LEGAL NOTICE No 66/2003

HEAVY METALS REGULATIONS

PART I

PRELIMINARY

Art. 1 Short Title

These Regulations may be cited as the "Heavy Metals Regulations Legal Notice No 66/2003".

Art. 2 Scope of Application

(1) These Regulations lay down the measures for the monitoring of the heavy metals: Mercury, Lead and Cadmium in fishery and aquaculture products.

(2) The basic purpose for the establishment of sample preparation procedures and criteria of methods for analysis is to obtain a representative and homogenous laboratory sample without introducing secondary contamination so as to obtain representative results for the determination of the levels of the contaminants which may be heterogeneously distributed in a lot.

(3) The provisions for the sampling and methods of analysis have been drawn up on the basis of present knowledge and they may be adapted to take into account the advances in scientific and technological knowledge.

Art. 3 Sampling

(1) The Fish Inspection and Quality Control Division (The Competent Authority (CA)) of the Ministry of Fisheries shall take all measures necessary to ensure that the sampling for the official control of the levels of lead, cadmium and mercury in fishery and aquaculture products is carried out in accordance with the methods described in this part of the Regulations.

(2) The Fish Inspection and Quality Control Division (CA) of the Ministry of Fisheries shall take all measures necessary to ensure that the sample preparation and methods of analysis for the official control of the levels of lead, cadmium and mercury in fishery and aquaculture products shall comply with the criteria described in Part IV of these Regulations.

PART II

SPECIFICATIONS, LIMITS and MAXIMUM LEVELS

Art. 4 Mercury content

(1) The mean total mercury content, as determined by the analysis of the edible parts of the fishery products shall not exceed 0.5ppm (0.5mg/kg of fresh weight).

(2) This average limit is, however, increased to:

1 ppm (1 mg/kg of fresh weight) for the edible parts of the following species:

Lophius (Anglerfish)
Anarhichas lupus (Atlantic catfish)
Dicentrarchus labrax (Bass)
Molva dipterygia (Blue ling)
Sarda spp (Bonito)
Anquilla spp (Eel)
Hippoglossus hippoglossus (Halibut)
Euthunnus spp (Little tuna)
Makaira spp (Marlin)
Esox lucius (Pike)
Orcynopsis unicolor (Plain bonito)
Centroscymnes coelolepis (Portuguese dogfish)
Raja spp (Rays)
Sebastes marinus, S. mentella, S. viviparus (Redfish)
Istiophorus platypterus (Sail fish)
Lepidopus caudatus, Aphanopus carbo (Scabbard fish)
Shark (all species)
Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens (Snake mackerel)
Acipenser spp (Sturgeon)
Xiphias gladius (Swordfish)
Thunnus spp (Tuna)

Art. 5 Lead content

(1) The mean total lead content, as determined by the analysis of the edible parts of the fishery products shall not exceed 0.2ppm (0.2 mg/kg of fresh weight).

(2) This average limit is, however, increased to:

(a) 0.4 ppm (0.4mg/kg of fresh weight) for edible parts of the following species:

Dicologoglossa cuneata (Wedge sole)
Anguilla anguilla (Eel)
Dicentrarchus punctatus (Spotted seabass)
Trachurus trachurus (Horse mackerel or Scad)
Mugil labrosus labrosus (grey mullet)
Diplodus vulgaris (Common two-banded seabream)
Pomadasys benneti (Grunt)
Sardina pilchardus (European pilchard or sardine)

(b) 0.5 ppm (0.5 mg/kg of fresh weight) for:
Crustaceans (excluding brown meat of crab)

(c) 1 ppm (1 mg/kg of fresh weight) for:
Bivalve molluscs and Cephalopods (without viscera)

Art. 6 Cadmium content

(1) The mean total cadmium content as determined by the analysis of the edible parts of the fishery products shall not exceed 0.05 ppm (0.05 mg/kg of fresh weight.

(2) This average limit is, however, increased to:

(a) 0.1 ppm (0.1mg/kg of fresh weight) for edible parts of the following species:

Dicologoglossa cuneata (Wedge sale)
Anguilla anguilla (Eel)
Trachurus trachurus (Horse Mackerel or Scad)
Mugil labrosus labrosus (grey mullet)
Diplodus vulgaris (Common two-banded seabream)
Sardina pilchardus (European pilchard or sardine)
Engraulis encrasicholus (European anchovy)
Luvarus imperialis (Louvar or Luvar)

(b) 0.5 ppm (0.5 mg/kg of fresh weight) for:
Crustaceans (excluding brown meat of crab).

(c) 1 ppm (1 mg/kg of fresh weight) for:
Bivalve molluscs and Cephalopods (without viscera)

PART III
METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF LEAD, CADMIUM AND MERCURY IN FISHERY AND AQUACULTURE PRODUCTS

Art. 7 Purpose and scope

Samples intended for the official control of the levels of lead, cadmium and mercury contents in fishery products shall be taken according to the methods described below. Aggregate samples thus obtained shall be considered as representative of the lots or sublots from which they are taken. Compliance with maximum levels laid down in Articles 4, 5 and 6 of Part II hereof shall be established on the basis of the levels determined in the laboratory samples.

Art. 8 Definitions

A number of the most commonly used definitions in describing methods of sampling are given below:

(a)	Lot:	an identifiable quantity of food delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings. In the case of fish, also the size of fish shall be comparable.
(b)	Sub-lot:	designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable.
(c)	Incremental sample:	a quantity of material taken from a single place in the lot or sublot.
(d)	Aggregate sample:	the combined total of all the incremental samples taken from the lot or sub-lot.
(e)	Laboratory sample:	sample intended for the laboratory

CHAPTER 1: General provisions for sampling

Art. 9 Personnel

An authorized qualified person, as specified by the Fish Inspection and Quality Control Division (CA) of the Ministry of Fisheries, shall conduct sampling.

Art. 10 Material to be sampled

Each lot must be sampled separately.

Art. 11 Precautions to be taken

In the course of sampling and preparation of laboratory samples precautions must be taken to avoid any changes that would affect the lead, cadmium and mercury contents and adversely affect the analytical determination or make the aggregate samples unrepresentative.

Art. 12 Incremental samples

As far as possible incremental samples shall be taken at various places distributed throughout the lot or sub-lot. Departure from this procedure must be recorded in the record provided for under Article 13 hereof.

Art. 13 Preparation of the aggregate sample

Uniting all incremental samples makes up the aggregate sample. It shall be at least 1 kg unless not practical, e.g. when a single package has been sampled.

Art. 14 Subdivision of aggregate sample into laboratory samples for enforcement, defense and referral purposes

The laboratory samples for enforcement, trade (defense) and referral purposes shall be taken from the homogenized aggregate sample. The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

Art. 15 Packaging and transport of aggregate and laboratory samples

Each aggregate and laboratory sample shall be placed in a clean and inert container that gives adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage on transit. All necessary precautions shall be taken to avoid change of composition of the aggregate and laboratory samples that might arise during transportation or storage.

Art. 16 Sealing and labeling of aggregate and laboratory samples

Each sample taken for official use shall be sealed at the place of sampling and identified using the standard laboratory instructions. A record, including the date and place of sampling together with any additional information likely to be of assistance to the analyst, must be kept for each sample so that each lot can be identified unambiguously.

CHAPTER 2: Sampling plans

Art. 17 Place of sampling

Samples should ideally be taken at a point where the commodity enters the food chain and a discrete lot becomes identifiable. The sampling method applied

shall ensure that the aggregate sample is representative for the lot that is to be controlled.

Art. 18 Number of incremental samples

(1) In the case of liquid products for which a homogeneous distribution of the contaminant in question can be assumed within a given lot, it is sufficient to take one incremental sample per lot which forms the aggregate sample. The sample collected should be given a reference to the lot number. The liquid product shall be shaken or homogenized by other suitable means before the incremental sample is taken.

(2) For other products, the minimum number of incremental samples to be taken from the lot shall be as given in Table 1 below. The incremental samples shall be of similar weight. Departure from this procedure must be recorded in the record provided for under Art. 17 hereof.

Table 1

Weight of lot (kg)	**Minimum number of incremental samples to be taken**
< 50	3
50 to 500	5
> 500	10

(3) If the lot consists of individual packages, then the number of packages that shall be taken to form the aggregate sample is given in Table 2 below.

Table 2

Number of packages or units in the lot	**Number of packages or units to be taken**
1 to 25	1 package or unit
26 to 100	About 5 %, at least 2 packages or units
> 100	About 5 %, maximum 10 packages or units

CHAPTER 3: Compliance of the lot or sublot with the specification

Art. 19 Laboratory sample for enforcement

The control laboratory shall analyze the laboratory sample for enforcement at least in two independent analyses, and calculate the mean of the results. The lot is accepted if the calculated mean is less than or equal to the respective maximum level as laid down in Articles 4, 5 and 6 of Part II hereof. It is rejected if the mean exceeds the respective maximum levels.

PART IV

SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICIAL CONTROL OF THE LEVELS OF LEAD, CADMIUM AND MERCURY IN FISHERY AND AQUACULTURE PRODUCTS.

Art. 20 Basic Requirement

The basic requirement is to obtain a representative and homogenous laboratory sample without introducing secondary contamination.

CHAPTER 1: Specific sample preparation procedures for lead, cadmium and mercury

Art. 21 Sample preparation procedures

There are many satisfactory specific sample preparation procedures that may be used for the products under consideration. Those described in the draft CEN Standard 'Foodstuffs — Determination of trace elements — Performance criteria and general consideration' were found to be satisfactory [b] but others may be equally valid.

Art. 22 Specific sample preparation procedures for bivalve molluscs, crustaceans and small fish

Where bivalve molluscs, crustaceans and small fish are normally eaten whole, the viscera shall be included in the material to be analyzed.

CHAPTER 2: METHOD OF ANALYSIS TO BE USED BY THE LABORATORY AND LABORATORY CONTROL REQUIREMENTS

Art. 23 Definitions

A number of the most commonly used definitions that are used by the laboratory to establish procedures for sample preparation and criteria for methods of analysis are given below:

(a) r — Repeatability: the value below which the absolute difference between two single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2.8 \times S_r$.

(b) S_r — Standard deviation: calculated from results generated under repeatability conditions.

(c) RSD_r — Relative standard deviation: calculated from results generated under repeatability conditions [$(S_r / \bar{x}) \times 100$], where $\bar{x}$ is the average of results over all laboratories and samples.

(d) R — Reproducability: the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardized test method), may be expected to lie within a certain probability (typically 95 %); $R = 2.8 \times S_R$.

(e) S_R — Standard deviation: calculated from results under reproducibility conditions.

(f) RSD_R — Relative standard deviation: calculated from results

generated under reproducibility conditions [(S_R / $\bar{x}$) x 100]

(g) $HORRAT_r$ The observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption r = 0.66R

(h) $HORRAT_R$ The observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation [a].

Art. 24 General requirements

Reliable and scientifically recognized methods of analysis should be used for food control purposes.

Art. 25 Specific requirements for lead, cadmium and mercury analysis

Specific methods for the determination of lead, cadmium and mercury contents are not prescribed. Nevertheless, reference methods for detecting heavy metals are laid down [c], inter alias, Atomic Absorption Spectrophotometry (AAS). Laboratories shall use a validated method that fulfils the performance criteria indicated in Table 3 below. Where possible, the validation shall include a certified reference material in the collaborative trial test materials.

Table 3: Performance criteria of methods for lead, cadmium and mercury analysis.

Parameter	**Value/comment**
Applicability	Fishery and aquaculture products.
Detection limit	Not more than one tenth of the value of the specification in Articles. 4, 5 and 6 hereof except if the value of the specification for lead is less than 0.1 mg/kg. For the latter, not more than one fifth of the value of the specification.
Limit of quantification	Not more than one fifth of the value of the specification in Articles. 4, 5 and 6 hereof except if the value of the specification for lead is less than 0.1 mg/kg. For the latter, not more than two fifths of the value of the specification.
Precision	$HORRAT_r$ or $HORRAT_R$ values of less than 1.5 in the validation collaborative trial.
Recovery	80-120 % (as indicated in the collaborative trial).
Specificity	Free from matrix or spectral interference.

Art. 26 Estimation of the analytical trueness and recovery calculations

Whenever possible, the trueness of the analysis shall be estimated by including suitable certified reference materials in the analytical run.

The 'Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement' [d] developed under the auspices of IUPAC/ISO/AOAC shall be taken into account.

The analytical result shall be reported either corrected or uncorrected. The manner of reporting and the level of recovery must be reported.

Art. 27 Laboratory quality standards

Laboratories must have implemented the Good Laboratory Practices (GLP) (c).

Art. 28 Expression of results

The results shall be expressed in the same unit as the maximum levels laid down in Articles 4, 5 and 6 hereof, that is in ppm (mg/kg).

PART V

REPEAL

Art. 29 Repeal

The provisions under sub-articles (3)(c) (i), (ii) and (iii) of Article 20 of the Legal Notice No 40/1998 is hereby deleted.

Art 30 Effective Date

These Regulations shall come into force on the date of their publication in the Gazette of Eritrean Laws.

Done at Asmara, this 30th day of April, 2003
Ahmed Haj Ali,
Minister of Fisheries.

ANNEX 1

REFERENCES

(a) W. Horwitz, 'Evaluation of Analytical Methods for Regulation of Foods and Drugs', Anal. Chem., 1982, No 54, 67A-76A

(b) Draft Standard prEN 13804, 'Foodstuffs — Determination of Trace Elements — Performance Criteria and General Considerations', CEN, Rue de Stassart 36, B-1050 Brussels.

(c) Directive 90/515 EEC

(d) ISO/AOAC/IUPAC Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement. Edited Michael Thompson, Steven L R Ellison, Ales Fajgelj, Paul Willetts and Roger Wood, Pure Appl. Chem., 1999, No 71, 337-348

(e) Directive 93/99 EEC