REPORT

OF A MISSION CARRIED OUT IN

PORTUGAL

FROM 21 JANUARY TO 1 FEBRUARY 2002

REGARDING THE IMPLEMENTATION OF:

COUNCIL DIRECTIVE 91/493/EEC (FISHERY PRODUCTS),

COUNCIL DIRECTIVE 91/492/EEC (LIVE BIVALVE MOLLUSCS)

Please note that certain comments from the Portuguese authorities have been included in the text of the report in bold, italic type
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<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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</thead>
<tbody>
<tr>
<td>AOAC</td>
<td>Association of Official Analytical Chemists</td>
</tr>
<tr>
<td>CRL</td>
<td>Community Reference Laboratory</td>
</tr>
<tr>
<td>DG</td>
<td>Director General</td>
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<tr>
<td>DGFCQA</td>
<td>Direcção-Geral de Fiscalização e Controlo da Qualidade Alimentar (Directorate-General for the Supervision and Inspection of Food Quality)</td>
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<tr>
<td>DGPA</td>
<td>Direcção-Geral das Pescas e Aquicultura (Directorate General for Fisheries and Aquaculture)</td>
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<tr>
<td>DGV</td>
<td>Direcção-Geral de Veterinária (Directorate General for Veterinary Health)</td>
</tr>
<tr>
<td>DSP</td>
<td>Diarrhoeic Shellfish Poisoning</td>
</tr>
<tr>
<td>EC</td>
<td>European Community</td>
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<tr>
<td>EEC</td>
<td>European Economic Community</td>
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<td>EN</td>
<td>European Norms</td>
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<tr>
<td>FVO</td>
<td>Food and Veterinary Office</td>
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<tr>
<td>HACCP</td>
<td>Hazard Analyses and Critical Control Point</td>
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<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
</tr>
<tr>
<td>IPIMAR</td>
<td>Instituto de Investigação das Pescas e do Mar (Institute for Fish and Maritime Research)</td>
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<tr>
<td>IRP</td>
<td>Inspeção Regional das Pescas (Regional Inspectorate of Fisheries (in the Azores))</td>
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<td>ISO</td>
<td>International Standard Organisation</td>
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<tr>
<td>LBM</td>
<td>Live Bivalve Molluscs</td>
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<tr>
<td>LNIV</td>
<td>Laboratório Nacional de Investigação Veterinária (National Research Veterinary Laboratory)</td>
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<tr>
<td>LC-MS</td>
<td>Liquid Chromatography/Mass Spectrometry</td>
</tr>
<tr>
<td>MADRP</td>
<td>Ministério da Agricultura, do Desenvolvimento Rural e de Pescas (Ministry of Agriculture, Rural Development and Fisheries)</td>
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<tr>
<td>MPN</td>
<td>Most probable number</td>
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<td>NRL</td>
<td>National Reference Laboratory</td>
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<tr>
<td>OJ</td>
<td>Official Journal of the European Communities</td>
</tr>
<tr>
<td>PSP</td>
<td>Paralytic Shellfish Poisoning</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operation Procedure</td>
</tr>
<tr>
<td>SANCO</td>
<td>Health and Consumers Protection Directorate General</td>
</tr>
<tr>
<td>TVB-N</td>
<td>Total volatile basic nitrogen</td>
</tr>
<tr>
<td>European legislation</td>
<td>Official Journal</td>
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1. INTRODUCTION

The mission took place in Portugal from 21 January to 1 February 2002. The mission team comprised three inspectors from the Food and Veterinary Office (FVO) and an expert from one of the Member States.

The mission was undertaken as part of the FVO’s planned mission programme.

The inspection team was accompanied during the whole mission by representatives from the central competent authority and regional services.

An opening meeting was held in Lisbon on 21 January 2002 with representatives of the central competent authority. At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team. Additional information required for the satisfactory completion of the mission was requested.

2. OBJECTIVES OF THE MISSION

The objectives of the mission were:

- to assess the performance of the competent authority concerning the implementation of the relevant EU legislation on fishery products and bivalve molluscs;
- to evaluate the implementation by the competent authority of follow up actions after the previous missions on bivalve molluscs (report ref. no. XXIV/1038/99).

The mission forms part of a wider series of missions to all Member States evaluating control systems and operational standards in these sectors.

In pursuit of the objectives, the following sites were visited:

<table>
<thead>
<tr>
<th>COMPETENT AUTHORITY VISITS</th>
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<tbody>
<tr>
<td>Competent authority</td>
</tr>
<tr>
<td>Central</td>
</tr>
<tr>
<td>Regional</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LABORATORY VISITS</th>
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<tbody>
<tr>
<td>Central/reference</td>
</tr>
<tr>
<td>Regional</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>SITES VISITED</th>
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<tbody>
<tr>
<td>Factory vessels</td>
</tr>
<tr>
<td>Fishing vessels</td>
</tr>
<tr>
<td>Auctions</td>
</tr>
<tr>
<td>Fishery product establishments</td>
</tr>
<tr>
<td>Canneries</td>
</tr>
<tr>
<td>Purification/Dispatch centres</td>
</tr>
</tbody>
</table>
3. **LEGAL BASIS/BASIS FOR THE MISSION**

The mission was carried out under the general provisions of Community legislation and, in particular:


4. **BACKGROUND**

4.1. **Summary of previous mission findings**


The main conclusions and recommendations were:

– The practical absence in the clarity in the definition of competencies of the different authorities, which results in the overlap of tasks and a lack of coordination of the control of the chain of bivalve molluscs and the evasion of legal requirements by the operators;

– Written guarantees were requested from the Ministry of Agriculture, Rural Development and Fisheries (MADRP) to ensure that powers were effectively used and to guarantee the enforcement of the existing legislation;

– To draft and implement a comprehensive National Programme of Control on bivalve molluscs in Portugal.

The Portuguese authorities gave their reaction on the report and agreed that “Generally speaking, the Community mission report paints an accurate picture of the operation of the bivalve mollusc production and marketing sector in Portugal”.


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1 Decreto-Lei
5. MAIN FINDINGS

5.1. Description of the system

5.1.1. Legislation

Community-legislation on fishery products and bivalve molluscs is transposed in Decree-Laws. The main pieces are:


The Commission Decisions on specific issues are directly applicable in Portugal and do not need transposition into Portuguese national law.

5.1.2. Competent Authority

5.1.2.1. Central Level

Three Directorates Generals and several other services are responsible for the areas covered by the mission. The four main services are mentioned in the table with their responsibilities.

<table>
<thead>
<tr>
<th>Name</th>
<th>Responsibilities</th>
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<tbody>
<tr>
<td>Directorate-General for Veterinary Health (DGV)</td>
<td>- Laying down general guidelines for the implementation of health regulations governing the production and placing on the market of fishery products and live bivalve molluscs, including the production of a national public health programme intended to monitor compliance with the above mentioned regulations;</td>
</tr>
<tr>
<td></td>
<td>- initial approval and official supervision of establishments where fresh fishery products are handled and processed;</td>
</tr>
<tr>
<td></td>
<td>- attribution of the approval number to wholesale markets and auctions, after the initial approval;</td>
</tr>
<tr>
<td></td>
<td>- official supervision of auctions and wholesale markets;</td>
</tr>
</tbody>
</table>

2 Declaracao de Rectificao
The Directorate-General for the Navy\textsuperscript{4}, the Inspectorate-General for Fisheries\textsuperscript{5}, the Inspectorate-General for Economic Activities\textsuperscript{6} and the Republican National Guard\textsuperscript{7}, are responsible for carrying out surveillance and enforcement activities as defined in their individual laws or in specific laws. They also have to co-operate and participate in monitoring activities defined in the existing national public health monitoring programme when required to do so by the national veterinary health authority.

\textsuperscript{4} Direcção-Geral de Marinha  
\textsuperscript{5} Inspecção Geral das Pescas  
\textsuperscript{6} Inspecção Geral das Actividades Económicas  
\textsuperscript{7} Guarda Nacional Republicana

\textsuperscript{3} In their comments the Portuguese authorities explained that the actual situation is that the DGV and DGPA are responsible for the initial approval and that DGV is responsible for the official supervision.
5.1.2.2. Regional level

**Autonomous Region of Madeira**

The Directorate-General for the Navy\(^8\), the Inspectorate-General for Fisheries\(^9\), the Inspectorate-General for Economic Activities\(^10\) and the Republican National Guard\(^11\), are responsible for carrying out surveillance and enforcement activities as defined in their individual laws or in specific laws. They also have to co-operate and participate in monitoring activities defined in the existing national public health monitoring programme when required to do so by the national veterinary health authority.

**Autonomous Region of Azores**

Three services are responsible for the licensing and approval procedures and the official supervision of the establishments, which are:

- The Veterinary Service\(^12\) of the Azores, which is part of the Secretariat for Agriculture and Fisheries\(^13\). This service has a veterinary inspection service at each of the islands of the Azores.

- The Regional Inspectorate of Fisheries\(^14\) (IRP), which is also part of the Secretariat for Agriculture and Fisheries. The IRP is established by Regional Implementing Decree\(^15\) N° 11/2000/A of 6 March 2000. This decree also attributes the tasks to the IRP. Reportedly this service will become responsible for the practical execution of Council Directive 91/493/EEC in the Azores. However, no date is set for this transfer of responsibilities.

- The Regional Secretary of Economy\(^16\), which issues the Licence for Operation\(^17\). This allows the establishment to start its operation but is not the sanitary approval.

5.1.2.3. Local level (Municipality of Lisbon)

The Municipality of Lisbon has the responsibility for the inspection of an auction and wholesale market, *which are in the same building*. Four inspectors *inspect the product and* supervise the premises.

The auction and the wholesale market, *are managed* by Docapesca (the state company that owns/manages the auctions in Portugal). The wholesale market is owned by the Municipality of Lisbon.

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\(^8\) Direcção-Geral de Marinha

\(^9\) Inspecção Geral das Pescas

\(^10\) Inspeção Geral das Actividades Económicas

\(^11\) Guarda Nacional Republicana

\(^12\) Serviços de Veterinária

\(^13\) Secretaria da Agricultura e des Pescas

\(^14\) Inspeção Regional das Pescas

\(^15\) Decreto Regulamentar Regional

\(^16\) Secretaria Regional de Economia

\(^17\) Autorização de Laboração
5.1.3. **The laboratory network**

5.1.3.1. Public Health

IPIMAR in Lisbon is the NRL for marine biotoxins. It also carries out the checks on potentially toxic phytoplankton. IPIMAR has three regional laboratories, responsible for the North, the Centre and the South of Portugal.

The Portuguese authorities have not yet nominated the NRL for bacteriological and viral contamination in bivalve molluscs.

5.1.4. **Approval, registration and suspension of establishments**

5.1.4.1. Lists of approved premises and vessels

Two lists were available. One was sent to the Commission services on 28 August 2001, the other was part of the Portuguese reply to the pre-mission questionnaire. The totals of the main categories are summarised in the table.

The table only shows the differences in the totals. However, closer examination of the lists shows that the list with the lowest number includes premises that are not listed in the other.

<table>
<thead>
<tr>
<th>Category</th>
<th>Letter 28 August 2001</th>
<th>Reply pre-mission questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fishery products establishments</td>
<td>170</td>
<td>173</td>
</tr>
<tr>
<td>Canneries</td>
<td>26</td>
<td>43</td>
</tr>
<tr>
<td>Auctions</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Factory vessels</td>
<td>52</td>
<td>43</td>
</tr>
<tr>
<td>Fishing vessels</td>
<td>Not available</td>
<td></td>
</tr>
</tbody>
</table>

5.1.5. **Official supervision**

5.1.5.1. Fishery products

**Auctions**

Inspectors are present when fish is landed. Organoleptic checks are carried out on all fish that are landed, but no microbiological and chemical analyses are carried out.

The supervision at fifteen auctions is carried out by 43 veterinarians and 44 assistants, who are *reporting to DGV, the figures include one co-ordinative function*. 
Checks on product
In the establishments no samples are taken for official laboratory test on microbiological and chemical contamination.

Contaminants present in the aquatic environment
There is sampling programme for laboratory tests on Hg, but not for contaminants in the aquatic environment.

5.1.5.2. Bivalve molluscs (public health)

List of production areas and its classification
Portugal has 31 production areas for bivalve molluscs, which are published in the national official journal. Almost all production areas are divided in catching/culture zones. The classification is given to a (cluster of) catching/culture zone(s) and not to the production areas. The classification for each catching/culture zone is based on analyses of one (sometimes two to five) indicator species. The most recent classification was officially published on 16 July 2001.

Quality of shellfish water
IPIMAR is responsible for the monitoring of the seawater in the production area. Monitoring takes place only on mercury and does not include the other physico-chemical parameters required by Council Directive 79/923/EEC.

Phytoplankton monitoring
Water samples (200 ml preserved in situ and 1 l. alive water sample) are taken from surface with a bucket or from a five meters integrated water column taken with a hose.

Water samples are taken at least twice a month by fishermen and/or by our technicians. When toxic species start to occur or are sporadically found, another sample from the same area is requested, switching to intensive sampling (at least weekly or twice a week).

All phytoplankton species are counted, but special attention is given to potentially toxic species.

Microbiological monitoring in molluscs
IPIMAR is responsible for the microbiological monitoring which is carried out by its regional laboratories.

Biotoxin monitoring
Blue mussel and Donax clams are used as indicator species.

The regular monitoring for DSP, ASP and PSP covers all wild exploited bivalves banks as well as aquaculture sites. There are 45 fixed sampling stations and the number is increased when toxic phytoplankton species start appearing in the water, or when there is a positive result from toxin analysis. Each station is sampled at

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18 The Portuguese competent authorities commented this point in their response to the draft report.

19 Diário da República
least once a month and more frequently twice a month, by fishermen and/or by our technicians. When toxic species are found or there are positive results in biotoxin analysis, the sampling is intensified (weekly or even twice a week) until bivalves are cleared from toxins and the toxic species are not found or rare in the water samples. However, in areas where toxins are found yearly, like Aveiro, Óbidos and Formosa lagoons, samples are taken weekly all year round.

Laboratory methods:
- DSP toxin analysis: DSP analysis is carried out by mouse bioassay (Yasumoto et al., 1984 with minor modifications when the whole tissue is used) and confirmatory analysis by LC-MS (Suzuki et al., 2000 with a prior alkaline hydrolysis step);
- ASP toxin analysis: Domoic acid is determined by HPLC using the method of Quilliam et al. (1995);
- PSP toxin analysis: PSP analysis is performed by mouse bioassay (AOAC, 1990) and confirmatory analysis by HPLC (Lawrence et al., 1995).

Closing/re-opening of the production areas
If in a sample Dinophysis spp. are found between 200-1000 Cells/l., depending on the amount of the accompanying species, precautionary closure of the zone can be made until DSP analysis are negative, and the monitoring starts to be twice a week in this zone. An identical criteria is used for PSP referring to Gymnodinium catenatum/Alexandrium minutum. But in the last 2 years there was no reason to use it. For ASP attention is given to Pseudonitzschia spp mainly P. australis. In this case the number of cells it is above 100000 cells/l.

DSP
In the mouse bioassay the shellfish should be considered unsafe for consumption if two mice out of three die in the first 24 hours. However, the observation time is 48 hours. In the LC-MS the shellfish should be considered unsafe for consumption if levels of total OA are above 16µg/100g.

ASP
Shellfish are considered unsafe for consumption at levels above 20µg domoic acid/g shellfish tissue.

PSP
The mice are observed for classical PSP symptoms, such as jumping in the early stages, followed by death in less than 15 minutes by respiratory arrest. The time from initial injection to mouse death is recorded and the toxicity is determined from Sommer’s table. One mouse unit is referred as the amount of PSP toxin required to kill a 20g mouse within 15 minutes.

When the unsafe toxin level (ASP, DSP or PSP) is reached in any species of bivalve molluscs or toxic species are found in worrying concentrations, IPIMAR requests the Directorate-General for the Navy to proceed with the immediate closure of the affected species in the sampled area. When the results of all the samples from the designated area are lower than the tolerance level and the toxic phytoplankton species are not found or rare, the IPIMAR request the Directorate-General for the Navy to reopen the area for harvesting.
5.2. Verification of the activities in place

5.2.1. Competent authority

5.2.1.1. Central level

During the course of the mission the mission team verified the activities of the different services concerning the official supervision of the activities for placing fishery products on the market. The mission team observed a diffuse and fragmented system in which many services are involved. It also observed that many activities that are required under EU legislation are not carried out at all or in such a low frequency that it can be regarded as not meeting the EU requirements. Details on points where the system fails can be found in the following paragraphs.

Factory and fishing vessels

The approval procedures and supervision of factory vessels and the inspection and control of fishing vessels staying at sea more than 24 hours were checked and discussed.

The mission team received information that the factory vessels that were in operation before 1995 received approval by an administrative decision in that year. When they moor in a Portuguese port, reportedly they are inspected. The mission team saw no inspection reports. If they do not moor in Portugal they are not inspected.

Factory vessels that came into operation after 1995 were inspected and approved when they meet the requirements. For the official supervision, the same system is in place: inspection when they moor in a Portuguese port, no inspection if they do not come to Portugal.

DGV and DGPA made a start with the joint control and inspection of fishing vessels that stay at sea for more than 24 hours. However, the mission team was informed that the inspections stopped after some time.

Lists

A specific point observed by the mission team concerns the updating of the lists of approved premises and vessels. The lists are not an accurate reflection of reality. They contain names of establishments that are no longer in operation, while establishments were missing that are actually processing fish and fishery products. Beside that some establishments that were visited by the mission team fall below the standards required under Community legislation.

5.2.1.2. Autonomous Region of Azores

In practice the responsibilities/competencies were not clearly established and divided between the Veterinary Service of the Azores and the IRP and the actual situation could not clearly be explained to the mission team. This situation could explain the deficiencies observed by the mission team.

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The Portuguese competent authorities commented this point in their response to the draft report.
The mission observed a lack of co-ordination between the regional services and the central services in Lisbon.

**Veterinary Service**

The inspections concerning hygiene, food safety and public health aspects of fishery products are currently carried out by the Veterinary Service. It also attributes the approval numbers for establishments/vessels, although the Veterinary Service was only recently orally informed about this.

The following shortcomings were observed in the implementation of the EU requirements by the Veterinary Service of the Azores:

- The list of approved establishments contains names of establishments that are no longer in operation;
- In some of the files checked by the mission team, there was no evidence of initial approval of those establishments;
- Some establishments were operating and placing fishery products on the market within Portugal and other Member States, without an approval number;
- Inspection reports for the establishment checked by the mission lacked detail, while there was no follow up of corrective actions mentioned in the mission report;
- The establishment visited by the mission showed serious deficiencies, which were not observed and mentioned in the inspection reports of the Veterinary Service;
- HACCP-plans are not assessed by the Veterinary Service and staff is not trained for this;
- Inspections and controls on fishing vessels are not carried out, as required in Council Directive 92/48/EEC.

**Regional Inspectorate of Fisheries (IRP)**

The IRP started in September 2001. All inspections concerning hygiene, food safety and public health aspects of fishery products will be transferred from the Veterinary Service to the IRP.

All auctions in Azores, except one, were visited by the end of 2001. Detailed reports of the inspection of each auction were available. All reports mentioned shortcomings on several aspects. The reports did not give deadlines for corrective actions. The mission was informed that corrective actions will be proposed to the auctions based on the reports. Reportedly inspections are foreseen every year.

A list with the names and registration numbers of 85 fishing vessels that stay at sea for more than 24 hours was handed over to the mission team.

IRP checks the incoming raw material for the canneries and samples the final product in the canneries for histamine and mercury. Samples are taken from all consignments with destinations outside Portugal by the IRP-inspector. Sampling is based on a Portuguese guideline (of the former Instituto Portuguesa de Conservas
de Pescas, which is now incorporated in DGPA). The samples are sent to the Department of Oceanography and Fisheries of the University of the Azores\textsuperscript{21} for analysis. Samples are sent by mail and are not sealed. There is no written procedure for the handling of the sampling. The results of the analyses comply with the requirements in the EU legislation.

5.2.1.3. Local level (Municipality of Lisbon)

The situation was discussed during the mission with a representative of the Municipality of Lisbon. It became clear that the situation concerning the supervision is inconsistent. The Municipality brought the following points to the attention of the mission team:

- The Municipality supervises the auction and wholesale market although it is not their legal responsibility. It is the continuation of historical practice and it is carried out because the formally responsible services did take up this task;
- The Docapesca wholesale market does not meet the standards. MARDP was informed about this, but no action was taken;\textsuperscript{22}
- The inspectors are not always informed in time of the landing of fish and therefore the Municipality cannot guarantee that all fish is adequately inspected;
- Bivalve molluscs are traded, but it is not sure whether they have undergone purification when needed;
- A problem arises with the laboratory tests on samples, if required. LNIV was doing this in the past, but is no longer available for this. According to the DGV, this could be done at IPIMAR;
- Lorries with fish from third countries (Morocco was named) are unloaded, but it is not clear whether the proper import procedures are followed. The auction is not a border inspection post.

The mission team received information that a similar situation exists in the Docapesca auction in the Porto area.

5.2.2. The laboratory network

National reference laboratory for marine biotoxins

IPIMAR is the only laboratory that performs the laboratory tests on biotoxins in bivalve molluscs.

<table>
<thead>
<tr>
<th>General</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>Name: Instituto de Investigação das Pescas e do Mar (IPIMAR)</td>
<td></td>
</tr>
<tr>
<td>NRL for: Biotoxins</td>
<td></td>
</tr>
<tr>
<td>Accreditation: IPIMAR is not accredited for biotoxin,</td>
<td></td>
</tr>
<tr>
<td>Quality system: - Participation in the ring tests organised by the CRL in Vigo; - Duplicates for the bio-assay once every two months;</td>
<td></td>
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</tbody>
</table>

\textsuperscript{21} Departamento de Oceanografia e Pescas da Universidade dos Açores

\textsuperscript{22} The Portuguese competent authorities commented this point in their response to the draft report.
- Summarised procedures for the preparation of the samples and the protocols for the laboratory tests are present;
- Records containing the details of the tests carried on the samples.

**Sampling:**
Weekly or bi-weekly sampling of all production areas by own staff. In each production area all commercial species are sampled and tested.

**Methods of analysis:**
- **DSP:** mouse bio-assay (Yasumoto 1984), hepatopancreas is used for the large species and the flesh and hepatopancreas for the small species;
- **ASP:** HPLC method;
- **PSP:** mouse bio-assay (AOAC method).

- **DSP:**
  * The method is adjusted for the small species;
  * In the case of one dead mouse a new sample is taken and tested;
  * Regular observations during the first half-hour after injection, then every hour up to five hours and then after 24 and 48 hours.

- **ASP** is weekly analysed by HPLC in all the species.
- **PSP** is not analysed in all the weekly routine samples as there have been no outbreaks for many years. Tests are always done in the case of high counts of *Alexandrium minutum*/*Gymnodium catenatum*.

**Traceability:**
The system is partially computerised. At reception a computer file is created from each sample. The results from the various tests are recorded on a hand written document. Only the final results of the tests are put in the computer file.

**Reporting / notification:**
In the case of unsatisfactory results, reporting by fax to official authorities and to various operators in the field such as auctions, producers organisations. The notification also states that the production area concerned is closed.

In practice results are available 72 hours after sampling.

N.B. The mission was informed that IPIMAR in Lisbon will be appointed as NRL for microbiological and viral contamination in live bivalve molluscs. They perform tests in live bivalve molluscs on:
* *E. coli*
* Faecal coliform;
* Salmonella

IPIMAR is accredited for the microbiological analyses and has a quality system.
Regional laboratory for bacteriological contamination in bivalve molluscs IPIMAR Olhão

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<tr>
<th>General</th>
<th>Remarks</th>
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<tbody>
<tr>
<td><strong>Name:</strong></td>
<td>IPIMAR Olhão</td>
</tr>
<tr>
<td><strong>Tasks carried out by laboratory for microbiology in foodstuffs:</strong></td>
<td>This laboratory depends on IPIMAR Lisbon but has no written agreement for its activities.</td>
</tr>
<tr>
<td>- The team of IPIMAR Olhão (4 people) do the sampling and microbiological analyses.</td>
<td>Chemical analysis on water is also assessed in the laboratory.</td>
</tr>
<tr>
<td>- Sampling of bivalve molluscs and water in production areas, dispatch and purification centres.</td>
<td></td>
</tr>
<tr>
<td>- Sending of samples to IPIMAR Lisbon for the detection of biotoxins, phytoplankton and <em>Salmonella</em>.</td>
<td></td>
</tr>
<tr>
<td>- Determination of the bacteriological contamination of bivalve molluscs (only faecal coliforms);</td>
<td></td>
</tr>
<tr>
<td>- Classification of production areas</td>
<td></td>
</tr>
<tr>
<td><strong>Accreditation:</strong></td>
<td>Not accredited</td>
</tr>
<tr>
<td><strong>Quality system:</strong></td>
<td></td>
</tr>
<tr>
<td>- No quality system or procedure has been written for IPIMAR Olhão. During the visit, the technical instruction for faecal coliforms that was sent by IPIMAR Lisbon (fax dated from 28/01/2002) was available.</td>
<td></td>
</tr>
<tr>
<td>- No written procedure exists for the sampling method and the transport of samples to IPIMAR Lisbon.</td>
<td></td>
</tr>
<tr>
<td><strong>Methods of sampling:</strong></td>
<td></td>
</tr>
<tr>
<td>- There is no written procedure for sampling.</td>
<td>Positive results for the own checks regarding faecal coliforms are not reported.23</td>
</tr>
<tr>
<td>- The team of IPIMAR Olhão takes approximately 50% of the samples analysed in the laboratory (in 2001, 480 for bacteriological tests and 215 samples for biotoxins).</td>
<td></td>
</tr>
<tr>
<td>- Private persons take also samples, without formal instructions.</td>
<td></td>
</tr>
<tr>
<td>- Maps of the areas are available but the sampling points are not fixed. For production areas, there are 32 stations for bacteriological sampling (bivalve molluscs and water) and 15 points for biotoxins (phytoplankton and bivalve molluscs). Around 10 samples are taken from each area each year for area classification.</td>
<td></td>
</tr>
<tr>
<td>- In case of detection of toxic phytoplankton or biotoxins, IPIMAR Lisbon sends a fax to IPIMAR Olhão and more samples have to be taken (1 or 2 times a week up to normalisation). There is no written procedure for this intensified sampling available.</td>
<td></td>
</tr>
<tr>
<td><strong>Methods of analysis:</strong></td>
<td></td>
</tr>
<tr>
<td>The determination of the bacteriological contamination consists of counting the</td>
<td></td>
</tr>
<tr>
<td>- There is no control, calibration or</td>
<td></td>
</tr>
</tbody>
</table>

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23 *The competent authority stated in their comments that positive results were reported orally.*
faecal coliforms. The laboratory has to follow the instructions and method prescribed by IPIMAR Lisbon: MPN method with 5 tube and 3 dilutions as provided for in Directive 91/492/CEE is used. In 2001, 965 analyses for faecal coliforms on bivalve molluscs or water were made.

<table>
<thead>
<tr>
<th>Traceability:</th>
<th>There are 2 registers: one for the samples taken and one with the results of the analyses.</th>
</tr>
</thead>
</table>

| Reporting/notification: | - There are no reporting or notification systems. The results are processed to make the classification of production areas. If results from a dispatch or purification centre are outside accepted limits, IPIMAR Olhão informs the establishment and asks for more analysis to assess the problem.24  
- In case of positive *Salmonella*, IPIMAR Olhão receives a notification from IPIMAR Lisbon but no further action is made. |
|------------------------|-----------------------------------------------------------------------------------------|

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National laboratory for phytoplankton

IPIMAR is also responsible for research and the routine monitoring of phytoplankton.

Water samples for phytoplankton are taken by the staff from the regional IPIMAR laboratories. In the lagoons, with more shallow waters, surface samples are taken at the surface with a bucket. In deeper waters an integrated sample to a depth of 5 meter is taken with a tube.

The samples are sent to IPIMAR in Lisbon for determination. All phytoplankton species are determined.

Reportedly, the sampling point for the relevant area is validated, although no validation results were produced during the mission.

IPIMAR preventively closes a production area when toxic phytoplankton species are found. Shellfish samples are then taken for the bio-assay on biotoxins. Depending on the results, the production area will then be re-opened or remain closed for some or all of the bivalve mollusc species caught in that area.

National Research Veterinary Laboratory (LNIV)

This laboratory is part of **MADR**. It carries out laboratory tests at the request of the inspection service of DGV and other public services.

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24 The Portuguese competent authorities commented this point in their response to the draft report.

25 The competent authority stated in their comments that results that exceed the limits were reported orally.
In 2001 280 analyses were carried out on fishery products; 252 for the border inspection posts, 18 in fresh and frozen products on *E. coli* and 20 in aquaculture products on residues.

The laboratory has a quality system, which includes a Laboratory Information and Management System, but is not accredited. The laboratory indicated that it will take several years before they are accredited.26

The samples are not taken by LNIV staff but by the organisation/establishment requesting the analysis.

Private laboratory

The activities of two closely co-operating private laboratories responsible for the microbiological checks on bivalve molluscs in the dispatch and purification centres were assessed, although they were not visited. The assessment is based on reports that were available in two visited purification and dispatch centres. The sampling is organised (planning available in the establishments) by one laboratory (Laboratory 1) and the analyses are done by the other (Laboratory 2).

<table>
<thead>
<tr>
<th>General</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accreditation:</td>
<td>Accredited under the Portuguese Quality Control System27 and recognised by IPIMAR Lisbon. In this report, IPIMAR Lisbon did not audit Laboratory 1.28 Laboratory 2 was audited and classified as good.</td>
</tr>
<tr>
<td>Methods of analysis:</td>
<td>Laboratory 2 follows the methods prescribed by IPIMAR Lisbon. The following analysis are made on water and bivalve molluscs: - faecal coliform counts, - <em>Salmonella</em> detection. - The dates of start and end of analysis are not available in the report of analysis. - The dates of collecting and reporting are noted in the report.</td>
</tr>
<tr>
<td>Reporting/notification:</td>
<td>The report is available for the establishment between 10 days and 4 weeks after the sampling of bivalve molluscs or water. - No corrective action in the establishment after results that exceed the limits, - No corrective action possible if report is available between 10 days and 4 weeks after sampling.</td>
</tr>
</tbody>
</table>

5.2.3. Sites visited

Several sites were visited. Details on the observations are summarised in the Annex.

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26 *The Portuguese competent authorities commented this point in their response to the draft report.*

27 Sistema Português da qualidade.

28 *The Portuguese competent authorities commented this point in their response to the draft report.*
5.2.3.1. Fishing vessels

One fishing vessel was visited in the port. It was a longliner that stayed at sea for four to five days.

5.2.3.2. Establishments

Six establishments were visited, two establishments were smokehouses.

In one of the establishments the file of the inspection service contained a letter dated 24 September 1997, by which an approval number was given, and it was approved as a cold store. However, it is actually a processing plant that is in operation since 1995. It is dispatching product to several EU Member States without using the approval number on the packaging or on the accompanying documentation. The management of the establishment did not know its approval number and had requested it from the competent authority, but the number had not been officially communicated. The files of the establishment contained several documents by which the sanitary licence was extended. The last one was issued on 19 November 2001 and extended it to November 2002.

Shortcomings in the official supervision were observed in all establishments. As a result the knowledge of the legal requirements and the hygiene awareness in the establishment is insufficient. The major points were:

- No evidence of initial approval in one establishment;
- No regular inspections to verify whether the conditions for approval were still being met;
- If visited, there was no follow up to check whether the establishments implemented corrective actions;
- No official samples were taken to verify the microbiological quality of the products and the effectiveness of cleaning and disinfecting;
- Several establishment were approved without a HACCP plan and without (or deficiencies in) a cleaning and pest control programme.

5.2.3.3. Canneries

Three canneries were visited. However, one cannery, which opened in June 1999, stopped production in April 2000 for economic reasons. No detailed assessment by the mission team was made of this plant.

In one cannery the last official inspections was carried out in 2000. In January 2000, it focussed on HACCP and in May 2000 a complete inspection was carried out. In the other cannery the official supervision showed serious shortcomings. The reports of the official inspections lacked detail and did not mention the serious shortcomings observed during the mission. The competent authority does not take official samples, it relies on the results from the own checks. After an official inspection, the company receives a document stating that they are approved for commercialising and selling canned products. Inspection reports did not provide information on the status of the cannery.
5.2.3.4. Auctions

Two auctions were visited of which one was located in continental Portugal and the other at the Island of Madeira. Both only supply the regional market.

The official supervision at the auctions in continental Portugal is carried out by DGV and at the Island of Madeira by the regional authorities. At both auctions organoleptic checks are carried out by the official inspector, who is always present when the auction is open. At both auctions a special form is filled in for rejected fish.

At the auction in Madeira the competent authority is reportedly responsible for the checks on histamine and TVBN. At the other auction in mainland Portugal the mission team was informed that these checks on products would only be carried in suspicious cases, until now this has not happened.

At one auction the competent authority is also responsible for the checks on ice and potable water. Ice is not checked in the other auction and water is sampled by staff from the auction and sent to IPIMAR-Lisbon for analysis. This is based on a protocol between Docapesca and IPIMAR. The results are not made available to the inspector at the auction and were not shown to the mission team.

It is the intention to sample the seawater. It is understood that this is also covered by the aforementioned protocol. Until now no sampling and analysis took place.

Marine gastropods were landed at one of the auctions visited, but no samples were taken for microbiological and biotoxin tests. Checks on parasites are carried out at that auction.29

5.2.3.5. Purification and dispatch centres

Two combined purification/dispatch centres and one dispatch centre were visited.

Many services are responsible for the official supervision. DGPA has the overall supervision for the initial approval. Other responsible services are DGV, DGFCQA, IGP and IPIMAR. The efficiency of the purification was checked and approved by IPIMAR in one purification/dispatch centre. It was not checked yet in the other centre, as the purification part was in the process of being approved. The faxes from IPIMAR with the closure and re-opening of the production areas were present in all centres. Official supervision by DGPA and DGV is carried out at a frequency of approximately once a year. However, the follow up of deficiencies was not enforced. The mission observed that official reports of the inspections were generally sent to the centres several months after the visit had taken place.

29 In their comment the Portuguese competent authority stated that the requirements Council Directive 91/492/EEC in relation to marine gastropods, echinoderms and tunicates are not transposed in the relevant national legislation.
5.2.4. **Production zones**

The production areas for the bivalve molluscs had a geographical name but the mission team was informed that the boundaries are not fixed, as required under Council Directive 91/492/EEC.

Sampling for the classification is carried out, but not according to a fixed sampling plan. The sampling points are not fixed and as a result they are not validated for the catching/culture zone concerned. When the legal limits for the faecal coliform counts were exceeded, the sampling was not intensified and/or did not lead to declassification of the production zone concerned.

The coastal zones are always classified as "A-area", but these zones are not sampled at all. The mission team found records from own checks in a purification/dispatch centre that showed bacterial counts of more than 300 faecal coliforms/100 gr. flesh in bivalve molluscs originating from these zones (several samples, varying from 470 to 16,000 faecal coliforms/100 gr. flesh).

6. **Conclusions**

6.1. **Follow up mission bivalve molluscs 1999**

The recommendations of mission report ref. XXIV/1038/99-MR-final, the measures mentioned in the letter from the Portuguese authorities of 17 May 1999 and the annexed “National Public Health Monitoring Programme for the Production and Placing on the Market of Live Bivalve Molluscs” have not been implemented.

6.2. **Legislation**

The Community requirements concerning the placing on the market of fishery products and bivalve molluscs have been transposed into national Portuguese legislation.

6.3. **Competent authority performance**

Non-compliance was observed in the performance of the Competent Authority. The main points are:
- Deficiencies in the initial approval of establishments;
- No initial approval for most of the factory vessels;
- (Almost) no official supervision of establishments and factory vessels after initial approval;
- (Almost) no follow up by the competent authority to check whether the establishments, where inspections were carried out, implemented the corrective actions;

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20 The competent authority stated in their comments that coastal areas are sampled and that results are available on computer.

31 The Portuguese competent authorities commented this point in their response to the draft report.
- Concerning the auctions: not all relevant information was made available to the responsible inspector of the DGV;
- No inspection and control of fishing vessels that stay at sea for more than 24 hours;
- No official sampling and laboratory tests;
- Deficiencies in the accuracy and updating of the list of establishments;
- The boundaries of the production areas for the bivalve molluscs are not fixed;
- Deficiencies in the classification and monitoring of the production areas for bivalve molluscs in the coastal zones;
- No declassification of the production zone for bivalve molluscs in the case of high bacterial counts;
- No written procedures for several aspects relating to the various samplings (biotoxins, phytoplankton, microbiological checks) of bivalve molluscs;
- The National Reference Laboratory for bacteriological and viral contamination in bivalve molluscs has not yet been nominated.

6.4. Laboratory service

The Laboratory IPIMAR Lisbon for bacteriology and biotoxins has adequate facilities and has competent staff for carrying out bivalve molluscs controls in Portugal. The method for faecal coliform counts is an in house method and the validation report available is not sufficient. The accreditation of the biotoxins and phytoplankton parts should be shortly finalised.

The Laboratory IPIMAR Olhão for bacteriology has adequate facilities but some technical points and the absence of procedure for analysis, controls and sampling negatively influence the quality of the tests. IPIMAR Lisbon should ensure that an efficient supervision of these activities be made as soon as possible.

In one cannery the last official inspection was carried out in 2000. In January 2000, it focussed on HACCP and in May 2000 a complete inspection was carried out. In cannery 3 of the official supervision showed serious shortcomings. The inspection reports lacked detail and did not mention the serious shortcomings observed during the mission. The inspector does not take official samples, the competent authority relies on the results of the own checks. After the most recent official inspections (August 2000, May 2001 and November 2001) the cannery received an official document stating that they are approved for commercialising and selling canned products.

7. General conclusion

Serious shortcomings were observed in the execution of almost all areas related to the implementation of the EU legislation on fishery products and bivalve molluscs. Many deficiencies were observed in the premises visited. The situation can be regarded as unsatisfactory.
8. **CLOSING MEETING**

A closing meeting was held in Lisbon on 1 February 2002 with representatives from the responsible services and the Autonomous Region of Azores. At this meeting, the main findings and conclusions of the mission were presented by the inspection team.

With respect to the shortcomings highlighted by the team during the visits, the competent authority was requested to take immediate action with the aim of remedying the situation in establishments where deficiencies were found. It was also mentioned that written information should be forwarded to the Commission services on the results of the actions undertaken.

The representatives largely accepted the findings and conclusions of the mission team. DGV explained that the unsatisfactory situation could partially be explained by the efforts to establish a food authority in Portugal that would bring together the tasks that are now divided over the different services. The establishment of this food authority was stalled because of recent political developments.

The representative from the DGPA did not agree with the observation that the situation regarding the bivalve molluscs had not improved since the previous mission in February 1999.

9. **RECOMMENDATIONS**

9.1. **To the competent authorities of Portugal**

The Competent Authority is requested to take corrective actions on the following points:

a. To implement the recommendations of the previous mission report and the measures provided for in the “National Public Health Monitoring Programme for the Production and Placing on the Market of Live Bivalve Molluscs”.

b. To rectify the deficiencies found in the initial approval of establishments. This should include the introduction and assessment of an HACCP-plan.

c. To carry out the initial approval for the factory vessels which have only been approved by an administrative decision. This should include the introduction and assessment of an HACCP-plan.

d. To put in place an ongoing official supervision system for establishments and factory vessels after the initial approval. It should include at least the following elements:
   - inspection of the general conditions on hygiene and maintenance;
   - official checks on the own checks;
   - official sampling and laboratory tests;
   - follow up by the competent authority to check whether the recommended corrective actions have been implemented.
e. Related to the protocol between Docapesca and IPIMAR: to take the necessary actions that give the responsible inspectors access to all relevant information, including the analysis results. If necessary, the said protocol should be amended to facilitate the exchange of information.

f. To initiate the inspection and control of fishing vessels that stay at sea for more than 24 hours.

g. To update the list of establishments and factory vessels.

h. To fix the boundaries of the production areas for the bivalve molluscs.

i. To correct the deficiencies found in the classification and monitoring of the production areas for bivalve molluscs in the coastal zones.

j. To put in place a system for declassification of the production area for bivalve molluscs in the case of high bacterial counts.

k. To put in place written procedures for the various samplings (biotoxins, phytoplankton, microbiological checks) concerning bivalve molluscs.

l. To nominate the National Reference Laboratory for bacteriological and viral contamination in bivalve molluscs before 1 April 2002. (As agreed during the final meeting, the NRL will be nominated before "the end of next month").

9.2. Written guarantees

Within one month of receipt of the draft report, the competent authorities of Portugal should inform Commission Services of the progress and result of the measures taken including a timetable for completion of measures and actions still outstanding at that time.

The competent authorities of Portugal should also inform the Commission Services every six months on the progress made in the execution of the measures mentioned in the above mentioned action plan until all those measures have been put in place completely.
ADDENDUM TO MISSION REPORT DG(SANCO)/8512/2002

Competent Authorities response to the recommendations in the report

Certain comments received from the Portuguese Competent Authorities and related to factual inaccuracies have been included in the text of the report. A copy of the full comments will be published on the SANCO website together with the final report.

Regarding the recommendations made in the report, the Competent Authorities gave the following information:

1. As response (dated 12/03/2002) to the request from the FVO (dated 7 February 2002):

   - Three establishments visited by the mission team were inspected by the Portuguese services. As a result the approval one establishment was suspended and another was given deadlines for the implementation of corrective actions.

   - The competent authority started before the FVO mission a complete round of inspections in all approved establishments in order to evaluate compliance with directive 91/493/EEC. So far, these are the results of these inspections:
     * 3 Establishments whose approval was cancelled and the control number was withdrawn;
     * 3 Establishments whose approval is in process of cancelling.
     * 11 Establishments whose approval was cancelled and the control number is in process of withdrawn;
     * 5 Establishments whose approval and control number is in phase of cancelling;
     * 1 Establishment in phase of licence reformulating;
     * 3 Establishments in full compliance with the 91/493/EEC directive.

   - Additional information was provided on the production and trade of oysters originating from the area Lagos Zona litoral.

   - An updated list was sent of 25 auctions, 9 warehouses, 1 wholesale market, 4 factory vessels and 8 fish processing establishments which are established/based at the Azores.

2. With their comments on the draft mission report (dated 17 June 2002):

   - DGV and DGPA started joint technical visits to fishing vessels staying at sea for more than 24 hours with the aim all such fishing vessels. Visits to 30 vessels in the Algarve region are already scheduled;

   - Changes in the legislation are foreseen to clarify the competencies between the different authorities involved in the official control;

   - Technical visits to nine establishments were carried and it is planned to visit the remaining establishments before the end the current year;

   - The planned establishment of a Sanitary Fish Inspection Service is being effectuated at present, in particular to check the follow up of the technical visits;
- The plan for chemical control of fresh fish sold at auctions was approved and is due to be implemented soon;

- A quality system will be put in place and written procedures for the IPIMAR Laboratory in Olhão will be drafted by the end of 2002;

- Written procedures for sampling and transport of samples for the IPIMAR Laboratory in Lisbon are being drafted;

- The results of positive laboratory analyses, carried out by IPIMAR, will be transmitted in writing;

- Training is planned for private persons, external to IPIMAR, carrying out the sampling. Its implementation is foreseen to be finished by the end of 2002;

- The establishment of boundaries and of fixed sampling points in the production areas for bivalve molluscs will be finalised in the first semester of 2003;

- Written procedures for several steps in the sampling are being drafted. Its finalisation is foreseen in the third trimester of 2002;

- The sampling programme for biotoxins and phytoplankton is being reviewed;

- IPIMAR Lisbon is already implementing the method for *E. coli* recommended by the CRL (CEFAS in Weymouth). The request to the national accreditation body (IPQ) for the accreditation of the method is foreseen in 2003;

- IPIMAR Lisbon is putting in place a quality system to be finalised by the end of 2002. It is not covering all the relevant requirements of the ISO Norm 17025, in particular those related to staff and premises;

- IPIMAR Lisbon will carry out supervision audits of the IPIMAR regional laboratories performing microbiological analyses in the second semester 2002.
Visits to the establishments and vessels

1. **Fishing vessels**

<table>
<thead>
<tr>
<th>Condition of equipment</th>
<th>The vessel was in an acceptable, although not perfect, state of maintenance.</th>
</tr>
</thead>
<tbody>
<tr>
<td>General conditions of hygiene</td>
<td>The following deficiencies were observed:</td>
</tr>
<tr>
<td></td>
<td>- The hold for the fish and the ice is made of polyester, which was mouldy in some places;</td>
</tr>
<tr>
<td></td>
<td>- A wooden board is used as separation in the holds;</td>
</tr>
<tr>
<td></td>
<td>- Sleeping places and toilet were dirty.</td>
</tr>
<tr>
<td>Ice supply</td>
<td>Ice is taken in before departure and stored in the hold. Five tonnes of ice are used for ten tonnes of fish.</td>
</tr>
</tbody>
</table>

2. **Establishments**

Six establishments were visited, hereafter referred to as establishments 1, 2, 3, 4, 5 and 6. Establishments 5 and 6 were smokehouses.

<table>
<thead>
<tr>
<th>General conditions relating to structure and equipment</th>
<th>The situation in four establishments was generally satisfactory.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Establishment 2 was under reconstruction and was in a poor condition in the areas outside the main production area.</td>
</tr>
<tr>
<td></td>
<td>In establishment 3 the floor and walls of the packaging store need urgent corrections.</td>
</tr>
<tr>
<td></td>
<td>Some other deficiencies were observed in all establishments.</td>
</tr>
<tr>
<td></td>
<td>Establishment 5 was in a very poor state of structure and maintenance in all areas (loose wiring, cracks in the floor).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General conditions of hygiene</th>
<th>Problems were observed in the implementation of hygiene practices and the hygiene awareness of the staff in all establishments. The following main observations were made:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Establishment 1 had problems related to the separation of the block frozen fish, condensation on the ceilings in the production area and a dirty air-conditioner sited above exposed product. Clams were unpacked and re-packed in the main production area.</td>
</tr>
<tr>
<td></td>
<td>In establishment 2 unpacking and packing in the main production area, as a consequence old and new empty cartons were present. A dirty plastic hose was used to fill the container for glazing.</td>
</tr>
<tr>
<td></td>
<td>In establishment 3 roe was put in trays with stagnant and dirty water. The same staff members who packed the exposed product also handled the dirty outer carton packaging.</td>
</tr>
<tr>
<td></td>
<td>In establishment 4 staff from the main processing area could go in and out without changing their protective cloths and boots. A door in the main production area gave access to outside the building and was open and a second door did not close properly. Boards for filleting were scored and unpacked frozen fish was laid on the floor of the cold store.</td>
</tr>
<tr>
<td></td>
<td>In establishments 1 and 2 staff could move easily from the “dirty” to the “clean” areas.</td>
</tr>
<tr>
<td></td>
<td>In establishments 1 and 3 final product that fell on the floor was returned to the production line.</td>
</tr>
<tr>
<td></td>
<td>Establishment 5 needed thorough cleaning in all areas. Hygiene awareness of the management is low.</td>
</tr>
</tbody>
</table>

| HACCP | HACCP systems were in place in two of the establishments visited. However in general they did not meet the requirements and/or were not updated. Establishment 3 had no HACCP-plan, although the competent authority had regularly requested such a |
plan for more than five years.
- Establishments 4 and 5 had no HACCP-plan.

| Own-checks | - Establishment 1 had problems with microbiological contamination in product (one sample Salmonella positive in 25 g., several samples with Total Plate Count > 10^6).
- Microbiological checks on product were carried out at a low frequency in establishment 2 (every three months).
- In establishment 3 checks on parasites were carried out, but at a low frequency. Parasites were found regularly.
- Establishment 4 had no own checks on product, water, nor on the effectiveness of the cleaning and disinfecting.
- Establishments 5 and 6 did not carry out own checks, nor checks for Listeria monocytogenes although they produced cold smoked products.
- External laboratories that carried out the analyses for the own checks were accredited.

| Temperature records | Establishments 4 and 5 had no permanent temperature registration in their cold store.

| Cleaning programme | - Results from microbiological checks that were available showed in general acceptable results. In establishment 2 these checks were carried out at irregular intervals.
- The disinfectants and detergents used are approved for the food processing industry.
- Establishment 4 had no cleaning programme.

| Pest control | - Indications that establishment 1 has problems with vermin.
- Establishment 5 had no pest control programme.

| Identification marks | In establishment 4 boxes with raw material from another Portuguese establishment were present without an approval number.

3. **Canneries**

Three canneries were visited, hereafter referred to as cannery 1, cannery 2 and cannery 3. No detailed assessment by the mission team was made of cannery 2.

| General conditions relating to structure and equipment | - In cannery 1 the situation was generally satisfactory. Some shortcomings were observed that need correction, they relate to rusty covers of drains in the production area and dirt and rust above the door of the chilling room that can contaminate exposed product.
- Cannery 3 has serious problems in structure and maintenance, which need urgent correction (large openings in the outer walls in areas where fish is processed, dirty and rusty structures sited above exposed product, loose dirty wiring, doors in the processing area that open directly to outside floors with stagnant water, rusty equipment, lack of maintenance of the chiller).

| Conditions around the buildings | In cannery 1 the main area between the buildings is unpaved (only covered with gravel) and dusty when dry. Improvement is urgently needed.

| General conditions of hygiene | - In cannery 1 the situation was generally satisfactory. No footbaths with disinfectant were present at the entrances to the areas where products are handled and the doors between different areas in the main building. Fish, or fish parts, were on the floor in a few places of the production area.
- Cannery 3 was in poor state of hygiene, the main points are:
  = toilets: taps and a flush not functioning;
  = outer doors in processing area were open;
  = area between the cookers and walls very dirty;
  = cooked fish is cooled in open containers in a large open area with a high risk of contamination;
  = cold store with a large amount of ice;
  = containers with pre-cooked fish covered with pieces of carton;
= chiller is dirty;
= pieces of cooked fish are cut to size on wooden equipment;
= the area around the 3 glass/cannery lines is dirty and dusty and
the open glasses/cans with product are not adequately covered;
= main storage is very dirty and dusty; it is used for the storage of
ready products, batches of rejected product and packaging
material.

HACCP
- In cannery 1 HACCP system was in place, which is revised
regularly. Record keeping was generally satisfactory.
- Cannery 3 has an HACCP in place, which is satisfactory.

Own-checks
- Cannery 1 has an own laboratory for:
  = organoleptic checks;
  = incubation of cans at 37.0° C (one week) and 55° C (two weeks);
  = a plate test on water for Total Plate Count and Total coliforms;
  = a plate test to check the effectiveness of the cleaning programme
  for Total Plate Count and Total coliforms;
  = control of seams.
- In cannery 1 results from the water company are available on
  microbiological criteria and some physico-chemical parameters,
  but not for heavy metals and other potential contaminants as
- In cannery 1 reportedly *Clostridium botulinum* is only checked
  when the incubation test gives unsatisfactory results. An
  accredited external laboratory will carry this out. Until now this
  never happened.

Cannery 3 has a small laboratory that is not approved by the
competent authority. The following checks and analyses are carried
out:
- Histamine;
- TVBN;
- Mercury;
- Salt;
- Incubation at 37.0° C (one week);
- Water is checked;
- seams of the cans.

Medical checks
In cannery 3 annual medical checks were carried out with satisfactory
results and recording.

Pest control
- In cannery 1 the programme and its results are satisfactory.
- Results in cannery 3 indicate the possible presence of vermin
  (mice) inside the building close to, although not in, the main
  processing area. There was no evidence of corrective actions.

Cleaning programme
- In cannery 1 there are no major remarks on the cleaning
  programme. The record keeping showed some shortcomings,
  mainly in the records of the daily cleaning.
- The records in cannery 3 show that there are problems, but no
  corrective actions are undertaken. Detergents and disinfectants
  are authorised for use in the food processing industry.

4. **Auctions**

Two auction were visited (auction 1 and auction 2). Both only supply the regional
market.
Auction 2 had good hygiene conditions and practices.

<table>
<thead>
<tr>
<th>Identification</th>
<th>In both auctions crates have a label with an identification number, this is put into a computer together with other relevant information. The auctions use this number for their sales systems and traceability.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical checks</td>
<td>The medical records of the staff, which were checked in auction 2, were available for 2000. In 2001 no medical checks were carried out.</td>
</tr>
</tbody>
</table>

5. **Purification and dispatch centres**

Two purification and dispatch centres were visited. Hereafter referred to as centre 1 and centre 3. Centre 2 is only a dispatch centre.

<table>
<thead>
<tr>
<th>General conditions relating to structure and equipment</th>
<th>These are acceptable in centres 1 and 2. Centre 3 had problems in its layout, mainly due to the lack of space for purification and dispatch activities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>General conditions of hygiene</td>
<td>Hygiene conditions are acceptable in all centres.</td>
</tr>
<tr>
<td>Efficiency of purification</td>
<td>Crates with live bivalves were stacked too high for effective purification in centre 3.</td>
</tr>
<tr>
<td>Record keeping</td>
<td>Satisfactory in all centres with good traceability of the product.</td>
</tr>
</tbody>
</table>

**Own-checks**

- Reportedly IPIMAR takes samples for biotoxins in the premises every two weeks.
- In centre 1 bi-weekly samples taken by IPIMAR from product and water and checked for faecal coliforms, *E. coli* and *Salmonella*. Records from purified final product that was placed on the market, showed counts of faecal coliforms/100 gr. flesh that exceeded the limit (3 samples of 330, 1 result of 1300 and 1 of 5400);
- In centre 1 results on shellfish before purification were presented in such a way that it was not possible to assess if they could be purified (> 16000 faecal coliforms/100 gr. flesh);
- In centre 2 a low number of checks was carried out, with bacterial counts that exceeded the legal limit (1 sample of 470, 2 results of 2400 and 1 of 16000);
- In centre 3 results were available after two weeks.
- The checks are carried out by an external laboratory that is reportedly accredited or approved by IPIMAR-Olhão.

**Health marks**

The health marks are used adequately in all centres.

**Registration document**

- In centre 1 the registration documents, originating from Portugal, were correctly filled in.
- In centre 2 the registration documents accompanying the incoming product were not always filled in completely; missing points: production area, name and address of the producer. Sometimes the classification was not mentioned and the owner assumed that molluscs originated from an A-area.
- In centre 3 the registration documents that originated from Portugal, were filled in correctly. In a few from Spain the health status of the production area was not indicated.