in closed containers. Only the section dedicated to fishery products originating from abroad was fenced off.

The mission team observed landing of fish from a factory vessel. A representative from the vessel informed the mission team that unloading could take up to 12 hours. The mission team observed that frozen fish in carton boxes were kept on pallets on the quayside for a long period of time.

A representative from the owner of the vessel informed the mission team that this could happen since the boxes had to be sorted on land. This took place in a separate building on the quayside without any refrigeration. Pallets of frozen fish were kept in this building for a long period (probably a few hours). The mission team also observed that some pallets

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were placed into freezer containers. However, the cooling systems on the containers were not turned on.

One of the auction markets visited was also approved for gutting fish. The auction market was well maintained and tidy. However, in a corner of the facilities salting of fish took place from time to time. In this area both empty tubs, tubs with waste and fish on salt were kept. This activity had received a separate approval from MAST. Fish not fit for human consumption was delivered to an establishment for production of feed. Fish of poor quality was delivered to an establishment for drying and export to a third country and intended for human consumption.

Another auction market visited was found in reasonable conditions of maintenance. However, the mission team observed a large number of dirty tubs stored within the premises and some of these tubs had labels indicating that they had not been cleaned for weeks. At the auction market no special facilities were dedicated for cleaning and disinfecting of tubs and crates. Tubs and crates were therefore cleaned and disinfected in a corner using high pressure equipment and a combination of chlorine and soap. The representative of the auction market informed the mission team that they accepted dirty crates coming back from the customers into the main market area where crates with fish on ice were stored.

6.11 Miscellaneous

In one of the establishments visited producing salted fish fillets the mission team was informed by the food business operator that polyphosphates were used in the brine for cod fillets before dry salting. This had been addressed in reports from the IB and followed-up by MAST. However, any conclusion on possible illegal use of polyphosphates had not been made.

7 Final meeting

A final meeting was held on 30 September 2008 at the MAST headquarters in Selfoss with representatives from the Ministry of Fisheries and Agriculture, MAST and LPHAs. At this meeting, the mission team presented its main findings and some preliminary conclusions from the mission.

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.

The competent authority did not disagree to the findings presented. However, the Director General of MAST was of the opinion that the mission team, by inspecting establishments approved by the LPHA had defined the scope of the mission as being outside what could be considered relevant in relation to Council Directive 91/493/EEC. To this the mission team replied that it had only inspected establishments that were producing fishery products and consequently should comply with Directive 91/493/EEC.

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8 Conclusions

8.1 Competent Authority

8.1.1 Approval fishery products establishments

Compliance with Council Directive 91/493/EEC and, in particular, Article 7 thereof, could not be ensured since approval of two establishments producing fishery products was not based on that Directive.

In general Iceland has defined local market as the whole of Iceland. This is not in accordance with Article 2(15) of Council Directive 91/493/EEC.[9]

8.1.2 Enforcement

Compliance with Article 7(4) of Council Directive 91/493/EEC could not always be ensured as MAST had not taken the necessary measures in cases where its inspections had revealed that establishments were not complying with the requirements of the Directive.

8.1.3 Training of personnel

The training given to the inspection staff could not always ensure that inspectors were allowed to assess the establishments' own-checks systems. Full compliance with Article 7 of Commission Decision 94/356/EC on own-checks could therefore not be ensured.

8.1.4 Special checks

Compliance with Council Directive 91/493/EEC, and in particular point II(3)(A)(b) – on Histamine - of Chapter V of the Annex thereto, could not be assured, since no sampling and analyses were carried out on sensitive fish species.

8.1.5 Own-checks including HACCP

Full compliance with Article 6(1) of Council Directive 91/493/EEC on own-checks and Commission Decision 94/356/EEC on HACCP could not be fully ensured as MAST had not ensured that persons responsible for establishments had taken the necessary measures for the specifications in the Directive to be complied with at all stages of the production of fishery products and in particular in relation to the establishments' own-checks.

8.2 Farms, vessels and establishments

8.2.1 Own-checks systems including HACCP

Deficiencies related to the own-checks systems and HACCP were observed in all establishments visited. For example, all potential hazards had not been listed and the plans were not updated and in accordance with the actual production taking place. Compliance with Article 6 of Council Directive 91/493/EEC and with Commission Decision 94/356/EEC could therefore not be ensured.

8.2.2 Hygiene and production

Processing and handling of fishery products were not always carried out in such a way as to avoid contamination or spoilage. This is not in compliance with the requirements of, *inter alia*, points I, II, III and IV of Chapter IV of the Annex to Council Directive 91/493/EEC.

[9] *See comment from MAST on page 29 of the report.*

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8.2.3 Premises and equipment

There was not a clear separation between clean and contaminated parts of the facilities in any of the establishments visited. Some outer doors were not closing properly or not kept closed during processing. Compliance with the requirements in point I and II(A) of Chapter III of the Annex to Council Directive 91/493/EEC could therefore not always be ensured.

8.2.4 Packaging, storage and transport

In most of the establishments visited packaging materials were not protected from dust and contamination during storage. This is not in compliance with the requirements of Point 4 of Chapter VI of the Annex to Council Directive 91/493/EEC.

8.2.5 Traceability

Fishery products were observed without labelling. This is not in compliance with Chapter VII of Council Directive 91/493/EEC.

8.2.6 Miscellaneous

Polyphophates were used in the production of salted fish fillets. This is not in compliance with Article 2(4) and Annex IV of the European Parliament and Council Directive 95/2/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.

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Annex 1 List of abbreviations and terms used in the report

AOAC	Association of Analytical Communities
Authority	EFTA Surveillance Authority
BIP	Border Inspection Post
CA	Competent Authority
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis and Critical Control Point
GRT	Gross Register Tonnage
IB	Inspection Body
IQF	Individual Quick Frozen
LPHA	*Heilbrigðiseftirlit*/Local Public Health Authority
MAST	*Matvælastofnun*/Icelandic Food and Veterinary Authority
SLV	Statens Livsmedelsverk
SWEDAC	Swedish Board for Accreditation and Conformity Assessment
TVB-N	Total Volatile Basic Nitrogen
TMA-N	Trimethylamine Nitrogen

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Annex 2 Other relevant legislation

In addition to the acts referred to in Chapter 3 of this report, the main EEA Acts regarding health conditions for the production and the placing on the market of fishery products and relevant for this mission are:

a. The Act referred to at point 6.1.9 of Chapter I of Annex I to the EEA Agreement, *Council Directive 92/48/EEC of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC.*

b. The Act referred to at point 7a of Chapter II of Annex XX to the EEA Agreement, *Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.*

c. The Act referred to at point 6.2.13 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 93/51/EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish.*

d. The Act referred to at point 6.2.14 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 93/140/EC of 19 January 1993 laying down the detailed rules relating to the visual inspection for the purpose of detecting parasites in fishery products.*

e. The Act referred to at point 6.2.21 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 94/356/EC of 20 May 1994 laying down the detailed rules for the application of Council Directive 91/493/EEC, as regards own health checks on fishery products.*

f. The Act referred to at point 6.2.28 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 95/149/EC of 8 March 1995 fixing the total volatile basic nitrogen (TVB-N) limit values for certain categories of fishery products and specifying the analysis methods to be used.*

g. The Act referred to at point 18 of Chapter XII of Annex II of the EEA Agreement, *Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs,* as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.

h. The Act referred to at point 54zb of Chapter XII of Annex II to the EEA Agreement, *European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners,* as corrected and amended.

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i. The Act referred to at point 54zn of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs,* as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.

j. The Act referred to at point 54zn of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 221/2002 of 6 February 2002 amending Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs*.

k. The Act referred to at point 54zn of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 78/2005 of 19 January 2005 amending Regulation (EC) No 466/2001 as regards heavy metals.*

l. The Act referred to at point 54zn of Chapter XII of Annex II to the EEA Agreement, *Council Regulation (EC) No 2375/2001 of 29 November 2001 amending Commission Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs*.

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

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

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Annex 3 Information on production and trade

Figure 2: Number of different aquaculture farms, vessels, landing sites, auction markets and establishments registered by the CAs

Types	Number
Aquaculture farms (2006)	
Broodstock farms (total)	16
Farmed	12
Wild	4
Hatcheries	11
Ongrowing farms	32
Vessels (2007)	
Factory vessels	39
Freezer vessels	22
Fishing vessels	1,536[10]
Landing sites (2007)	59
Auction markets (2007)	27
Establishments (2007)	458[11]

Figure 3: Total production in tonnes for the years 2005 to 2007 with breakdown by main products

Categories	2005	2006	2007
Catch fisheries			
Frozen	330,028	317,096	619,534
Salted	49,732	48,848	47,662
Fresh	89,993	87,275	77,959
Dried	14,935	14,748	13,312
Fish meal/fish oil	245,694	166,600	184,281
Other	24,133	26,631	10,690
Total catch fisheries	**754,514**	**661,197**	**619,534**
Aquaculture			
Aquaculture shellfish/molluscs	5	7	10
Aquaculture fish	8,415	9,953	5,583
Fresh water prawns	0.1	0.2	0.3
Abalone	4	0.4	0.4
Total aquaculture	**8,424.1**	**9,960.6**	**5,593.7**
Total	**762,938.1**	**671,157.6**	**625,127.7**

[10] Included in this number are 1,101 vessels of size below 15 GRT.

[11] One establishment can have more than one approval number/license. According to information from MAST representatives provided during the mission, the total number of establishments is between 250 and 300.

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Figure 4: Production placed on the EEA market with a breakdown by main importing EEA countries (ISK)

	2005	2006	2007
Belgium	3,721	4,407	4,167
United Kingdom	28,512	31,149	34,636
Denmark	4,804	4,726	6,459
France	5,711	6,811	5,689
Netherlands	5,937	8,648	9,136
Norway	3,360	6,029	6,999
Portugal	4,825	5,109	7,217
Spain	12,677	14,156	12,833
Germany	5,688	6,325	5,626
Other	10,368	10,184	9,321
TOTAL EEA	**85,603**	**97,544**	**102,083**

Figure 5: Production placed on third country markets (ISK)

	2005	2006	2007
Europe other than EEA	2,998	4,711	5,652
Asia	8,019	8,383	7,747
Africa	3,253	3,844	3,740
North America	9,966	9,468	7,947
South America	238	345	317
Oceania	54	80	132
TOTAL third countries	**24,531**	**26,831**	**25,535**

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Annex 4 Comments to the draft report

Comments from MAST to the factual content of the report

6.3.3. Paragraph 3. The IBs are accredited according to the standard IST EN ISO/IEC 17020:2004 “General criteria for the operation of various types of bodies performing inspections”. They are accredited by SWEDAC the Swedish Board for Accreditation and Conformity Assessment.

6.3.8. Paragraph 6. The statement in the last sentence that official control of production of dried fish for the Icelandic market is not carried out is not correct. The official control has been carried out by LPHAs in all areas except one.

6.3.9. Paragraph 6. The representative from MAST told the Food Business Operator (FBO) that the conditions outside the establishment were not acceptable and if the conditions would be unchanged the day after, without specifying the time further, MAST would temporarily withdraw their approval.
The inspection team visited the establishment at 8 o’clock next morning, but the FBO phoned later that morning having arrived at 9 o’clock. Since this incident the establishment has been visited twice by MAST inspectors and once by an inspector from the IB. The producer has stopped production temporarily.

6.3.9. Paragraph 7. During the visit in the mentioned establishment, the MAST representative discussed this issue with the FBO. His reaction was to remind what had been said at the opening meeting just before, that this inspection was an inspection of the CA and the comments made were to be understood as comments on the industry in general but not particularily on this establishment.
MAST fully agrees with the comment from ESA that the FBOs have different approach to observations made during inspection visits. However in this case the FBO should have taken immediate action where possible.

6.3.10 The Inspection Manual contains no details of official sampling. In the Inspection Manual there is a description of the sampling that should be performed by the producers (i.e water, cleaning verification) and the inspectors should check if the FBOs have taken the samples.

6.4.2. Paragraph 6. Since the potable water is mostly from wells, there has been no demand for analysis of *Cl. perfringens* in water and therefore no need for accreditation of the method.

6.4.2. Paragraph 16. According to Icelandic law the laboratories should notify MAST if they report samples positive for *Listeria monocytogenes*. There is no obligation to notify Listeria spp.

6.5.1.2. Paragraph 4. All establishments controlled by the LPHA should have an own-check system according to the Icelandic legislation. Three levels of own-checks system have been defined. The type of production and the size of establishment is taken into account when deciding the level in each case.

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8.1.1. From January 2008 all establishments producing fishery products should have been inspected and approved by MAST, regardless whether the establishments produced fishery products for export or domestic markets. The inspections and approval ought to be in compliance with Act no. 55/1998 regarding handling, processing and distribution of fishery products and Regulation no. 233/1999 on fishing, handling, processing and distribution of fishery products, which implements Council Directive 91/493.

MAST will take the necessary measures to ensure that all fishery production establishments will be inspected and approved, according to the abovementioned legislation.

There are no provisions in the Icelandic legislation regarding the definition of a local market nor is there a general definition that Iceland as a whole is a local market. Neither MAST nor the Local Competent Authorities have put forward any such definition.

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Annex 5 Plan for corrective measures

Plan for corrective measures
MAST has chosen to summarize most of the answers to chapter 8 Conclusions without referring to each point in particular. Mast also refers to a letter to ESA dated 28.10.2008 regarding the first corrective actions taken.

As stated in the above mentioned letter meetings were held in October 2008 with the Ministry, stakeholders and the inspection bodies to present and discuss the preliminary results of ESA´s mission on fishery products.

ESA´s remarks concerning the establishments and the competent authorities have been analyzed. Most of the remarks concern the prerequisite programs and HACCP, design of production facilities and handling of ice, fish and fishery products and organization and harmonization of official control.

Since the production of safe fish and fishery products is the responsibility of the food business operators (FBO) a working group with participation of representatives from the stakeholders and representatives from MAST has been established. It is MAST´s opinion that steps for improvements in the fish industry must be taken in cooperation with the stakeholders.

The following steps will be taken to inform the FBOs on ESA´s findings and to increase their awareness of the situation.

- A letter where ESA´s main findings are presented will be sent to all the FBOs. Emphasis will be on the necessity of improvements in certain areas and they will be informed on amended procedures for the follow-up of serious deficiencies registered during inspections.
- Series of meetings will be arranged around the country.
- Articles will be written and published in magazines and on MAST´s website.
- Training courses dealing with requirements of legislation, GHP, HACCP and the prerequisite program will be organized in cooperation with consultants organizing such courses.

Interpretations of some requirements in the legislation will be revised. There is a need for changes in the following areas:

- Separation of clean and contaminated parts of the production facilities
- Handling of fish and fishery products
- Handling of waste
- Storage and cleaning of tubs and crates
- Handling of ice

MAST will develop guidance documents for FBOs on requirements in the legislation. Increased emphasis will be on the prerequisite program.

The following steps will be taken to improve the quality of inspections and audits:

- Inspection manual will be revised.
- Inspectors will be trained.

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- Training courses in HACCP and auditing will be organized.
- Visits to CAs and fish processing establishments in other countries will be organized.

MAST is in the process of designing a system of inspection taking into the account the risk and the past results of the food business. It is not foreseen when this work will be finished. The inspections in the fish sector will, until then, continue with a frequency of 4 inspections per year for each establishment in full year production. From 1st of January 2009 the organization of inspection will be changed. The IBs will be required to organize their inspections so that complete audit of the HACCP system will be performed once per year. In the other inspections the emphasis will be on documentation of the own-check system and the HACCP system and on specific tasks organized by MAST. The aim of these changes will be to focus on handling of fish, fishery products and waste, handling of ice, handling of tubs, handling and storage of packaging material, separation of clean and unclean areas and to improve the functioning of the HACCP systems. MAST will organize a seminar for IBs and MAST´s inspectors in the beginning of 2009 where audits of HACCP will be discussed and harmonized.

Special checks (8.1.4)
Of the clupeida family only herring (*clupea harengus*) is caught commercially in Iceland. Recently Atlantic mackerel (*Scomber scombrus*), of the scombridae family, has been caught in some quantities. The mackerel goes into fishmeal production but is also frozen on board the vessels destined for human consumption. The main markets for herring in the EEA area are Poland, Lithuania and Latvia. Mackerel is mainly sold to markets outside the EEA area.
Herring and mackerel are caught fresh and chilled immediately in RSW tanks.
The products are mainly frozen, filleted or in some cases whole. The risk of histamine contamination should therefore be minimal. MAST will however look into this in more detail and take samples of both herring and mackerel in order to evaluate the risk of histamine formation better.

Use of polyphosphates (8.2.6)
Reference is made to ESA case no. 65363 and the response by MAST. This case is still in progress and future communications will be directed to that case number.

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Timetable for corrective measures.

Description of corrective measures	Date	Responsible person
Presentation of ESA´s preliminary results. 1. Ministry 2. Stakeholders 3. Inspection's bodies	 21 October 2008 21 October 2008 24 October 2008	JG
Classification and analysis of ESA´s remarks	November 2008	DG
First meeting in a working group	9 January 2009	GG
Meeting with inspections body. Presentation and discussion of the changes in organization of inspection from January.	19 December 2008	GS
Letter to fish producing establishments	January 2009	SÖH
Series of meetings	2009	GG
Articles	2009	GG
Revision of procedures for follow up	7 January 2009	GS
Letter to inspections bodies	6 January 2009	GS
Organization of courses for FBO	January – April 2009	GG
Encourage development of sector specific guidelines on GHP and HACCP	February – May 2009	DG
Revision of interpretation of some requirements in regulation	January –April 2009	DG
Guidance for FBO on requirements in regulations	February – May 2009	DG
Harmonization of HACCP inspections	February – April 2009	GG
Revision of inspection manual	April – December 2009	DG
Training of inspectors	September – December 2009	GS
Courses for inspectors on Audits of HACCP systems	November 2009	SÖH
Visit to CA and fish producing establishments in neighbouring countries	2009	SÖH
Organization and harmonization of official control	2009	JG
Sampling of mackerel and herring for histamine analysis	September 2009	GG

ESA will be kept informed if changes are done in the time schedule and of the completion of measures in the timetable.

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