

**MEDITERRANEAN ACTION PLAN**

Consultation on the compliance of  
maximum permissible levels  
of contaminants in seafood

Larnaca, Cyprus, 24-26 June 1998

**FISH AND SHELLFISH SAFETY: STANDARDS, GUIDELINES,  
MONITORING SYSTEMS, SAMPLING PLANS AND ANALYSIS**

In cooperation with:



FAO



WHO

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## **BACKGROUND**

The MED POL Programme includes aspects related to the protection of human health. Even in Phase I pilot projects dealt with microbiological contamination in recreational waters and with the levels of chemical contaminants in seafood. In particular two pilot projects concerned the levels of heavy metals (especially mercury and cadmium) and of chlorinated hydrocarbons (especially DDTs and PCBs) in marine biota. The first data showed that mercury concentrations in some species were higher than in the same species coming from the Atlantic ocean. More specifically, scientists were able to detect “low mercury” and “high mercury” populations of tuna coming from the Atlantic and the Mediterranean respectively. High mercury concentrations were also found in other species but these came from well known polluted sites.

The reported high mercury values created justifiable concern for the human health. For this reason, a study was initiated in 1983 to investigate whether in fact the Mediterranean population in general was at risk. The countries chosen for this study were: Italy, Croatia and Greece and the populations were high-risk groups such as fishermen and their families. After preliminary screening of more than 4,000 persons through dietary surveys a total of 1098 hair samples were analysed for total mercury and, where appropriate, for methylmercury. On the basis of the criteria adopted (25 ppm of mercury in hair for adults and 6 ppm in maternal hair for newborns) no at-risk individuals were identified in Croatia and only very few people in the other two countries exceeded these criteria. However, no clinical effects were detected.

As a consequence to the above, the Contracting Parties to the Barcelona Convention at their Fourth Ordinary Meeting (Genova, September 1985), adopted interim environmental quality criteria for mercury on the basis of which they should establish (if national circumstances so require) standards for maximum concentration of mercury in seafoods, taking into consideration the Provisional Tolerable Weekly Intake (PTWI) proposed by the joint FAO/WHO Committee of experts. The PTWI for a 60 kg person is 0.3 mg of mercury of which not more than 0.2 mg is methylmercury.

The decision of the Contracting Parties also included to the extent possible the sampling and analysis of species of seafood, known to accumulate mercury, in their national monitoring programmes. The full decision appears as Annex I to the present document.

During the 1996 Meeting of MED POL National Coordinators and MAP National Focal Points, the issue of legal provisions for maximum permissible levels of contaminants in seafood was brought up in relation to the adoption and enforcement of common measures for the protection of human health and as a consequence a relevant activity was approved by the Extraordinary Meeting of the Contracting Parties to the Barcelona Convention (Montpellier, July 1996).

In pursuance to the above, the Secretariat decided to organise, jointly with FAO and WHO, a “Consultation on the compliance of maximum permissible levels of contaminants in seafood” where experts from Mediterranean states will exchange information and views on the subject and specifically on the need for harmonization. The present document was prepared for the needs of the above Consultation.

## **1. INTRODUCTION**

Fish is an important source of proteins, trace elements, vitamins and omega fatty acids. For this reason they constitute desirable components of healthy diets. The need to turn to more healthy diets in order to prevent food related diseases, has led to a considerable increase in the consumption and demand of seafood in the last years. As a consequence the importance of fish and fish products in international

trade has also increased. Therefore, besides its role as nutritious food, seafood is an important contributor to the Gross National Product of many countries. The particular fish market represents one of the most important income for several developing countries. Seafood safety is thus very crucial from both a health and an economic viewpoint.

Major health risks from the consumption of seafood, are associated with biological contamination and hygienic condition of handling and transport of fish before consumption. Chemical contaminants in fish are considered a potential risk for fish harvested from coastal zones and inland habitats that are exposed to varying amounts of environmental contaminants. Agro-chemicals and heavy metals may accumulate in products that can cause public health problems. There are also a number of important biotoxins to consider with priority for ciguatoxin and phycotoxins. At more serious risk are certain groups of people including the elderly, immunosuppressed individuals, and those with underlying chronic disease conditions. Young children and pregnant women are at risk from long-term effects of ingestion of certain chemical contaminants and should be protected from eating fish from contaminated areas. Therefore, adequate attention should be given to the harmonisation of standards and monitoring programmes.

Marine pollution may result in risks for human health and in effects on fish stocks. The Mediterranean being aware of these risks have agreed on a programme to prevent a combat marine pollution. In the framework of the Euro-Mediterranean Partnership the EU and the Mediterranean states have called for action for the same purpose. The establishment of a free trade area in the framework of the economic and financial partnership, in accordance with the principles included in the Barcelona Declaration and with due regard to the GATT agreement, will be based on measures including: harmonisation of standards and adoption of measures related to legislation on foodstuffs (including the maintenance of safety standards of seafood).

According to the GATT agreement, international consensus regarding any measures for the protection of public health, which may affect international trade, must be based on scientific principles which are reflected in the standards, guidelines and other recommendations adopted by the FAO/WHO Codex Alimentarius Commission.

## **2. STANDARDS FOR SEAFOOD**

Problems related to food contamination, led to the establishment of maximum levels and guidelines, for the protection of public health and international trade. Maximum levels and guidelines have been set for foodstuffs, including seafood, concerning their levels of contaminants and natural toxins.

### Maximum Level - ML\*

MLs have been established (or proposed) for contaminants which have been identified as health problems, and for foods (or group of foods) which:

- (a) are responsible for a great proportion of the total dietary intake of the contaminant (for example: vegetables, cereals and shellfish are responsible for a great proportion of the total dietary intake of Cadmium),
- (b) may contain the contaminant in amounts which are significant for the consumers' total exposure to the contaminant (for example: fish may contain mercury in amounts which are significant for the consumers' total exposure), and

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\* N.B. A number of definitions of terms used in this document are found in Annex II

- (c) may cause trade problems because of their contaminant levels.

For pesticide and veterinary residues in foodstuffs, the Maximum Levels are called Maximum Residue (or residual) Levels (MRL).

#### Guideline Level - GL

GLs have been set for contaminants which could cause health problems.

Although many standards have been set, there is still a lack of adequate standards and analytical methods for monitoring the presence of various toxins and other contaminants in fish and shellfish. Especially for aquatic biotoxins, only a limited number of toxins have been covered by legislation and standards. On the other hand, there are some problems regarding the existing standards, which need to be addressed, for example:

- (a) Some of the provisions laid down in the relevant legislation concerning the levels of contaminants in seafood, do not include maximum levels or guidelines but general, descriptive requirements of the type “not to exceed Permissible Daily Intake”, or “food shall not be placed on the market if contaminant level is not accepted from the public health viewpoint and particularly at a toxicological level”.
- (b) In some cases there are different guidelines /maximum levels for the same contaminant or toxin, established by different bodies.
- (c) In some cases, there is a potential lack of conformity between nutritional guidelines and food safety considerations for the protection of public health.

For points (b) and (c), the case of mercury could serve as an example:

Point (b): There are different standards for mercury. The Commission of the European Communities has adopted a Decision determining MLs for total mercury in fish. The Codex Alimentarius has adopted Guidelines for methylmercury in fish. The standards are of the same numerical value (concentration): 0.5 ppm in the edible part of species except predatory and 1ppm in the edible part of predatory fish. The Food and Drug Administration of the United States (FDA) has set only one action level for methylmercury in fish: 1 ppm methylmercury in the edible part of fish. Some member states of the European Community are using standards/ guidelines, which vary from country to country and differ from those adopted by the Commission. For example, for the purposes of the Joint Monitoring Programme of the Oslo and Paris Commission, three arbitrary, purely descriptive guidelines including lower, medium and higher limits have been set, which are also adopted for the purposes of seafood monitoring in Great Britain.

Point (c): There could be a contradiction between nutritional guidance concerning fish consumption and safety considerations regarding mercury levels in fish. The contradiction derives from the following facts:

The Provisional Tolerable Weekly Intake (PTWI) of mercury for humans according to Codex Alimentarius and FDA, is 0.005 mg/kg body weight for total mercury and 0.0033 mg/kg body weight for methylmercury. This means that the tolerable intake per week of a person with a body weight of 60 kg, is 0.3 mg of total mercury out of which not more than 0.2 mg should be methylmercury.

The tolerable intakes of the contaminant, can be used for the estimation of the corresponding tolerable levels of fish consumption when the fish is found to contain total mercury or methylmercury levels close to the limits.

The tolerable levels of fish consumption are: (i) 600 gms per week of fish other than predatory and 300 gms per week of predatory fish (e.g. large fish like swordfish) containing total mercury at levels equal to the European MLs and (ii) 400 gms per week of fish other than predatory and 200 gms per week of predatory fish, containing methylmercury at a level equal to the Codex GL.

Considering that 300 gms is the weight of one serving, the tolerable levels of consumption in case (i) correspond to about two servings per week of fish other than predatory and to about one serving per week of predatory fish with permitted but close to the maximum, levels of total mercury. In case (ii) the tolerable levels of consumption correspond to less than one serving per week of predatory fish and a little more than one serving per week of fish other than predatory, with permitted but close to the maximum, levels of methylmercury. It is important to note that the calculations are made on the assumption that total mercury exposure is derived only from fish, without considering other sources of exposure. This of course is not a realistic assumption since mercury is everywhere.

It is probable that consumers who follow healthy diet guidance recommending increased proportions of fish in their diets may exceed the tolerable exposure to this toxic contaminant (on a chronic basis), even if the fish they consume are in compliance with the limits. A health problem may also occur for consumers frequently eating a particular species of fish - instead of a variety - and for some groups of consumers for example pregnant women and women of childbearing age.

The FDA for example advises consumers to limit the consumption of shark and sword fish to no more than once a week and pregnant women as well as women of childbearing age to no more than once a month. They also advice consumers to eat a variety of fish instead of one particular fish.

## 2.1 Codex Alimentarius standards

Standards and relevant requirements have been established by the WHO/FAO Codex Alimentarius.

The need to maintain a consistent policy on the establishment of maximum levels, is stressed by the Codex Alimentarius Commission. To this effect a number of criteria should be used regarding the information which is needed in order to evaluate contaminant problems in food, and to establish maximum levels. This information includes: *toxicological information, analytical data, intake data, fair trade and technological considerations, risk assessment and risk management considerations.*

Annex IV of the draft "Codex General Standard for contaminants and toxins in food", contains an annotated list of contaminants and toxins, which provides an overview of the situation regarding contaminants and natural toxins in foods and of actions required from the Codex Committee on Food Additives and Contaminants and from Governments.

Annex IV-B contains a situation review of contaminants and toxins in food. For each contaminant the following information is provided:

- (a) Identification of the contaminant, and about the background of the problem.
- (b) Toxicological guidance, data about occurrence in food and total intake.
- (c) Potential health problems.
- (d) Potential barriers to international trade.
- (e) Technological and other aspects of the problem.
- (f) Proposals for action by the Codex Committee on Food Additives and Contaminants.

Annex V provides a Food categorisation system to be used in the General Standard for Contaminants. This classification has been developed by the Codex Committee on pesticide residues. It is intended primarily to ensure the use of uniform nomenclature and also to classify foods into groups (and subgroups), for setting group maximum levels.

Schedule I of the “Codex General Standard for contaminants and toxins in foods”, is a list of Codex Standards for individual contaminants and toxins in foods, existing or being elaborated or proposed by the end of 1994.

Maximum Levels for contaminants in fish and shellfish (e.g. for lead) and guidelines (e.g. for mercury) are also presented in the list.

The Codex Committee on fish and fishery products has completed a full review of standards. Codes of practice for fish and fishery products and for the products of aquaculture are circulating for comments. A Hazard Analysis and Critical Control Points (HACCP)-based approach has been considered as recommended by General Principles of Food Hygiene.

## 2.2 The European Communities, FDA/EPA and other national standards

Standards, guidelines and other relevant requirements have been established by the European Council, the FDA and EPA (for pesticide residues) as well as in the framework of national legislation on foodstuffs of various countries.

## 3. **LEGISLATION**

Legislation is available laying down standards, official monitoring, inspection, sampling and analysis of seafood.

### 3.1 The European Communities legislation

The Commission of the European Communities has issued a Guide to certain rules governing the production, marketing and importation of products of animal origin intended for human consumption, which includes a review of the relevant European legislation. The Guide contains in Parts II and III of the Annex III respectively: “Specific Provisions for Live Bivalve Molluscs” and “Specific Provisions for Fishery Products”.



This document refers not only to specific legislation laying down standards, official monitoring, inspection, sampling and analysis of seafood. It also refers to general legislation on foodstuffs which is applicable to seafood as well as to specific legislation covering other foodstuffs, including criteria for the development of sampling plans and monitoring systems, which could be considered or used along with the specific criteria adopted for seafood, when developing a protocol for monitoring fish, fishery products and shellfish.

The sampling procedures and the treatment of the samples as well as the qualitative and quantitative analysis, must be carried out in accordance with Community methods. The laboratory samples taken in accordance with these methods shall be considered as representative of the lot and compliance with maximum levels laid down by Directives and Regulations, shall be thus established on the basis of the levels determined in them.

When Community methods do not exist, the responsibility to support the representativeness and the reliability of the laboratory results with scientifically sound procedures, remains with the competent authorities of the Member States. Relevant procedures are laid down in specific Directives and in the European Standard EN 45001.

If one or more of the laboratory samples exceeds the maximum limits, the total lot of the foodstuff is rejected.

### 3.1.1 Specific legislation

**Directive 79/923/EEC** on the quality required for shellfish waters, recognises the need to establish the health requirements to be observed for shellfish products. The Directive includes a list of contaminants to which refer other Directives laying down control of certain fish and shellfish.

**Council Regulation (EEC) No 2377/90** laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. In accordance with this Regulation MRLs must be established progressively for all active substances used in veterinary medicinal products intended for administration to food producing animals, after the examination of all relevant information on the safety of residues of the concerned substance.

A list of pharmacologically active substances used in veterinary medicinal products and their MRLs are found in Annex I.

A list of active substances for which it appears that it is not necessary to establish MRLs are found in Annex II.

A list of substances in respect of which provisional MRLs have been established are found in Annex III.

A list of active substances in respect of which MRLs cannot be established, because at whatever limit the residues constitute a health hazard for the consumers, are included in Annex IV.

The Regulation has been amended by Regulations (EC) No 675/92, 762/92, 3092/92, 3093/93, 2901/93, 3425/93, 3426/93, 2701/94, 2034/96, 1350/97 and 121/98.

The Annexes include specific MRLs for fish and other animals and MRLs for all animals including fish.

**Council Directive 91/492/EEC** laying down the health conditions for the production and placing on the market of live bivalve molluscs. The Directive recognising that :

- (i) it is necessary to establish health requirements to be observed for shellfish products,
- (ii) these requirements should be laid down for all the stages from harvesting to distribution of live bivalve molluscs in order to safeguard public health, and,
- (iii) it is important to be able to trace back the establishment of dispatch and the harvesting area when a health problem occurs, includes provisions which require, amongst others, the following:

Article 5: The competent authority shall approve and maintain a list of approved dispatch centres and a list of production and relaying areas, and shall carry out regularly inspection and monitoring of these centres and areas.

Article 8: Provisions applied to imports shall be at least equivalent to those governing Community products.

**Chapter V of the Annex** to the Directive, sets requirements concerning live bivalve molluscs. Live bivalve molluscs intended for immediate human consumption must comply with requirements including :

- (i) microbiological limits for faecal coliforms, E coli (the method of analysis is specified) and salmonella,
- (ii) a general requirement for chemicals listed in the Annex to Directive 79/923/EEC, according to which live bivalve molluscs must not contain these contaminants in such quantities that the calculated dietary intake exceeds the permissible daily intake PDI of the contaminant,
- (iii) the upper limits for the radionuclide contents must not exceed the Community limits for foodstuffs,
- (iv) limits for PSP (Paralytic Shellfish Poisoning) and for DSP (Diarrhetic Shellfish Poisoning) and,
- (v) in the absence of routine virus control and relevant standards, health checks must be based on faecal bacteria counts.

Compliance with the requirements of Chapter V should be checked with proven methods which are scientifically recognised. Sampling plans, analytical methods and tolerances must be established.

**Chapter VI** lays down the requirements for Public Health control and monitoring of production. A public health control system must be established by the competent authority including:

- (a) Periodic monitoring including control of:
  - microbiological quality of the live bivalve molluscs;
  - the presence of toxin producing plankton in waters and of biotoxins in live bivalve molluscs;

- the presence of chemical contaminants (the maximum authorised levels to be fixed by 31 December 1992), and
- (b) Sampling Plans : According to the Chapter, sampling plans should take account of :
  - likely variations in faecal contamination at each production and relaying area;
  - likely variations in production at relaying areas in the presence of plankton containing biotoxins. The sampling should be periodic unless there is a suspicion of accumulation of toxins in molluscs. In this case intensive sampling should be implemented;
  - possible contamination of the molluscs in the production and relaying area.

If the result of sampling shows that the placing on the market of live bivalve molluscs may constitute a hazard to human health, the competent authority must close the production area, as regards to molluscs concerned, until the situation has been restored; The following are some definitions of terms referred to above:

**Decisions Number 96/333/EC** on health certificates for live bivalve molluscs and 97/20/CE on establishing the list of third countries for bivalve molluscs, amend this Directive, but they do not include provisions relevant to sampling plans and analytical methods.

**Council Directive 91/493/EEC** on the health conditions for the production and placing on the market of fishery products.

The Directive recognising:

- (i) the need to establish essential requirements for the correct hygienic handling of fresh and processed fishery products at all stages of production and during storage and transport,
- (ii) the need to fix the health quality of fishery products by applying marketing standards, products comply with the health requirements, and
- (iii) that the competent authorities must carry out checks and inspections in order to ensure that producers and manufacturers comply with the health requirements,

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

“Fishery products” means a seawater or freshwater animals or parts thereof, including their roes, excluding aquatic mammals, frogs and aquatic animals covered by other Community acts.

Article 3(1) sets conditions for the placing on the market of fishery products. Fishery products caught in their natural environment, aquaculture products and processed bivalve molluscs, shall be subject to conditions including the following:

- ...The competent authority may authorise the transfer of fishery products ex quay into containers for immediate delivery to an approved establishment or registered auction or wholesale market to be checked there.

- They must have undergone a health check in accordance with Chapter V of the Annex.
- They must have been given an identification mark.

Article 5 forbids the placing on the market of poisonous fish (Tetraodontidae, Molidae, Diodontidae) and of fishery products containing biotoxins such as ciguatera or muscle-paralysing toxins. Article 5 Requires that the competent authorities shall draw up a list of approved establishments each of which shall have an official number.

Article 6 introduces the principle of own-checks system (HACCP) and requires the implementation of some of its elements: identification of Critical Control Points (CCPs), establishment and implementation of methods for their monitoring and checking and record keeping. The requirements need to be completed and clear definitions and specifications need to be introduced.

**Chapter V** contains requirements for health control and monitoring of production conditions by the competent authority, including:

**(a) Parasites checks**

Visual inspections for detecting visible parasites should be carried out before fish are released for human consumption. Fish or parts of fish which are obviously infested by parasites, must not be placed on the market.

**(b) Chemical checks**

- (i) Control of TVB-N (total volatile basic Nitrogen) and of TMA-N (trimethylamine Nitrogen). The maximum levels for each category of species have been fixed in the Commission Decision No 95/149/EC, specifying also the analysis methods to be used.
- (ii) Control of Histamine in fish samples (of the families Scombridae and Glupeiidae). Some sampling requirements and criteria for compliance are specified : nine samples must be analysed from each batch and the mean value of histamine must not exceed 100 ppm ; two samples may have a value of more than 100 ppm, and no sample may have a value exceeding 200 ppm. Fish which have been undergone enzyme ripening in brine may have higher but not more than twice the above levels.
- (iii) Control of contaminants present in the aquatic environment, such as heavy metals and organochlorins. The fishery products must not contain them in their edible parts at such levels that the calculated dietary intake exceeds the Acceptable Daily or Weekly Intake for humans.

The sampling plans and the methods of analysis for the control of the chemical parameters, as well as, their acceptable levels, shall be decided by not later than 31 December 1992. Nevertheless only one Decision has been adopted to this respect, the Decision No 93/351/EEC on analytical methods, sampling plans and MLs of mercury in fishery products. Additionally, the Directive No 96/23/EC includes provisions for the control of aquaculture products.

**(c) Microbiological analysis.**

Microbiological criteria, sampling plans and methods of analysis may be laid down when there is a need to protect public health. The Commission will submit proposals for measures by 1 October 1992.

Microbiological criteria have not been established yet. In order to advise the Commission in this area the Scientific Committee for Foods has given its opinion on the "Principles for the development of Microbiological Criteria for foodstuffs" as covered by the Directive 93/43/EEC.

**Directives Nos 95/71/EC and 92/48/EEC** on Fishing vessels-Freezer vessels and Decisions Nos 93/25/EEC on Heat Treatment of bivalve molluscs and gastropods, 93/51/EEC on Microbiological criteria for cooked crustaceans and shellfish, 93/140/EEC on Paracites, 93/356/EEC on HACCP and 95/328/EC on health certificates for Fishery Products coming from third countries, amend Directive 91/493/EEC, but they do not include provisions relevant to sampling plans and analytical methods.

**Commission Decision 93/351/EEC**, determining analysis methods, sampling plans and maximum limits of mercury in fishery products.

Article 3 requires that Sampling Plans shall take account of :

- (a) the results obtained from national checks,
- (b) the product type (species listed and species not included in the Annex),
- (c) the minimum number of samples to be taken per lot of each product type.

The Decision also contains requirements for the preparation of the sample for analysis and adopts the following maximum limits for total mercury:

The mean total mercury content of the edible parts must not exceed 0.5 ppm of fresh product for the species not listed in the Annex, and 1 ppm for those included in the Annex. The Annex is a list of predatory fish.

**Commission Decision 94/356/EEC** laying down detailed rules for the application of Council Directive 91/493/EEC as regards own-checks on fishery products.

**Council Directive 96/23/EC** on measures to monitor certain substances and residues in live animals and animal products, and Council Decision 97/747/EC on the establishment of levels and frequency of sampling referred to in 96/23/ EC.

The Council of the European Communities has adopted the Directive No 96/23/EC having regard to various Directives including the provision of the Directive No 91/493/EEC, which requires a monitoring system to be established by the Member States for the control of contaminants levels in fishery products.

Article 5 requires that Member States shall submit to the Commission their national plan for the monitoring of residues and other substances in animals and their water as well as in the environment where they are bred or kept. The plan shall comply with the sampling rules laid down in Annex IV.

Annex I, to the Directive includes two groups of substances, the residues of which shall be monitored in animals listed in Annex II, including aquaculture animals. Group A includes substances having anabolic effect and unauthorised substances. Group B includes veterinary drugs, pesticides and environmental contaminants.

Annex III on Sampling Strategy requires the following:

- (a) The residues control plan is aimed at surveying and revealing the reasons for residues hazards in foods of animal origin on farms, slaughterhouses, dairies, fish processing plants, and egg collecting and packing stations.

Official samples are to be taken in accordance with the relevant chapter of Annex IV.

Wherever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week. The Member States must take all the precautions necessary to ensure that the element of surprise in the checks is constantly maintained.

- (b) For Group A substances, surveillance should be aimed at detecting the illegal administration of prohibited substances and the abusive administration of approved substances, respectively. The emphasis of such sampling must be concentrated according to the relevant chapter of Annex IV.

The samples must be targeted taking account of the following minimum criteria: sex, age, species, fattening system, all available background information and all evidence of misuse or abuse of substances of this group. The details of these criteria are laid down in the relevant Commission Decision.

- (c) For Group B substances, surveillance should be aimed particularly at:
- (i) controlling the compliance with MRLs of veterinary medicinal products fixed in Annexes I and III to Regulation (EEC) No. 2377/90 (Annexes to Regulation No 2377/90 and its amendments include MRLs for fish), and the maximum levels of pesticides fixed in Annex III to Directive 86/363/EEC, and
- (ii) monitoring the concentration of environmental contaminants.

Unless random sampling can be justified by Member States when presenting their national plans to the Commission, all the samples shall be targeted according to criteria laid down in the Commission Decision provided for in Article 15(1).

Annex V on Sampling Levels and Frequency, defines the minimum number of animals from which the samples must be taken. Each sample can be analysed for detecting the presence of one or more substances.

Chapter 3 on Aquaculture products, includes the following:

**Finfish farming products:**

A sample is one or more fish, according to the size of the fish in question and of the requirements of the analytical method.

Member States must respect the minimum sampling levels and frequencies given below, depending on the production of farmed fish (expressed in tonnes). The minimum number of samples to be collected each year must be at least 1 per annual 100 tonnes of production. The compounds sought and the samples selected for analysis should be selected according to the likely use of these substances. The following breakdown must be respected:

Group A: one third of the total samples: all the samples must be taken at farm level, on fish at all stages of farming, including fish which is ready to be placed on the market for consumption. For sea-farming, in which sampling conditions may be especially difficult, samples may be taken from feed in place of samples from fish.

Group B: two thirds of the total samples: the sampling should be carried out:

- (i) preferably at the farm, on fish ready to be placed on the market for consumption;
- (ii) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.

In all cases, samples taken at farm level should be taken from a minimum of 10% of registered sites of production.

### **Other aquaculture products:**

When Member States have a reason to believe that veterinary medicine or chemicals are being applied to the other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.

**Commission Decision 97/C 355/08**, amending the Annex to the Directive 91/492/EEC. The Decision establishes maximum levels of Amnesic Shellfish Poisoning in the edible parts of shellfish.

#### 3.1.2 General legislation on the control of foodstuffs

**Council Directive 85/ 591/EEC** on the establishment of measures for sampling and methods of analysis of foodstuffs. The Directive contains only general provisions relevant to the establishment of such measures and methods by the Committee (Scientific Committee for Food), or, possibly by the Council.

The Annex to the Directive lays down requirements concerning analytical methods.

**Council Directive 89/ 397/EEC** laying down the general principles for the official control of foodstuffs.

Article 2 requires that Member States take all necessary measures to ensure that control is carried out in accordance with this Directive.

Article 4 requires that inspection covering all stages of production, manufacture, import, processing, storage, transport, distribution and trade, shall be carried out (a) regularly and (b) when non-compliance is suspected. As a general rule inspection must be unexpected. In each case the stages which are the most appropriate for inspection must be selected.

Article 5 requires that control shall comprise one or more of five operations. The first operation is inspection. The second operation is sampling and analysis.

Articles 6(1)(b) to (f) and 7 require that subject to inspection and sampling shall be: raw materials, ingredients, technological aids and other products used for the production of foodstuffs; semi-finished products; finished products; materials and articles intended to come into contact with foodstuffs; cleaning and maintenance products.

Article 7 also requires that analysis shall be carried out by official laboratories. Member States may also empower other laboratories to carry out these analysis. Steps should be taken to ensure that those concerned by the inspection may apply for a second opinion.

Article 12 requires that Member States take the necessary measures to ensure that natural and legal persons concerned by the inspection have the right of appeal against measures taken by the competent authority for the purpose of inspection.

**Commission Decision 90/515/EEC** laying down the reference methods for detecting residues of heavy metals and arsenic. The reference methods are established pursuant to Article 4(1)(b) of Directive 64/433/EEC, amended by Directive 89/662/EEC, on health problems affecting intra- Community trade in fresh meat and Directive 86/469/EEC on the examination of animals and fresh meat for the presence of residues. Reference methods are necessary:

- (a) for assessing the results of the examinations for residues (cadmium, lead, mercury and arsenic) and,
- (b) for confirming all positive findings, if challenged.

**Council Regulation 315/93** laying down Community procedures for contaminants in food.

The Council of the European Communities has adopted this regulation recognising, amongst others, the following:

- (i) That contaminants may enter into the food at any stage from production to consumption.
- (ii) That is essential in the interest of public health protection, to keep these contaminants at levels which are toxicologically acceptable.
- (iii) That further elimination must be carried out through good working practices whenever it is achievable and that public authorities can effectively monitor the compliance with such practices and
- (iv) That in terms of health protection it is appropriate to encourage the search of comprehensive approaches to the question of contaminants in food.

According to Article 2:

1. Food containing a contaminant in an amount which is not acceptable from the public health viewpoint and in particular at a toxicological level, shall not be placed on the market.
2. Contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all the stages from production to consumption.
3. In order to protect public health and pursuant to 1. where necessary, Maximum Tolerances for specific contaminants shall be established. These Tolerances shall be published in the form of a non exhaustive Community list and may include limits for the same contaminant in different foods, analytical detection limits and a reference to the sampling and analytical methods to be used.



Where a Member State has a reason to suspect that a contaminant in food although complying with this or a specific Regulation, adopted pursuant to this Regulation, constitutes a health risk, it may temporarily suspend or restrict application of the provisions in question in its territory and immediately inform the Commission.

Where Community maximum tolerances do not exist, national provisions shall be applicable subject to compliance with the provisions of the Treaty.

The regulation shall not apply to contaminants which are subject to more specific Community rules.

**Council Directive 93/43/EEC** laying down general rules for safe food.

This Directive lays down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with them recognising :

- (a) the need to ensure confidence in the standard of safety of foodstuffs, and in particular their standards of hygiene, as a precondition for the completion of internal market,
- (b) the need to harmonise the general rules of hygiene for foodstuffs which are to be observed at the time of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply and,
- (c) the use of hazard analysis, risk assessment and other techniques to identify, control and monitor critical points.

Article 3 requires that food business shall develop their HACCP - Hazard Analysis and Critical Control Points system, following certain steps.

Article 8 requires that the competent authorities shall carry out controls in order to ensure that the provisions of Article 3 are being complied with by food industries. Controls shall be carried out also on foodstuffs imported into the Community.

The competent authorities shall carry out controls in accordance with Directive 89/397/EEC.

**Council Directive 93/99/EEC** on additional measures concerning the official control of foodstuffs, supplements Directive 89/397/EEC.

The additional measures relate mainly to quality standards for the official laboratories, to technical and administrative competence of the staff of the competent authorities and to the co-operation between the Commission officials and the officials of the Member States.

Member States shall ensure that official laboratories comply with the European Standard EN 45001, supplemented by standard operating procedures and also by the random audit (in accordance with the OECD principles 2 and 7, section II, Annex 2 to the Decision of 12 May 1981 setting out principles of Good Laboratory Practice), by Quality Assurance personnel.

In assessing the laboratories the European Standard EN 45002 shall be applied and the participation in proficiency test shall be required, as far as appropriate.

Article 4 requires that the validation of analytical methods used within the context of official control referred to in Directive 89/397, shall comply whenever possible with the provisions of paragraphs 1 and 2 of the Annex to Directive 85/591/EEC.

### 3.1.3 Legislation on other foodstuffs which could be considered when developing seafood monitoring protocols

**Council Directive 79/700/EEC** establishing methods of sampling for the official control of pesticide residues in or on fruit and vegetables.

Reference is made to this Directive although it is not relevant to seafood, for the reasons given in page 28 (overview of sampling plans) and because the requirements in the specific Directives on fish and live bivalve molluscs regarding the establishment of sampling plans, have not yet been fully satisfied.

More recent legislation presented below, either adopt the Annex to this Directive on methods for sampling, or, amend its provisions in order to apply to the official control of other foodstuffs and other contaminants.

In the formulation of the methods established in Directive 79/700/EEC, it has been recognised that on account of the variation in size, state and packaging (if any) of the fruit and vegetables which are in circulation, the methods will only be practicable if certain operations are sufficiently empirical. The methods of sampling, include general provisions such as:

- (i) Each lot to be examined must be sampled separately.
- (ii) Precautions should be taken to avoid any changes in the sample which would adversely affect the analytical determination or make the laboratory samples unrepresentative.
- (iii) Incremental samples should be taken at various places distributed throughout the lot.
- (iv) Goods which are wholly or extensively spoiled are not to be used for sampling.
- (v) Aggregate samples shall be prepared by mixing the incremental samples. The aggregate samples shall be used as final samples unless they are too large. In this case the final samples shall be prepared by a suitable method of reduction (an example of suitable methods is given in the Directive)
- (vi) Requirements for packaging and transmission of laboratory samples are also laid down.

In addition to the above general provisions, specific provisions for different types of products concerning the minimum numbers of incremental samples, the weight of each laboratory sample, the number of laboratory samples and other details are included in the Annex.

**Council Directive 97/41/EC** amending Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC, relating to the fixing of MRLs for pesticide and their toxic metabolites residues (traces) in/on foodstuffs.

According to Article 1 of the Directive 79/700/EEC, sampling for the official control of pesticide residues in and or fruit and vegetables provided for in Article 6 of Directive 76/895/EEC, shall be carried out in accordance with Community methods of sampling laid down in Annex to Council Directive 79/700/EEC. Compliance with maximum levels shall be established on the basis of the levels determined in the laboratory samples, taken according to the planning methods and thus considered to be representative.

**Directive No 86/363/EEC** on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin, shall apply to the foodstuffs of animal origin listed in Annex I (which does not at the moment include any type of seafood), to the products obtained from them after drying or processing and to the composite foods in which they are included. These products, from the time they are put into circulation shall not contain pesticide residues levels higher than the established MRLs.

Although this Directive does not include provisions for the control of fishery products, it is relevant to the Directive 96/23/EC which includes also provisions and maximum levels for fishery products: the control of compliance with MRLs established by the Directive 86/363/EEC, is one of the aims of surveillance to be carried out in accordance with Directive 96/23/EC.

The Directive requires in Article 4, that Member States shall take measures to ensure compliance with the maximum levels at least by check sampling. The necessary inspection and control shall be carried out according to Directives 89/397/EC and 93/99/EEC.

**Regulation (EC) No 194/97**, setting maximum levels for certain contaminants in foodstuffs having regard to Council Regulation (EEC) No 315/93 which lays down Community procedures for contaminants in food. The Annex to Regulation 194/97, sets maximum levels for Nitrates in certain vegetables. The Annex requires the implementation of the methods of sampling laid down in Directive 79/700/EEC, which relates to the control of pesticide residues in and on fruit and vegetables, without any amendment.

The products contained in the Annex must not when placed on the market contain higher contaminant levels than those specified in the Annex.

**Working document, DOC VI 1669/97** (which does not necessarily represent the views of the Commission services), is a pre-draft Regulation amending the Commission Regulation (EC) No 194/97, with the aim to set maximum levels for aflatoxins in certain foods. The Annex to the document lays down methods of sampling which contain either the same provisions, or having minor differences with those in Directive 79/700/EEC. The following more substantial differences relate to requirements which are not included in both Annexes:

- (a) The Annex to the pre-draft Regulation, contains a provision for subdividing large lots in units to be sampled separately.
- (b) The Annex to Directive 79/700/EEC, contains a provision for reducing the aggregate sample if it is too large, using a suitable method of reduction (an example is given of such a suitable method).
- (c) The Annex to 79/700/EEC requires that goods which are wholly or extensively spoiled are not to be used for sampling.
- (d) The Annex to the pre-draft contains a requirement for replicate samples: The replicate samples for enforcement, trade (defence) and referee purposes are to be taken from the homogenised laboratory sample.

Besides the general provisions, specific additional provisions are laid down for the different types of foods included in the Annex.

Acceptance of a lot or unit shall be decided as follows:

- acceptance if none of the subsamples exceeds the maximum limit

- rejection if one or more of the subsamples exceeds the maximum limit.

Although neither the Directive 97/41/EC nor the Regulation No 194/97 and the pre-draft Regulation lay down any specific provisions for seafood, their provisions for sampling plans shall for certain reasons be discussed in this document's overview of sampling plans.

## **Enforcement**

The Member States have the obligation to develop and implement their National Monitoring Programmes in accordance with the European legislation. When Community Standards/Sampling Plans/Analytical Procedures have not been established, the compliance should be decided on the basis of National Standards.

An example of a monitoring protocol which is implemented by the British Centre of Environment, Fisheries and Aquaculture Science (CEFAS), Burnham Laboratory, includes the following :

(a) Objectives:

1. Continuing assurance of the safety of Marine foodstuffs.
2. Health of the marine environment in the entire ICES North Atlantic Areas.
3. Analysis of trends over time in pollutants concentration in selected areas.

(b) Sampling to meet objectives:

- (i) To meet objective 1 samples shall be collected every second year. Numbers of fish and shellfish and criteria for selecting the samples are specified. The minimum areas from which samples should be collected are specified.
- (ii) To meet objective 2 samples shall be collected every five years. Numbers of fish and shellfish and criteria for selecting the samples are specified. Samples should be collected from as many locations as is practicable throughout the ICES area.
- (iii) To meet objective 3 the samples shall be collected every year. Numbers of fish and shellfish and criteria for selecting the samples are specified. Sampling should be conducted annually from the same areas, from the same stock and at the same time at each year. Mussel samples should be collected at the same position in relation to tidal height each year. The minimum areas to be covered concerning sampling are specified.

The commodities of interest shall be selected on the basis of national priorities set in accordance with information on fish stock composition and history and the known or perceived problems. It is preferable to use a fish species which continues to grow throughout its life. The species recognised as priorities are mentioned but it is stressed data relating to other species are also required.

(c) Storage and pretreatment of samples prior to analysis:

General requirements to meet all three objectives and specific, detailed requirements to meet objectives 1 or 2 as well as specific requirements to meet objective 3 are specified.

(d) Reporting of results:

For all objectives the results should be reported on a wet weight basis along with details of the size range of the sample, of site/date/method of collection, of preservation (if appropriate) and analytical methods used. In the case of PCBs the formulation or isomer(s) and the method of quantification used should be reported.

For objective two and three additional common and/or specific requirements on reporting of results are included.

(e) Notes on length stratification:

These notes stress the significance of length as stratification variable in most statistical analysis of data on contaminants in fish tissues. Suggestions concerning length intervals to be used and the need to keep the length stratification identical from one year to the next, are included in these notes.

A second example concerns the monitoring in Sweden. Sweden has implemented the directive 91/493/EEC for sampling plans and criteria for the in house control in factories. In addition, a proposal on microbiological criteria for seafood has been submitted by the National Food Administration to the Board and after its approval it has been forwarded to EU for notification. This proposal covers raw fresh or frozen fish filet, cured or smoked fish, shellfish cooked, frozen or stored in brine, with or without shells.

### 3.2 United States legislation and monitoring

#### Action / Tolerance/ Guide Levels

The United States Food and Drug Administration (FDA) has the authority to set tolerances, action levels and guide levels (guidelines) for contaminants and biotoxins in food including seafood, except for pesticide residues which are set by the Environmental Protection Agency (EPA).

- (i) Action levels and tolerances have been set for contaminants which have been identified as national problems, e.g. mercury. They do not represent permissible levels. They are established based on the unavoidability of the contaminants, in order to limit the extent of food contamination. Action levels and tolerances are the maximum amounts of contaminants or residues at or above which the FDA will take legal action to remove products from the market.

The action levels are established and revised in accordance to the criteria of the Code of Federal Regulations, title 21, Parts 109 and 509 and they are revoked when a Regulation setting a tolerance becomes effective.

- (ii) Guidelines are developed when there is a need to take some regulatory action to control exposure to a contaminant but FDA does not choose to establish tolerances.

Compliance with a tolerance/action/guide level is determined by analysing representative, commingled subsamples of edible parts from a fish shipment.

The Federal Food, Drug and Cosmetic Act This Act is the basic legal framework for the control of food, including seafood.

The FDA Regulation (21 CFR 123 ): “Seafood HACCP Regulation”.

The final FDA Regulation (21 CFR 123 ): “Seafood HACCP Regulation”, requires the implementation of HACCP- Hazard Analysis and Critical Control.

Points systems in processing fish and fish products. The regulation was published in the Federal Register on 18/12/1995.

### **The FDA Fish and Fisheries Products Guide**

The issuance of the interim first edition of Fish and Fisheries Products Guide of the FDA coincides with the issuance of the Seafood HACCP Regulation.

The primary aim of the Guide is to assist processors to develop their HACCP plans. In the Guide a HACCP- strategy is proposed, according to which : No lot of fish may exceed the established tolerances, action levels or guidance levels for environmental contaminants and pesticides.

The Guide contains a list of published FDA and EPA tolerances, action levels, and guidance levels for pathogens, contaminants, and residues in fish and fishery products.

Tolerances for PSP and ASP are applicable to all fish, while the European MLs are applicable only to shellfish.

### **Enforcement**

FDA is responsible for enforcing tolerances for contaminants and biotoxins in seafood under the regulatory aspect of FDA’s monitoring programme. The FDA operates an oversight annual compliance programme for fishery products, to verify compliance with Regulations promulgated under the Federal Food, Drug and Cosmetic Act and other relevant legislation. The FDA also operates other programmes and surveys.

According to the FDA’s Residue Monitoring Programme (covering also the residues in seafood and aquaculture products), the following criteria should be used as a basis for the development of sampling plans:

- (i) Sampling points should be as close as possible to production / import. Samples are classified either as “surveillance” (taken for monitoring) or as “compliance” (taken when there is evidence that a problem exists). Most samples collected are the surveillance type.
- (ii) Types and numbers of samples should be decided on the basis of factors such as :
  - review of recently generated residue data,
  - intelligence on regional pesticide use,
  - dietary importance of food,
  - toxicity and chemical characteristics of pesticides,
  - production volume / pesticide usage patterns,

- amounts of imported and locally produced food that enters the market.

### **Guidance Documents**

As a result of the growing concern regarding the public health significance of the presence of contaminants in shellfish (bivalve molluscs and crustacea) the FDA has developed, instead of a single guide level, a broader guidance approach. The broader guidance approach helps to address the relevant information on a contaminant, as part of the overall determination of public health significance of contaminants in shellfish.

Surveys for contaminants in shellfish are carried out by the FDA and the National Marine Fisheries Service in order to determine their mean contaminant levels. The FDA estimates the range of possible consumers exposure to a contaminant, resulting from the consumption of shellfish, by combining these results with shellfish consumption information and calculating the average daily intake of the contaminant.

On the basis of the produced data, FDA is developing a series of guidance documents for contaminants which could cause health problems, based on the toxicity of the contaminant and on the potential exposure.

These documents have no statutory authority. They are designed to assist local and state authorities in decision making concerning contaminants in shellfish and the possible need to either close waters for fishing, or to issue fish consumption advisories. This decision may be determined by the particular circumstances of each case.

The first guidance documents address contaminants which accumulate in shellfish and are most likely to occur. These contaminants are: arsenic, cadmium, chromium, lead, and nickel.

The Guidance Documents include the following general criteria for sampling:

- (i) Collecting, processing, preserving and shipping primary samples are important procedures for the assurance of valid analytical data.
- (ii) Sampling plans should include site locations, target species and contaminants, sampling times, types of samples (numbers / size / uniformity / weight) and sample replication.
- (iii) Sampling steps must be conducted in a manner that preserves the integrity of the sample and precludes inadvertent contamination. For processed shellfish, specific sampling procedures are included in the FDA Inspection Operations Manual (FDA 1990).

More specific requirements for sampling procedures include the following:

- (i) For a representative site or lot, a minimum of three replicate composite samples from each sampling location is recommended.
- (ii) The sample should satisfy any legal requirement for harvestable size and weight, or should be of consumable or market size.
- (iii) For a worst-case exposure sampling, it is recommended to collect the largest samples.
- (iv) Subsamples in a composite sample should be of similar size. The total length of the smallest animal must be not less than 75% of the total length of the largest animal.

- (v) Composites should contain equal numbers of 10 to 50 animals for a total minimum weight of 500gms of tissue homogenate.
- (vi) The relative difference between the overall size of replicate composites and the mean length (size) of any individual composites should not be greater than 10%.

Detailed requirements for laboratory sample preparation and for analytical methodology are also included in the document.

Reliability of analytical data should be documented by Quality Assurance/Quality Control procedures.

### **Levels of concern (maximum permitted levels)**

Daily consumption of shellfish (chronic shellfish consumption) and contaminant levels in shellfish are used to estimate levels of concern (maximum permitted levels).

Levels of concern include: contaminant levels of concern in shellfish and levels of concern for chronic shellfish consumption. The total contaminant level of concern is the ratio of the Tolerable Daily Intake (TDI) to the highest mean concentration of the contaminant in shellfish. The consumption level of concern is the ratio of the TDI to the Daily Intake of shellfish. In this estimation it is assumed that the total exposure to contaminant is from shellfish.

**Voluntary Programmes.** The FDA also operates the following voluntary programmes:

- (i) The National Shellfish Sanitation Programme

The National Shellfish Sanitation Programme is a guide for State Participation. It is a voluntary tripartite programme, composed of shellfish producing and receiving States, the shellfish industry, and federal agencies. It provides a mechanism for certifying that shellfish in interstate commerce, meet sanitation and quality criteria. The NSSP's certification system includes also requirements for the laboratories which support the programme: American Public Health Association (APHA) laboratory procedures shall be followed for the collection, transportation, and examination of shellfish and shellfish waters.

- (ii) The Salmon Control Plan

It is a voluntary, cooperative program among the industry, the FDA and the National Food Processors Association, designed to provide control over processing and plant sanitation and to address concerns about decomposition in the salmon canning industry.

### 3.3 Other countries: Japan

Existing regulations for seafoods in Japan establish MRLs for oxytetracycline and PCBs (fish and shellfish), maximum allowable levels for PSP and DSP (in all shellfish) and dieldrin (in hard-shelled mussels). For oysters intended for raw consumption and for boiled octopus microbiological limits have been set. Sampling plans and procedures are not regulated as a standard/specification. Decision of the authority is in principle based on the results of analysis. There are not other official considerations based on HACCP implementation. Violative products are not allowed to be placed on the market.



## 4. OVERVIEW OF SAMPLING PLANS

### 4.1 The European Communities legislation

**Directive No 89/397/EEC** lays down the general principles for the official inspection, sampling and control of foodstuffs, which must, of course, apply to the official control of seafood. The official control shall include unexpected, regular or when non-compliance is suspected inspection, covering all or selected stages from production to distribution and trade and sampling of all or any selected of the following items: raw materials, ingredients, technological aids and other products used for the production of foodstuffs; semi-finished products; finished products; materials and articles intended to come into contact with foodstuffs; cleaning and maintenance products.

**Directive No 91/492/EEC** on the health conditions for the production and placing on the market of live bivalve molluscs, lays down only a few general requirements for sampling plans which should be included in the public health control system for the control of bivalve molluscs and requires the establishment of sampling plans, analytical methods and tolerances.

**Directive No 91/493** on the health conditions for the production and placing on the market of fishery products, requires that : (i) the sampling plans and the methods of analysis for the control of the chemical parameters as well as their acceptable levels in fishery products, shall be decided by not later than 31 December 1992 and (ii) that microbiological criteria, sampling plans and methods of analysis may be laid down when there is a need to protect public health. The Commission will submit proposals for measures by 1 October 1992. Despite this requirement, only one Decision has been adopted to this respect, the Decision No 93/351/EEC on analytical methods, sampling plans and MLs of mercury in fishery products.

**Decision No 93/351/EEC** requires that certain factors should be considered in the sampling plans for the control of mercury in fishery products.

**Directive No 96/23/EC**, refers to the requirement of Decision 91/493/EEC and determines in Annex III on sampling strategy, the aims and the minimum criteria to be considered for targeting the samples (unless random sampling can be justified by Member States when presenting their national plans to the Commission). This strategy applies to the control of animals and animal products (including all fish) in accordance with MRLs for veterinary residues, established in Annexes to Regulation 2377/90 and its amendments, and to the monitoring of their levels of environmental contaminants. In Chapter 3 of Annex IV, the Directive defines the minimum sampling levels and frequency to be respected by the Member States for aquaculture products as well as certain general criteria for the selection of compounds to be monitored, of samples, of sampling points and of sampling stages, when developing sampling plans for monitoring.

This Directive only partly satisfies the requirement of the Directive No 91/493/EEC for the establishment of sampling plans for monitoring contaminant levels in fishery products, by providing only general strategic criteria and only limited requirements concerning sampling levels and frequency for the control of aquaculture products. It remains with the responsibility of the competent authorities of Member States to develop their annual national plans for the control of fishery and other animal products, as required by the Directive, and submit it to the standing committee for approval.

**Directive No 97/41/EEC** fixing MLs for pesticides in foodstuffs, the Regulation No194/97 setting MLs for certain contaminants in foodstuffs and the pre-draft Regulation (working document DOC VI 166/97) setting MLs for aflatoxins in certain foods, do not lay down any provisions for seafood

sampling. Nevertheless the conclusion from the comparison between the provisions of the methods they include for sampling, is that they establish common or similar general requirements for a variety of products i.e. fruit and vegetables, nuts, cereals, dried fruit and milk, and for a variety of contaminants i.e. pesticide residues, nitrates, and natural toxins. When developing a seafood monitoring programme, it is useful to know and take account of these requirements, since:

- (i) these requirements have been established-especially in the pre-draft Regulation - on the basis of some factors which are also important for the control of seafood. These factors include the significant variation in food contamination, the lack of uniformity in the distribution of the toxins and contaminants in the samples, and the complexity of the matrix of the samples, and,
- (ii) the specific regulation on seafood neither include requirements to cover alone all essential components of a sampling plan, nor they take account of all important factors that may influence the representativeness and validity of determinations and the assessment of the situation concerning fish contamination.

#### 4.2 United States legislation and guidance documents

The FDA's sampling plans for the implementation of monitoring programmes are based on criteria and factors similar to those included in the respective provisions of the European legislation. Furthermore it is stressed that decisions on the types and numbers of samples should be based also on the dietary importance of food and on health considerations regarding the contaminants.

Sampling plans for the surveys for contaminants in shellfish carried out by the FDA and the National Marine Fisheries Service, as presented in the Guidance Documents, include criteria and factors similar to the respective European but additionally they set requirements on account of more factors and criteria aiming to address the likely variations in the levels of contaminants in seafood (e.g. sampling times, site locations sample replication, composite samples etc). Furthermore, Quality Assurance elements are included stressing the need for measures to ensure representativeness and validity of results as well as the integrity of samples. Detailed specific requirements concerning replicate composite samples and subsamples are also aiming at the production of representative and valid analytical data.

#### 4.3 Codex Alimentarius standards

The Codex Standards for Fish and Fishery Products, Supplements 2 and 3 to Codex Alimentarius Volume V, require that acceptance or rejection of a lot, shall be based on the application of an appropriate sampling plan as required in the Codex Sampling Plans for Prepackaged Foods.

According to the Codex Standards, sampling is the process of drawing or selecting containers or sample units from a lot or production. As a result of sampling, information is obtained by which an estimate can be made to accept, reject or negotiate the merchandise in question.

The Codex Sampling Plans for Prepackaged Foods lays down requirements for the development and application of sampling plans:

- (i) Sampling Plan is a sampling scheme which includes samples sizes, inspection levels, acceptance and/or rejection numbers, so that a decision can be made to accept or reject the lot or production based on the result of inspection and testing of the sample.

- (ii) For the application of the Sampling Plans, the information required concerns container size, inspection level, lot size, quality and acceptance requirements and classification of defectives.
- (iii) Inspection Level I is selected for normal sampling and Inspection Level II for disputes (Codex referee purposes sample size), enforcement or need for better lot estimate.
- (iv) The number of sample units (sample size), drawn at random from the inspection lot, should be determined considering container size, lot size, and inspection level.
- (v) Code or other identifying marks of the sample should be maintained.

One of the initial considerations in the development of a statistical acceptance sampling plan is the selection of an appropriate Acceptable Quality level. This characteristic is defined as the maximum percent defective units in lots that will be accepted most of the time (approximately 95 percent of the time). Lots or production containing more defective material will be accepted less often. The ration of rejection to acceptance is increasing as the sample size increases and as the percent defective material in the lot increases. This level is selected on the basis of years of experience and of the capability of industry to produce processed foods at this level under good commercial practice. Sampling procedures which contain both sample size and acceptance criteria are commonly referred to as “acceptance sampling”. The evaluation of the end product requires opening of containers and this type of inspection, called “destructive sampling”, is quite time consuming and results in loss of products.

Sample size must necessarily be relatively small in order to make the plan practical in application. On the other hand the larger the sample, the less risk involved in accepting “bad” lots. If the production contains an appreciable amount of defective material, a higher inspection level (i.e. a larger sample size) will reduce the risk of accepting these non-conforming lots.

A lot is considered acceptable (as meeting the final product requirements) if the number of defectives is equal to or is less than the acceptance number of the appropriate Sampling Plan contained in the Codex Sampling Plans for Prepackaged Foods. A lot is considered as failing if the number of defectives exceeds the acceptance number.

“Defective” is a sample unit which does not conform with a certain specified requirement (or requirements) of a Codex Standard. Although a defective is a sample unit which fails to meet certain specified requirements in Codex Standards, it does so only to an extent which is slightly below those requirements and which would not make the product objectionable to the consumer.

Criteria for assessing the effectiveness of a sampling plan in discriminating between “good” and “bad” lots are also included in the Standard. The effectiveness can be estimated by examination of the Operating Characteristic Curves for the various sample sizes.

#### 4.4 Publications and documents on developing monitoring programmes

A document prepared for the FAO by professor Douglas L. Park, Louisiana University, Department of Food Science, elaborating guidelines for shellfish monitoring programmes.

The guidelines begin with a statement that many of the components of seafood safety monitoring programs are similar for finfish and shellfish. The major difference derives from the ability of finfish to migrate between safe and potentially toxic harvesting areas.

According to the author, the substantive elements of a seafood safety programme which ensure its effectiveness, must include : the ability to monitor fish/shellfish harvesting areas and to screen for suspect fishery products in the marketplace, the establishment of regulatory limits or levels of concern for the toxin(s), and the management of unsafe fishing/harvesting areas and products.

It is suggested that in order to develop a Monitoring Programme the following steps should be followed:

**Step 1:** Determination of commodity(s) and aquatic biotoxin(s) of concern for the Programme.

To this effect, the pattern of consumption and harvesting, storage and commercial pathways practices should be identified. A relevant survey is recommended for the collection and assessment of valid, relevant information.

**Step 2:** Evaluation of analytical capabilities for each commodity/aquatic biotoxin. This evaluation should include laboratory facilities, availability of necessary equipment and trained personnel as well as budgetary limitations.

**Step 3:** Determination of appropriate Monitoring Programme components. One component is the early detection of blooms is important to avoid public health problems due to the accumulation of marine toxin seafood. Early detection would assist officials to forewarn people of the impending blooms and mariculturists or fishermen of pending economic disasters. Since most blooms originate offshore, satellite imagery or satellite-tracked monitoring buoys can assist in monitoring for algal blooms.

A second component is the selection of analytical methods according to the purpose of testing fishery products. In screening market-place products a screening method must be used if it satisfies the following conditions: (i) it is easy to be used and interpreted, (ii) it is rapid, (iii) it has the ability to accurately differentiate between toxic and non-toxic samples at the level of concern, (iv) it is cheap, and (5) it provides, where feasible, for a means of confirmation of positive samples. A method of confirmation of identity is more expensive and time consuming.

A third component is the understanding of how a product becomes toxic. This is necessary in order to develop analytical techniques for each critical point and to set up an effective monitoring programme.

**Step 4:** Establishment of analytical capabilities applicable to the selected Monitoring Programme to be set. The methods intended to be used in a specific seafood safety monitoring programme, must be standardised and validated with the use of appropriate Quality Control/ Quality Assurance procedures.

**Step 5:** Establishment of regulatory limits Factors to be considered in establishing regulatory criteria and limits for phycotoxins include:

- (i) the availability of survey and toxicological data,
- (ii) the distribution of phycotoxins throughout lots,
- (iii) the stability of the toxins in the samples or test portions,
- (iv) the availability of methods of analysis, and

- (v) the regulations in force in each country.

Scientists and health regulatory officers are not always aware of the complete identity and the relative potencies of the toxins involved in the foodborne diseases. Therefore, it is often necessary to either set up a program including the use of an indicator compound, or, to monitor an event such as toxic algae blooms, e.g., red tides.

Step 6: Establishment of the Sampling Plan. The sampling plan is composed of several components, including:

- (i) the frequency and location of sample collection,
- (ii) preparation of test portions for analysis,
- (iii) relative errors associated with sampling,
- (iv) error inherent to the analytical method utilised, and
- (v) measures to assure that the sample is representative of the product lot or sampling location, considering variation between individual specimens or within each fish or shellfish.

Step 7: Establishment of regulatory policy for contaminated products. The analytical results will lead to decision either to permit accepted lots to enter or continue in commercial channels or to address appropriate action for violative products. Such action must be well established and may include depuration, decontamination, withholding from the market, diversion to other less risk uses, etc. The most effective means of controlling quality during outbreaks of toxic algae is either by blanket closure during certain times of the year or by instituting a shellfish toxicity monitoring programme. Monitoring is crucial also for establishing re-openings.

#### 4.4.1 Preparation for detection and quantitation of natural toxicants in food and feed

An article published in the AOAC (vol.72. no 3 1989) by Douglas L. Park and Albert E. Pohland, presents a discussion relevant to the development of a sampling plan.

The authors suggest that an accurate and precise estimate of the concentration of a component in a lot is dependent on at least 3 factors: sampling, sample preparation, and analysis. Errors associated with these factors are by far the largest for sampling, and relatively minor for analysis.

Several factors must be considered in the development of a sampling plan, relevant to:

- (a) The purpose or potential use of the analytical result (e.g. as a decision factor in an in-house production scheme for the acceptance of a raw ingredient, or for the final acceptance of the product prior to marketing, or as a control sample used by a regulatory agency).
- (b) The costs associated with taking the sample, sample preparation, and analysis must be factored into the sampling plan.

- (c) The representativeness of a sample which is dependent on a variety of parameters including:
- the nature and distribution of the contamination or analyte throughout the lot;
  - the characteristics of the product being sampled (liquid, coarse or finely ground etc),
  - the procedure used in sampling and
  - the accessibility of the product to random representative sampling.

The above parameters comprise the following components in the case of monitoring marine biotoxins in seafood:

The nature and distribution of contaminant in seafood. Two essential factors should be considered :

- (i) Biotoxin contamination of shellfish and finfish, varies from relatively uniform contamination to highly variable depending on the commodity and the source of the contaminant.

Shellfish are sedentary in the environment, and the source of the toxins - dinoflagellate blooms (red tide) - covers a relatively large area. For this reason in monitoring PSP contamination, the results of the samples of shellfish which are collected along coastal areas and analysed, are a good indication of the contamination levels of the shellfish remaining in the harvesting areas.

On the other hand toxigenic microscopic dinoflagellates grow in areas such as reefs, and the herbivorous fish fed on it either are harvested for food or fall prey to carnivores. The larger fish travel over wider ocean areas and can enter fish harvesting areas that are considered safe and thus, a fisherman's catch in a safe area could contain a small number of highly toxic fish. Due to the heterogeneous nature of the fisherman catch it is more difficult to develop a representative programme for finfish and ciguatera than for PSP contamination.

- (ii) The nature or distribution of the contaminant within the individual fish. PSP toxins are water-soluble and usually concentrate in the dark (hepatopancreas) gland. They are excreted once the dinoflagellate bloom dissipates. Ciguatoxins, on the other hand, are lipid-soluble and are more evenly distributed throughout the fish tissue. They remain in the fish over a long period of time.

**Physical Characteristics of the Product** Instructions for sampling most commodities are not available. Sampling error is directly proportional to the variation within a given lot which can be extremely large. The smaller the size of the individual components the smaller the error.

Three factors have a significant influence on the analyst's ability to obtain representative samples especially when they coincide: (i) the nature of complex food matrices, (ii) the extremely low contaminant levels and the (iii) the lack of contamination homogeneity throughout the lot.

An increase in the amount of sample results in an increase of the reliability of the results, i.e. reduction of the number of good lots rejected and reduction of the number of bad lots accepted. The sample size, however, must remain representative of the lot, manageable for sample preparation and analysis, and cost effective.

## **Representative Sampling Procedures**

Ideally, to be most effective, equal portions must be taken at a sufficient number of random points, throughout the entire lot.

The authors conclude that shellfish monitoring programs can be used as a model for monitoring seafood and seafood toxin contamination, provided the characteristics of the contamination are similar.

There is, however, a need to do more research in order to determine the nature and distribution of the Ciguatera toxin(s) in affected fish species, before an appropriate sampling/monitoring program can be established.

### 4.4.2 The official methods of analysis of the AOAC International

In volume II of 16th edition, detailed requirements for sample treatment and sample preparation procedures are included.

## **5. CONCLUSIONS**

### 5.1 The importance of assuring safety and wholesomeness of seafood

Assuring safety and wholesomeness of seafood is crucial for the protection of health and for economic and nutrition considerations. It is also important for the protection of international seafood trade.

The importance of dietary assessment has grown with the conclusion of the Uruguay Round of Multilateral Trade Negotiations, particularly in the light of the “Agreement on the Application of Sanitary and Phytosanitary Measures” under which contracting parties are required to assure that sanitary and phytosanitary measures, established at national level “take into account risk assessment techniques developed by the relevant international organisations” and “available scientific evidence” so that they will not constitute non-tariff barriers.

The role of Codex Alimentarius in the development of internationally adopted food standards which are presented in a uniform manner and are based on sound scientific data, is vital. The Codex standards aim at protecting health and at ensuring fair practices in the food (including seafood) trade.

### 5.2 Standards and approaches in decisions making and measures

The conclusions concerning the establishment and enforcement of standards for contaminants and natural toxins in seafoods are the following:

More research is needed relevant to the Codex Alimentarius criteria, in order to establish new maximum levels and guidelines, covering a variety of contaminants and marine toxins in seafood.

The establishment of microbiological standards has not been achieved yet This is one of the first priorities to be addressed.

Better harmonisation in the existing standards as well as in the approaches regarding monitoring and decision making on the basis of the inspections, sampling and analysis, is also necessary.

Furthermore, there should be a reversible influence between nutrition education policies and food safety concerns occurring from the estimations of fish consumption and contaminants levels of concern. Policies regarding nutrition education of consumers for the promotion of healthy diets, should not overlook food safety aspects. On the other hand, nutritional aspects, recommendations and guidelines for healthy diets, should be considered in the procedures for setting standards and guidelines, as well as in developing monitoring programmes and sampling plans. If these considerations cannot be regarded as a major factor influencing the decisions for the levels to be established as tolerances, they should at least be regarded as an important factor imposing measures and action in order to protect consumers, or, groups of consumers when such “lack of conformity” problems arise.

The minimum action to be taken should be the issuance of guidance to consumers.

The responsibility for the issuance of such advice should be laid down in relevant legislations and guidelines.

The official control for the compliance of seafood with adequate standards, is necessary to assist the competent authorities in taking their decision to either permit or ban the import / harvest / sale of fish, or, to issue fish consumption guidance.

### 5.3 The need for the development of integrated monitoring programmes

The need for integrated programmes to monitor seafood safety is commanding, as a result of their significant nutritional value and of the many factors which may affect their safety and which are likely to occur under various conditions. Integrated monitoring programmes allow for better assessment of health significance of fish contamination. They also allow for estimation of expected levels of contaminants in seafood. In addition to that they are designed to monitor trends in seafood contamination.

In order to design more effective programmes, more research is needed internationally in order to:

- (i) identify areas, commodities, contaminants and consumption patterns of concern,
- (ii) increase analytical capabilities including the development of accurate rapid screening methods,
- (iii) set standards based on the established scientific criteria for all toxic contaminants and toxins, and
- (iv) collect and assess existing data on seafood contamination in different areas, to facilitate the development of sampling plans.

At the moment even the best developed existing monitoring programmes, need to be further developed regarding the number of chemical contaminants, microorganisms and toxins which they cover, or even the frequency of sampling and the sampling points or areas they cover.



An integrated monitoring programme should include all components of effective monitoring including prevention oriented HACCP and early identification systems, control of imported seafood, and control of local fish production and catch.

#### 5.4 The need for collaborative studies

Collaborative studies between countries in a region should be institutioned not only for the other well recognised advantages they can offer, but also because neither sea pollution nor fish and fishing practices are limited within boundaries.

Coordination of monitoring activities, communication of produced analytical data between neighbouring countries and saving of financial resources by avoiding duplication of work(when possible) will be beneficial to all and will help to better integrate control and surveillance. For countries with poor laboratory facilities, small budgets and lack of personnel or specialisation in some techniques, it is easier to develop the necessary infrastructure and initiate a national monitoring programme in the framework of a well organised and adequately supported collaborative study.

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## ANNEX I

### INTERIM ENVIRONMENTAL QUALITY CRITERIA FOR MERCURY

(Fourth Ordinary Meeting of the Contracting Parties, Genova, 9-13 September 1985, UNEP/IG.56/5).

- (1) According to the available evidence to date, on the basis of present concentrations of mercury in Mediterranean seafood, it appears that the consumption of seafood by the general population does not present any risk.
- (2) It is considered therefore that, at this stage, the adoption of upper limits for mercury concentrations in seafood on a common regional basis would not be a priori justified.
- (3) On the basis of the assessment of the quality of Mediterranean seafood with regard to its mercury content prepared by FAO/UNEP, the Contracting Parties:
  - (a) Take note of the interim criterion proposed by the joint FAO/WHO Committee of experts on food additives. According to this criterion, the Provisional Tolerable Weekly Intake of 0.3 mg of mercury, of which not more than 0.2 mg is methylmercury, for a person of 60 kg bodyweight, should not be exceeded;
  - (b) Take into consideration this criterion to establish, if national circumstances so require, standards for maximum concentration of mercury in seafoods;
  - (c) Use for the determination of total mercury the Reference Method "Determination of Total mercury in Selected Marine Organisms by Cold Vapour Atomic Absorption Spectrophotometry" (Reference Methods for Marine Pollution Studies No. 8/Rev. 1, UNEP/FAO/IAEA, 1984) and for the determination of methylmercury in marine organisms, the Reference Method "Determination of Methylmercury in Selected Marine Organisms by Gas Chromatography" (Reference Methods No. 13, UNEP, UNEP/FAO/IAEA, 1984). However, other methods giving comparable results could also be used;
  - (d) Include, to the extent possible, in their National Monitoring Programmes, the sampling and analysis of species of seafood, known to accumulate mercury, in addition to those already monitored in the framework of MED POL - PHASE II;
  - (e) Limit anthropogenic discharges of mercury into the Mediterranean Sea pending the eventual formulation of emission standards for mercury, as a result of the entry into force of the Protocol for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources, and in terms of article 5 of that Protocol, commence as early as possible, the elaboration of the necessary programmes and measures with respect to mercury;
  - (f) Provide the Secretariat to the Convention with the fullest information possible on:
    - present legislation and administrative measures on existing national criteria for levels of mercury in seafood;
    - measures taken on (b), (c), (d) and (e);
    - relevant monitoring data on (d) above;

- (g) Continue to carry out the monitoring and research component of MED POL PHASE II relevant to the assessment of mercury content of Mediterranean seafoods, and the risks affecting all sectors of the population arising from seafood consumption, in particular:
- identification of population groups at risk;
  - surveys on seafood consumption patterns among such populations;
  - surveys on mercury levels in affected population groups;
  - epidemiological studies to obtain the necessary information on the relationship between mercury intake and health effects;
  - studies of the relationship between total mercury and methylmercury content of seafood, and the effects of cooking on such content;
  - studies on biogeochemical cycles of mercury in the Mediterranean;
  - studies on the effects of selenium in decreasing mercury toxicity.

## ANNEX II

### DEFINITIONS

#### **A. Endorsed by the Codex Alimentarius**

“*Contaminant*”, means any substance not intentionally added to food, which is present in such food as a result of the production (including practices carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.

#### Maximum Level - ML

Maximum Level for a contaminant in a food, is the maximum concentration of that substance recommended by the Codex Alimentarius Commission to be legally permitted in the commodity.

#### Guideline Level - GL

The Guideline Level is the maximum level of a substance in a food which is recommended by the Codex Alimentarius Commission to be acceptable for commodities moving in international trade. When the GL is exceeded governments should decide whether and under what circumstances the food should be distributed within their territory of jurisdiction.

“*Codex maximum limit for pesticide residues*” (MRLP) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feed. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.

“*Codex Maximum limit for residues of veterinary drugs*” (MRLVD) is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food.

#### **B. Other definitions**

“*Marine biotoxins*”, according to the European Council Directive No 91/492/EEC, means poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxin.

Toxins accumulate also in fish when they feed on toxin producing plankton, or on other fish which have been fed on such plankton.

#### **Directive 91/492/EEC:**

“*placing on the market*” the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market of live bivalve molluscs for human consumption either raw or for the purpose of processing in the Community, excluding the direct transfer on the local market in small quantities by the coastal fisherman to the retailer or the consumer which must be subject to the health checks laid down by national rules for checking on retail business.

“*relaying*” an operation whereby live bivalve molluscs are transferred to approved sea, lagoon or estuarine areas under the supervision of the competent authority for the time necessary to remove contamination. This does not include the specific operation of transferring bivalve molluscs to areas suitable for further growth or fattening.

“*dispatch centre*” any approved on-shore or off-shore installation for reception, conditioning, washing, cleaning, grading and wrapping of live bivalve molluscs fit for human consumption.

**Directive 91/493/EEC:**

The term “*fishery products*” means all seawater or freshwater animals or parts thereof, including their roes, excluding aquatic mammals, frogs and aquatic animals covered by other Community acts.

The term “*placing on the market*” means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market in the Community, excluding retail sales and direct transfers on local markets of small quantities by fishermen to retailers or consumers, which must be subject to the health checks laid down by national rules for checking the retail trade.

**Directive 94/356/EEC:**

The definition for aquaculture products is the following: all fishery products born and raised in controlled conditions until placed on the market as a foodstuff. However, seawater or freshwater fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption are also considered to be aquaculture products.

Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculture products if they are merely kept alive without any attempt being made to increase their size or weight.