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EXTRAORDINARY

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PART I : SECTION (I) — GENERAL

Government Notifications

LDB 4/96 iii

FISHERIES AND AQUATIC RESOURCES ACT, No. 2 of 1996

REGULATIONS made by the Minister of Fisheries and Aquatic Resources, under paragraph (1) and (m) of Sub section (1) of Section 61 of the Fisheries and Aquatic Resources Act, No. 2 of 1996.

FELIX PERERA,
Minister of Fisheries and Aquatic Resources.

Colombo,
06th December, 2007.

Regulations

The Fish Products (Export) Regulations, 1998, published in Gazette Extraordinary No. 1045/1 of September 14, 1998, as amended last by regulations published in Gazette Extraordinary No. 1230/14 of April 03. 2002, are hereby further amended in Schedule "E" thereof, by the substitution for item (5), appearing under the heading " special checks" of the following new item :-

"5. Maximum limits for Lead (Pb), Cadmium (Cd) and Mercury (Hg) in fish and fishery products—

(1) The Competent Authority shall in fixing values for the Lead (Pb), Cadmium (Cd) and Mercury (Hg) contents in fish and fishery products consider the values appearing in the column under "Maximum Level" as the maximum acceptable limits and the products specified below shall not contain higher levels than those given in "Maximum Level".

	Product	Maximum Level (mg/kg wet weight)
Lead (Pb)	Muscle meat of fish species excluding the species listed below (1)(2)	0.20
	Muscle meat of the following fish species (1)(2) : (1) Common two banded sea bream *(Diplodus vulgaris)* (2) Eel *(Anguilla anguilla)* (3) Grey mullet *(Mugil labrosus labrosus)* (4) Grunt *(Pomadasys benneti)* (5) Horse mackeral or scad *(Trachurus trachurus)* (6) Sardine *(Sardina pilchardus)* (7) Sardinops *(Sardinops species)* (8) Spotted seabass *(Dicentrarchus punctatus)* (9) Wedge sole *(Dicologoglossa cuneata)*	0.40
	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans *(Nephropidae and Palinuridae)*	0.50
	Bivalve molluscs	1.50
	Cephalopods (without viscera)	1.00
Cadmium (Cd)	Muscle meat of fish species excluding the species listed below (1)(2) :	0.05
	Muscle meat of the following fish species (1)(2) : (1) Anchovy *(Engraulis species)* (2) Bonito *(Sarda sarda)* (3) Common two - banded seabream *(Diplodus vulgaris)* (4) Eel *(Anguilla anguilla)* (5) Grey mullet *(Mugil labrosus labrosus)* (6) Horse mackeral or scad (*Trachurus trachurus*) (7) Louvar or luvar *(Luvarus imperialis)* (8) Sardine (*Sardina pilchardus*) (9) Sardinops *(Sardinops species)* (10) Tuna *(Thunnus, Euthynnys species, Katsuwonus pelamis)* (11) Wedge sole *(Dicologoglossa cuneata)*	0.10
	Muscle meat of swordfish *(Xiphias gladius)*	0.30
	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae and Palinurida*e)	0.50
	Bivalve molluscs	1.00
	Cephalopods (without viscera)	1.00
Mercury (Hg)	Fishery products and muscle meat of fish species excluding the species listed below (1)(3) :	0.50

	Product	Maximum Level (mg/kg wet weight)
	Muscle meat of the following fish species ([1])([2]) : (1) Anglerfish *(Lophius species)* (2) Atlantic catfish *(Anarhichas lupus)* (3) Bonito *(Sarda sarda)* (4) Eel *(Anguilla anguilla)* (5) Emperor, organge roughy, rosy soldierfish *(Hosplostethus species)* (6) Grenadier *(Coryphae noides rupestris)* (7) Halibut *(Hippoglossus hippoglossus)* (8) Marlin *(Makaira species)* (9) Mergrim *(Lepidorhombus species)* (10) Mullet *(Mullus species)* (11) Pike *(Esox lucius)* (12) Plain Bonito *(Orcynopsis unicolor)* (13) Poor cod *(Tricopterus minutes)* (14) Potuguese dogfish *(Centroscymnes coelolepis)* (15) Rays *(Raja species)* (16) Redfish *(Sebastes marinus, S. mantilla, S. viviparous)* (17) Sail fish *(Istiophorus platypterus)* (18) Sabbard fish *(Lepidopus caudatus, Aphanopus carbo)* (19) Seabream. Pandora *(Pagellus species)* (20) Shark *(all species)* (21) Snake mackerel or butter fish (*Lepidocybium favobrunneum, Ruvettus pretiosus, Gemphylus serpens)* (22) Sturgeon *(Acipenser species)* (23) Swordfish *(Xiphias gladius)* (24) Tuna *(Thunnus, Euthynnys species, Katsuwonus pelamis)*	1.00

([1]) Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish.

([2]) Live fish, fresh or chilled fish, frozen fish, fish fillets and other fish meat (whether or not minced) fresh, chilled or frozen.

([3]) Live fish, fresh or chilled fish, frozen fish, fish fillets and other fish meat (whether or not minced) fresh, chilled or frozen.

Crustaceans, whether in shell or not, live, fresh chilled, frozen dried, salted or in brine ; crustaceans, in shell, cooked by steaming or by boiling in water, whether or not chilled, frozen, dried, salted or in brine ; flours, meals and pellets of fish, fit for human consumption.

Molluscs, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine ; flours, meals and pellets of aquatic invertebrates other than crustaceans, fit for human consumption.

Crustaceans, molluscs and other aquatic invertebrates prepared or preserved.

(2) **METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF LEAD, CADMIUM AND MERCURY IN FISHERY PRODUCTS.**

(*a*) **PURPOSE AND SCOPE**

Samples inteded 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 sub lots form which they are taken. Compliance with maximum levels laid down in these regulations shall be established on the basis of the levels determined in the laboratory samples.

(*b*) **DEFINITIONS**

1. 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.
2. Sub Lot : designated part of a large lot in order to apply the sampling method on that designated part. Each sub lot must be physically separated and identifiable.
3. Incremental sample : a quantity of materials taken from a single place in the lot or sub lot.
4. Aggregate sample : the combined total of all the incremental samples taken from the lot or sub lot.
5. Laboratory sample : sample intended for the laboratory testing.

(*c*) **GENERAL PROVISIONS**

1. Personnel

   Sampling shall be performed by an authorized qualified person as specified by the Competent Authority.

2. Material to be sampled

   Each lot which is to be examined shall be sampled separately.

3. Precautions to be taken

   In the course of sampling and preparation of laboratory samples precautions shall be taken to avoid any changes which would affect the Lead, Cadmium and Mercury content adversely and affect the analytical determination or make the aggregate sample unrepresentative.

4. Incremental samples

   As for as possible incremental samples shall be taken at various places distributed throughout the lot or sub lot. Departure from this procedure shall be recorded in the record under item 8 of paragraph (c) appearing under the heading “General Provisions”.

5. Preparation of the aggregate sample

   The aggregate sample is made up by uniting all incremental samples. It shall be at least 1 kg to the extent it is practicable.

6. Subdivision of aggregate sample in laboratory samples for enforcement, defence and referee purposes.

   The laboratory samples for enforcement, trade (defence) and referee purpose shall be taken from the homogenized aggregate sample unless this conflicts with regulations on sampling. The size of the laboratory sample for enforcement shall be sufficient to allow at least for duplicate analyses.

7. Packaging and transmission of aggregate and laboratory samples.

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

8. Sealing and labeling of aggregate and laboratory samples

Each sample taken for official use shall be sealed at the place of sampling and identified following the regulatory requirments. A record shall be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

(*d*) **SAMPLAING PLANS**

Sampling should ideally take place at the point where the commodity enters the food chain and discrete lot becomes identifiable. The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

1. Number of incremental samples

The minimum number of incremental samples to be taken from the lot shall be as given in Table I. The incremental samples shall be of similar weight. Departure from this procedure shall be recorded in the record under Item 8, of Paragraph (c) appearing under the heading "General Provisions".

Table 1 : Minimum number of incremental samples to be taken from the lot.

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

In the case of a lot consisting of individual packages, the number of packages which shall be taken to form the aggregate sample is given in Table 2.

Table 2 : Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual packages.

Number of packages or units in the lot	*Number of packages or units 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%, at maximum 10 packages or units

(*e*) **COMPLIANCE OF THE LOT OR SUBLOT WITH THE SPECIFICATION**

An approved or authorized official laboratory shall analyse the laboratory sample for enforcement at least in two independent analyses, and calculate the mean of the results. The lot is accepted if the mean conforms to the respective maximum level as laid down in these regulations. It is rejected if the mean exceeds the respective maximum level.

(3) **SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICIAL CONTROL OF THE LEVELS OF LEAD, CADMIUM AND MERCURY IN FISH AND FISHERY PRODUCTS.**

(*a*) **INTRODUCTION**

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

(*b*) **SPECIFIC SAMPLE PREPARATION PROCEDURES FOR LEAD, CADMIUM AND MERCURY**

There are many satisfactory specific sample preparation procedures, which 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' have been found to be satisfactory but others may be equally valid.

The following point shall be noted for any procedure used.

bivalve molluscs, crustaceans and small fish: where these are normally eaten whole, the viscera are to be included in the material to be analysed.

(*c*) **METHOD OF ANALYSIS TO BE USED BY THE LABORATORY AND LABORATORY CONTROL REQUIREMENTS.**

(i) **Definitions**

A number of the most commonly used definitions that the laboratory will be required to use 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 time) may be expected to lie with in 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 $[(S_r/\bar{x})x100]$ Where $\bar{x}$ is the average of results over all laboratories and samples.

(*d*) $R =$ reproducibility, 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 standard 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, devided 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.

(ii) **General requirements**

Methods of analysis used for control purposes must comply whenever possible with the provisions of paragraphs 1 and 2 of the Annex to Directive 85/591/EEC.

(iii) **Specific requirements**

Lead, Cadmium and Mercury analyses

Specific methods for the determination of Lead, Cadmium and Mercury contents are not prescribed. Laboratories shall use a validated method that fulfills the performance criteria indicated in Table 3. 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 analyses.

Parameter	*Value/comment*
Applicability	Fish and fishery products specified in these regulations.
Detection limt	No more than one tenth of the value of the specification in these regulations, except if the value of the specification for lead is less than 0.1 mg/kg. For the latter, no more than one fifth of the value of the specification
Limit of quantification	No more than one fifth of the value of the specification in these regulations, except if the value of the specification for lead is less than 0.1 mg./kg. For the latter, no more than two fifths of the value of the specification
Precision	$HORRAT_r$ or $HORRAT_R$ values less than 1.5 in the validation collaborative trial
Recovery	80 — 120 % (as indicated in the collaborative trial)
Specificity	free from matrix or spectral interferences

(iv) **Estimation of the analytical accuracy and recovery calculations**

The accuracy of the analysis shall be estimated by including suitable certified reference material in the analytical run as the case may be.

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

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

(v) **Laboratory quality standards**

Laboratories must comply with directive 93/99/EEC or equivalent.

(vi) **Expression of results**

The results shall be expressed in the same units as the maximum levels laid down in these regulations.

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