



EUROPEAN COMMISSION
DIRECTORATE-GENERAL XXIV
CONSUMER POLICY AND CONSUMER HEALTH PROTECTION
Food and Veterinary Office
Unit 03 - Food of Animal Origin (3) - Fish and Food of Non-Animal Origin

XXIV/1041/99 – MR Final

SPAIN

FINAL REPORT

DIRECTIVE 91/492/EEC (SHELLFISH)

EVALUATION MISSION (22-26.02.1999)

Please note that certain comments from the Spanish authorities have been included in the text of the report in bold, italic type



FINAL REPORT

DIRECTIVE 91/492/EEC (SHELLFISH) SPAIN

Evaluation Mission (22-26.02.1999)

1. OBJECTIVE OF THE MISSION

This mission is part of a cycle of missions carried out by the Food and Veterinary Office (DG-XXIV) to evaluate the control systems in the Member States for the placing on the market of shellfish destined for human consumption as mentioned in Council Directive 91/492/EEC, lastly modified by Directive 97/61/EC. As a consequence of this, some aspects of Council Decision 93/383 concerning exclusively the national reference laboratories for biotoxins, have been checked.

2. STRUCTURE OF THE MISSION

The mission was carried out by 2 inspectors of the FVO-Unit 3 and a Member State's expert. A representative from the Ministerio de Sanidad y Consumo and another from the *Ministerio de Agricultura, Pesca y Alimentación* (central competent authorities) accompanied the inspection team throughout the mission.

The mission consisted of an audit of the management of production areas, of the production area monitoring programmes for microbiological quality, phytoplankton, and chemical quality and of the implementation of the Directive in the establishment, emphasis was put on own checks systems and traceability of shellfish.

The programme consisted of an initial and a final meeting with the competent authorities. In the final meeting, the representatives of 10 out of the 17 Autonomous Communities of Spain were present. The EC team visited the production area of Ría de Arosa (Galicia); performed the inspection of three approved establishments for purification and dispatch (two in Galicia and one in Andalucía), and visited the National Reference Laboratory in Vigo (also acting as Community Reference Laboratory) together with the two regional laboratories of the regions visited (the CCCMM in Galicia and the DAP laboratory in Andalucía).

3. STRUCTURE OF THE PRODUCTION OF SHELLFISH

Galicia : Aquaculture, coastal catches (8.000 Tons in 1997) and traditional *marisqueo* (hand fishing) by foot or by boat (5.282 Tons in 1997) are the main types of production in Galicia. Due to the social and economical importance of this activity, the production sector is well organised in associations (*Cofradías*), who have a high degree of own-control of catches and origins.

Aquaculture production:

Mytilus galloprovincialis (mussels): intensive monoculture in 3.242 floating structures (*bateas*), mainly in the *Rías baixas* geographical area. 185.000 Tons produced in 1997.

Ruditapes decussatus, *Venerupis pullastra* (clams) and *Cerastoderma edulis* (cockles) : semi-intensive poly-culture in 1.203 parks. 237, 287 and 876 Tons produced in 1997.

Pecten maximus (king scallops) : intensive monoculture in 17 floating structures (*bateas*). 76.5 Tons produced in 1997.

Ostrea edulis (oyster) : intensive monoculture in 113 floating structures (*bateas*). 2.260 Tons produced in 1997.

Andalucía: also as an artisanal activity, Andalucía is more oriented to the *marisqueo* by boat of infaunal shellfish (eg.: clams) coming from the natural banks all along the Andalusian coast. 6.674 Tons in 1997. There are 397 boats approved for this activity.

Rest of Spain: Cantabria, Asturias, Murcia, Valencia, Cataluña, País Vasco, Baleares and the Islas Canarias, are the other regions producing shellfish in Spain.

4. LEGISLATION

Following the Spanish Constitution, the main legislation, the transposition of the EC Directives, is done at central level through a *Real-Decreto*. The secondary legislation is, then, done at regional level through *Decreto* and *Orden* of the different *Consejerías* of the respective Autonomic Community . Sometimes the secondary legislation of a Community (eg. : Galicia) serves as a guide for other Communities.

Council Directive 91/492/EC was transposed into Spanish legislation in 1993 splitted into two parts: the production requirements were included in the *Real-Decreto 345/1993* of the *Ministerio de Agricultura, Pesca y Alimentación* and the technical and sanitary conditions of establishments and products were included in the *Real-Decreto 308/1993* of the *Ministerio de Relaciones con las Cortes y de la Secretaría del Gobierno*.

Council Directive 97/61/EC was under transposition at the time of the visit, pending the approval of the *Consejo de Estado*. Official publication is expected on April-May 1999. The new *Real-Decreto* will consolidate as well the previous legislation of 1993.

5. COMPETENT AUTHORITY

The control of shellfish in Spain is shared by different authorities at central and regional level, this latter divided into 17 Autonomic Communities (CCAA). The CCAA have exclusive competence for the execution or implementation of the primary legislation.

Central level: the *Ministerio de Sanidad y Consumo* (MSC) and the *Ministerio de Agricultura, Pesca y Alimentación* (MAPA), have different tasks defined by Law.

- a) The MAPA is competent for the production areas, in particular, the extraction and transport of BM. This Ministry does not have the power of supervision and control of the CCAA. The Spanish Constitution gives exclusive competence in the fields of fishing in inland waters, *marisqueo* and aquaculture to the CCAA.

The MAPA proposes the general directives of the fisheries politics. Its *Secretaría General de Pesca Marítima* coordinates the CCAA through the *Junta Nacional Asesora de Cultivos Marinos* (JACUMAR) in the field of aquaculture. Its *Dirección General de Recursos Pesqueros* cooperates with the CCAA in aquaculture and controls the stocks. The *Conferencia Sectorial de Pesca*, chaired by the Minister and having the *Consejeros* of the CCAA, is the highest instance of coordination.

- b) The MSC is competent for the purification and dispatch centers, transport and commercialisation. In other words, it is responsible for the rest of the chain of BM. The *Subdirección General de Higiene de los Alimentos* of the *Dirección General de Salud Pública*, regulates the sanitary control of foodstuffs and coordinates the CCAA. The MSC has the power to supervise the derived legislation of the CCAA.

Coordination *between* the MSC and the CCAA is done through:

- ? *Comisión Interministerial de Ordenación Alimentaria* (CIOA). It deals with food safety legislation.
- ? *Consejo Interterritorial del Sistema Nacional de Salud*. It coordinates the MSC with the sanitary authorities of the CCAA via its plenary sessions, the *Comisión de Salud Pública*, at General Directors level, and the *Comisión de Cooperación y Coordinación en Salud Alimentaria* (COCOCOSA), who meets monthly and prepares the work for the plenary sessions.

Regional level: the CCAA are responsible for the execution of the requirements of Council Directive 91/492.

The division of tasks between the MAPA and the MSC is also repeated at regional level. Production areas are controlled by the fisheries services; in the case of this EC visit, the *Consellería de Pesca, Marisqueo e Acuicultura* (Galicia) and the *Consejería de Agricultura y Pesca* (Andalucía). From the purification centres on, the chain is controlled by the health services; in the case of this EC visit, the *Consellería de Sanidade e Servicos Sociais* (Galicia) and the *Consejería de Salud* (Andalucía).

The CCAA Central Services are responsible for the working guidelines, the technical programmes and the harmonisation of criteria. They have the power of doing the secondary legislation, as already explained.

The CCAA Periferic Services, in the different provinces, execute the official control of production areas and BM and are free to organise their services of inspection and control. Ten municipalities in Spain, of more than 50.000 inhabitants (Madrid, Barcelona, Sevilla), can also use their municipal sanitary services for inspection and control of BM.

The **inspection services** in Spain are integrated by veterinarians. Inspectors deal with the official control of all kind of foodstuffs. The number of inspectors varies in the different CCAA. As an example, in the Health services of Andalucía there are 381 veterinarians *to control all the establishments (61 establishments in the scope of Directive 91/492/EEC)*. In Galicia there are 256 veterinarians with 350 establishments to control *(56 establishments in the scope of Directive 91/492/EEC)*.

6. PRODUCTION AREAS

6.1. CLASSIFICATION

Classification of areas was first published by the MAPA in 1993. It was last amended by *Orden* of 28-1-1997. The CCAA are who propose the list of production areas and perform the classification. Each area is authorised for the extraction of specific species, including gasteropods.

There are 138 production areas in Spain, 68 A, 60 B and 5 C. They are distributed in 9 CCAA as follows: 5 areas in the País Vasco, 12 in Cantabria, 1 in Asturias, 30 in

Galicia, 31 in Andalucía, 5 in Murcia, 15 in Valencia, 10 in Cataluña and 5 in Baleares. Some areas are subdivided.

**Remark :* The Canary Islands, although having some shellfish production, do not control it.

Classification criteria: classification is made after environmental and oceanographic studies of the areas. JACUMAR has established a national "Protocol of Analysis of *Faecal coliforms* and *E. coli*", which is used for classification of all areas in Spain. In this protocol, the size of the sample (30 animals/sample), transport, processing, homogenisation, media and temperatures of incubation of samples, as well as the control of media are described.

6.2. SANITARY CONTROL AND SURVEILLANCE

Galicia :

The *Centro de Control da Calidade do Medio Mariño* in Vilaxoan (CCCMM) of the *Consellería de Pesca, Marisqueo y Acuicultura*, is the official regional laboratory. This fully equipped laboratory controls oceanographic conditions, phytoplankton, biotoxins, chemical contamination, microbiology and pathology. This laboratory is accredited (Norm 45.001) by the Spanish Accreditation Entity (ENA). Its objective is having permanently accurate information about the production areas, through a Programme of Control of quality of water and BM.

This **Programme of Control** has established the following fixed sampling points:

- Oceanographic points (31): in the *Rías* where culture is intensive. The whole water column is sampled once a week for physical, chemical and biological tests. The information is completed with the oceanographic satellite termograms and meteorological information, so that the action plans for the areas can be outlined.
- Coastal points (33): in the rest of the areas. They are located at the critical point of the area. Water and BM are sampled.
- Primary fixed points (46): in the different floating cultures (*bateas*) inside the *Rías*. Located at the most sensitive point for biotoxins and phytoplankton. Mussels are used as bioindicators.
- Secondary fixed points (187): are complementary points of the primary ones, and determine the degree of alteration of the different species of BM when a toxic phytoplanktonic bloom occurs.

Analytical checks in water: temperature, salinity, pH, oxygen, fluorescence, particles in suspension, nutrients, photosynthetic pigments, total organic carbon, phytoplanktonic population and petrol originated hydrocarbons. Frequency: 1/month for the coastal points and 1/week for the oceanographic points.

Analytical checks in Shellfish:

- Organo-halogenated substances: 10 polychlorobiphenils (PCBs) and 15 organochlorinated pesticides are analysed by electronic capture gas chromatography. Frequency: 1/year.
- Heavy metals: Ag, As, Cd, Cr, Cu, Hg, Ni, Pb and Zn are checked. Frequency: 1/year.

- Microbiology: *Faecal coliforms* and *E. coli* are analysed using the MPN method with at least 5 tubes and 3 dilutions, at 44±0.5°C. Presence and identification of *Salmonella spp* is done. Frequency: 1/3 months.
- Biotoxins: biotoxins control is fully regulated by *Orden* of 14-11-1995 of the *Consellería de Pesca*. There are different plans of action depending of the species, that regulate the routine (A), alert (B1, B2, B3), emergency (C1, C2, C3) and post-emergency (D) situations. Sampling frequencies and methods, supervision and control by the authorities, as well as closing and opening criteria are established.

PSP,DSP and ASP are checked. Methods: PSP by mice bioassay, DSP by mice bioassay (12 hours) and HPLC. ASP, domoic acid, by HPLC.

**Remark :* the diagnostic waiting time for the bioassay for DSP recommended by the Community Reference Laboratory is 24 hours and not 12 hours.

Closure and opening of areas

The CCCMM informs daily by fax at 8.00 a.m. the *Consellería de Sanidade* about the situation in all areas. The *Dirección General de Marisqueo y Acuicultura* of the *Consellería de Pesca* is the competent authority in this matter. When the parameters (*Orden* of 14-11-1995) exceed the tolerance levels, the areas are temporarily closed. All molluscs of the area are extracted and all the sectors informed by fax. Closure can also be preventive. When conditions are reestablished and, after intensive sampling and monitoring following the existing legislation (*Orden* of 14-11-1995), the area is re-opened.

The *Consellería de Sanidade* controls the registration documents entering the purification and dispatch centres. Whether any suspicion of diversion of toxic products exists, this is alerted through the Rapid Exchange of Information Co-ordinated System (SCIRI) and action is taken.

Andalucía:

There are 44 production areas in Andalucía (33 A and 11 B). In the area of the estuary of river Guadalquivir, a specific programme of control was set to study the possible consequences of the accident of the Aznalcollar mine well.

Programme of control : There are 44 sampling points in the production areas and 8 in the Guadalquivir area. Points can be modified following results of the sampling and the situation of the natural banks. For each point, a sample of the column of water and/or bioindicator species (primary or secondary) is taken monthly under the routine programme. In addition, *Acanthocardia tuberculata* is sampled for PSP, following a specific programme of control, as well as *Pecten maximus* and *Mytilus galloprovincialis*, which are sampled for PSP and DSP. Intensive sampling starts when parameters exceed the limits.

There is 4 sampling teams lead by a biologist. Samples are accompanied by an identification document and handled following the programme's instructions. Traceability of samples and analysis is correct. A full-computerised system has been developed to manage the programme.

Analytical checks in water :

Faecal coliforms: 1/month (528 tests/year). Toxic phytoplankton: 1/month, 1/2 weeks, 1/week, depending of the area (1.548 tests/year).

Analytical checks in Shellfish :

Faecal coliforms: 1/month (516 tests/year). *E. coli*: 1/month (516 tests/year), *Salmonella*: 1/month (516 tests/year). Heavy metals: Cu, Hg, Pb, Cd; 1/3 months or 1/6 months (440 tests/year). Organo-halogenated substances: 1/year (43 tests/year). Radionuclids: 1/year (43 tests/year).

PSP (mouse bioassay): 1/2 weeks, 1/month, 1/3 months, depending on the area (644 tests/year). DSP (mouse bioassay and HPLC): 1/month, 1/3 months, depending on the area (184 tests/year). The diagnostic official waiting time for PSP is 24 hours. ASP (HPLC): 1/month or 1/3 months (280 tests/year).

Closure and opening of areas :

When levels exceed the official limits, the *Delegaciones Provinciales* involved close temporarily the areas or forbid specifically the species involved if contamination is selective. All sectors are informed. When normality is reestablished and, after intensive sampling finding at least two negative results, the areas are re-opened.

6.3. REGISTRATION DOCUMENTS :

In both CCAA (Galicia and Andalucía), the competent authorities have established and official model of document that is distributed to the producers and accompany the products to the establishments. In addition, to assure the traceability of products, Andalucía created an identification label that must be attached to the packaging at origin and is linked to the registration document. In both CCAA, these documents are effectively controlled by the authorities.

7. PURIFICATION AND DISPATCH CENTRES

In Spain there is a total of 165 establishments, located in 10 CCAA. 22 out of these 165 are purification centres, 63 are dispatch centres and 80 of them perform both activities. Andalucía, Galicia and Cataluña hold the great majority of them. Traditionally, Galicia purifies almost the 100% of the BM, as a general rule, even if they come from A areas.

The level of compliance of the establishments visited in Andalucía and Galicia is homogeneous. The sanitary conditions of the establishments visited comply with the requirements of the existing legislation. Records of purification and own-checks are kept.

Official supervision is regular and copies of their visits are kept. The competent authorities draft annual programmes of inspection of the establishments and the rest of the chain of shellfish. HACCP systems are implemented in all establishments at different degrees. However, the treatment of water (chlorination) is not controlled.

Traceability of the products is good. All products enter the establishment accompanied by their registration document. The authorities recommend that products are packed in small packages ready for the consumers. There are also big packages (10 Kg) on the market that are opened for direct sale. However, some CCAA do not control properly the traceability of *Ensis ensis* (*navajas*), who arrive to the market without a proper identification.

8. NATIONAL REFERENCE LABORATORY (VIGO)

This official laboratory which has also the responsibility of being the Community Reference Laboratory for biotoxins and the laboratory of control of imports in Spain, is slowly starting to act as National Reference Laboratory, as stated in Council Decision 93/383. With only four staff,

although highly qualified, it is not able to face properly such an amount of work in these three different areas. A total of 4.562 analysis were done by this laboratory in 1998. Administrative tasks and organisation of co-ordination meetings with other laboratories are not sufficiently carried out

Official communication and co-ordination with regional laboratories is not sufficient. As National Laboratory it is subject to further co-ordination by the MSC in relation with other CCAA, which is also another link of the co-ordination chain to take into consideration. On the other hand, communication and advice to regions as Galicia and Andalucía is working thanks to personal contacts.

Inter-calibration tests between labs have not been possible up to now, due to the absence of toxic material in a sufficient amount. The laboratory is planning to focus on its national tasks along the first semester of 1999.

Note : The laboratory management declared, as Community Reference Laboratory, that the establishment of a Commission Decision concerning the recommended analytical methods for biotoxins, would be very helpful in improving the co-ordination of this matter at Community level.

9. CONCLUSIONS

The control of the production of shellfish in the two CCAA visited is satisfactory and complies with the existing legislation in general terms. However, the frequency of 1 analysis/3 months for microbiology in Galicia is considered to be low, unless a validation of this frequency is done. In addition, not all the chemical parameters stated in Council Directive 79/923/EEC are checked.

The present situation of the National Laboratory of Reference (Vigo) does not allow this laboratory to fully comply with the requirements stated in Council Decision 93/383/EEC.

This visit, as well as those of other Member States, showed the need of an EC discussion of some general items concerning the EC legislation as analytical methods (bioassay), labelling, packaging. Although it is not in the Directive, the direct sales of small quantities of shellfish by the producers to consumers (restaurants) should also be discussed. In addition, some considerations about the Community Reference Laboratory (Vigo) and further co-operation and information between Member States should be discussed.

10. RECOMMENDATIONS

Recommendations to the Spanish competent authorities :

-Action needs to be taken by the Spanish authorities regarding the situation of the Canary Islands, the control of the origin and traceability of *Ensis ensis* (navajas) and the situation of the National Laboratory of Reference.

-The frequencies of the microbiological checks must be re-validated to verify their reliability.

It is expected that the information about the actions taken concerning the previous points, are sent to the Commission before the end of May 99.

-The EC services shall be informed as soon as possible about the ongoing situation of the transposition of Council Directive 97/61/EC.

Recommendations to the European Commission :

The visit to Spain is part of a global evaluation of the 15 Member States. This series of visits are showing the need of a general set of recommendation to the Commission, an in particular:

- As required by the 97/61/EC Directive, a unique model of registration document should be established. Further consideration should be given to the use of the registration document when shellfish are trade between Member States.
- A working group should be established to further consider Directive 91/492/EEC on the basis of experience gained. Microbiological and phytotoxicity aspects, and repackaging activity, would have, in particular, to be considered.
- DSP and biotoxins intercalibration tests should be organised to ensure the same level of safety of shellfish produced in the Member States.

ADDENDUM TO THE REPORT

On 9-Abril-1999 the transposition of Council Directive 97/61/EC was officially published. Real Decreto 571/999 (Reglamentación Técnico-sanitaria que fija las normas aplicables a la producción y comercialización de moluscos bivalvos vivos).

This report includes the comments/clarifications of the Spanish Competent Authorities to the Draft Report received on 4 June 1999. The said comments were considered by the FVO services.