INDONESIAN SHELLFISH SANITATION SYSTEM

(Decree of the Minister of Marine and Fishery Affairs No. KEP.17/MEN/2004 dated April 19, 2004)

THE MINISTER OF MARINE AND FISHERY AFFAIRS,

Considering:

a. that shellfish can naturally accumulate biological toxin that may endanger human health;

b. that one of the measures to prevent an accumulation of biological toxin referred to in letter a is establishing an Indonesian Shellfish Sanitation System;

c. that it is necessary to stipulate a decree of the Minister of Marine and Fishery Affairs to that effect;

In view of:

1. Law No.9/1985 on Fishery (Statute Book of 1985 No.46, Supplement to Statute Book No.3299);

2. Law No. 7/1996 on Food (Statute Book of 1996 No.99, Supplement to Statute Book No. 3656);

3. Government Regulation No. 102/2000 on National Standardization (Statute Book of 2000 No.198, Supplement to Statute Book No.4019);

4. Government Regulation No. 54/2002 on Fishery Business (Statute Book of 2002 No.100, Supplement to Statute Book No.4230);

5. Presidential Decree No.17/2001 on the National Standardization Body;

6. Presidential Decree No.228/M/2001;

7. Presidential Decree No.102/2001 on the Position, Task, Function, Authority, Organizational Structure and Work Mechanism of Ministry, as has been amended by Presidential Decree No.45/2002;

8. Presidential Decree No. 109/2001 on Organizational Unit and Task of First Echelon Officials of Ministry, as has been amended by President Decree No.47/2002;

9. Decree of the Minister of Marine and Fishery Affairs No.KEP.24/MEN/2002 on Procedure and Technique for Drawing Up Regulations within the Ministry of Marine and Fishery Affairs;

10. Decree of the Minister of Marine and Fishery Affairs No.KEP.05/MEN/2003 on the Organization and Work Mechanism of the Ministry of Marine and Fishery Affairs;

D E C I D E S :

To stipulate:

DECREE OF THE MINISTER OF MARINE AND FISHERY AFFAIRS ON INDONESIAN SHELLFISH SANITATION SYSTEM

FIRST,

The Minister of Marine and Fishery Affairs shall enforce an Indonesia Shellfish Sanitation System referred to in Attachment to this Decree.

SECOND,

The Indonesian Shellfish Sanitation System referred to in the first dictum shall serve as a reference for fish farmers, fishermen, processors, traders, advisers, and shellfish quality controllers in Indonesia in conducting shellfish sanitation.

THIRD,

This Decree shall come into force as from the date of stipulation.

Stipulated in Jakarta
on April 19, 2004
THE MINISTER OF MARINE AND FISHERY AFFAIRS,
sgd.
ROKHMIN DAHURI

ATTACHMENT

INDONESIAN SHELLFISH SANITATION SYSTEM

SECTION I
INTRODUCTION

A. Background

Shellfish is one of fishery products which has important economic value. Shellfish is not only consumed at home but also is exported, particularly frozen shellfish and

canned . . . . .

canned shellfish. At home shellfish, particularly semi-processed one is not only used to meet household needs but also is served at large and small restaurants. The practice of serving shellfish will entail a great risk of endangering human health if the shellfish is obtained from uncontrolled or contaminated waters and is not handled in a sanitary way.

In general, shellfish, after being caught or farmed in Indonesian waters, is not handled well. The quality of shellfish is much influenced by the waters where it is caught or farmed. A number of developed countries, such as the United States, European Union and Canada have developed a shellfish sanitation system. Thus, to make Indonesian shellfish acceptable to the international market and ensure that it is safe for consuming, it is necessary to stipulate an Indonesian Shellfish Sanitation System.

Demands for fishery products, particularly shellfish will continue to increase and become increasingly complex, particularly with regard to the requirement of high quality and consumer security. In addition, many importing countries are imposing similar standard requirements on both local products and foreign products so that the method of handling and controlling the quality of shellfish must be adjusted to the regulations prevailing in the importing countries.

In the face of liberalized trade under the World Trade Organization (WTO), and trade among countries in several regional groupings, such as European Union, the North America Free Trade Area (NAFTA), ASEAN Free Trade Area (AFTA) and Asia Pacific Economic Cooperation (APEC), Indonesia must make serious, rational and effective efforts to play its active role in benefiting from the free trade for the greatest benefit of the state and people. One of the decisive factors to make Indonesian shellfish acceptable to the international market is the good handling, processing and control of shellfish in Indonesia.

In drawing up a Shellfish Sanitation System, the Directorate General of Fish Catch, Ministry of Marine and Fishery Affairs has involved a number of relevant agencies, such as the Office of the State Minister for the Environment and the Indonesian Institute of Sciences (LIPI). The Office of the State Minister for the Environment made regulations on the control of waters set forth in the Law on Environmental Management of 1985. In the meantime, LIPI conducted a number of researches to map algae in the Indonesian waters which has the potential to produce biological toxin. The shellfish processing industry has supported this program particularly by catching and farming shellfish from safe waters, having processing units according to the sanitation standard, applying and maintaining the condition of sanitation operation, putting an appropriate number of certificate on each party of shellfish and maintaining recordings for examination by the authorized agency which shows the original and disposition of products.

One of the activities under the ASEAN-Canada Fisheries Post Harvest Technology Project from 1992 to 1997 is making preparations for a Shellfish Sanitation System by, among other things, improving human resources, appointing an agency responsible for monitoring shellfish producing areas and mapping shellfish producing areas.

B. Aim

This system is aimed at providing guidance to parties related to the catching, farming, handling, production and control of shellfish. This is also used to make requirements and principles of controlling the sanitation of shellfish produced and distributed for export market and domestic market besides it is used to make a note of agreement with authorized agencies from the countries which will receive Indonesia shellfish.

The main target of this Indonesian Shellfish Sanitation System is to ensure that Indonesian shellfish is safe for consuming by local residents as well as for exports. The globalization and liberalized economy and trade sent a message to Indonesia to be able to compete with foreign rivals.

C. Definition

a. Shellfish means all species of shellfish including oyster (pinctada sp), kepah (meritrix meritrix), tiram (crassostrea cuculata), simping (common minolowpen), remis and kijing, live or separated from their shells, fresh or frozen, intact or part.

b. Biological toxin means toxic compound accummulated in shellfish eating toxic plankton.

c. Shellfish growing area means the waters where shellfish lives naturally or the waters or estuary which produces shellfish or place which is used to farm shellfish.

d. Removal .....

d. Removal means the act of removing harvested or caught shellfish from limited (class C) waters to a temporary pond for a certain period of time to make the shellfish free from being contaminated and safe for consuming.

e. Temporary pond means any waters which is established by an authorized agency, has clear borders using floats or other definite marks, and is used for natural removal.

f. Depuration means a process of cleaning shellfish using repeat water circulation to minimize the contamination of microbe, manure, heavy metal, etc.

g. Collecting unit means an installation at sea or on land which is allowed to receive, condition, clean, wash, sort and pack live shellfish which is fit for consuming.

h. Packing means an act of wrapping up or placing shellfish into a container using standard packing materials.

i. Captor means an individual or corporate body that captures shellfish from a shellfish growing area using whatever means.

j. Farmer means an individual or corporate body that farms shellfish in a shellfish growing area using whatever means.

k. Polluted waters means the entry of organism, substance, energy, and/or other components into waters due to intentional or unintentional human activities so that the quality of the waters drops to a certain level that makes it impossible for the waters to function according to its appropriation.

l. Feasibility certificate of processing means a certificate issued by the Minister of Marine and Fishery Affairs through the Director General of Fish Catch stating that the processing unit has met the given requirements.

m. Sanitation certificate means a certificate issued by the head of provincial office stating that the processing unit has met the given requirements.

n. Minister means the Minister of Marine and Fishery Affairs.

o. Director General means the Director General of Fish Catch.

p. Provincial Office means the provincial office responsible for marine and fishery affairs.

q. LPPMHP means laboratory for the development and test of the quality of fishery products.

D. Administration and Law

1. Brief Descriptions

The Ministry of Marine and Fishery Affairs through the Directorate General, and Provincial Offices across Indonesia is the agency which has the authority and is directly responsible for implementing, controlling and supervising the Indonesian Shellfish Sanitation System. Technically, the Directorate General assigns the Director of Quality and Product Processing to carry out tasks related to a nationwide shellfish sanitation system with the help of technical units (UPT) at the center for the development and test of the quality of fishery products (BPPMHP), particularly in monitoring shellfish sanitation nationwide. The Directorate General also has quality control officials assigned to test and control the quality of shellfish nationwide. They may work either for BPPMHP or the Directorate of Quality and Product Processing.

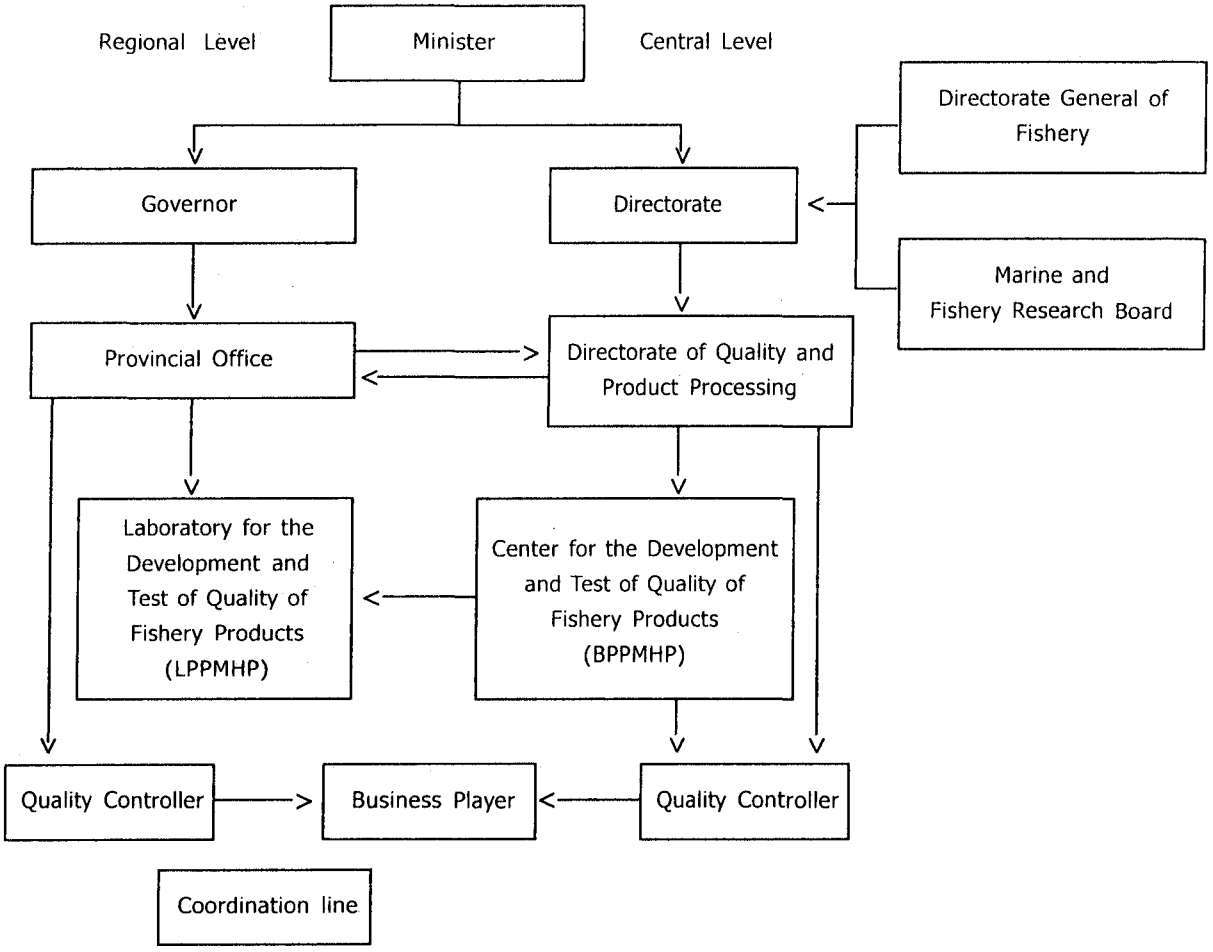
The Directorate General gets inputs from the Directorate General of Fish Farming and the Marine and Fishery Research Board with regard to safe locations or waters for shellfish farming and catching.

The Provincial Office which is structurally below and directly responsible to the Governor is a technical agency which administratively coordinates the implementation of shellfish sanitation system.

In performing its duties, the Provincial Office has one or more LPPMHPs assigned to issue certificates of health and monitor shellfish sanitation. In addition, the provincial government also has fishery controller officials assigned to test or control fishery products. They may work for the Provincial Office, LPPMHP and fish landing place.

Following .....

Following is the diagram of the above mechanism:



2. Institute and Authority

a. Central Institutes

Central Institutes consist of:

1. The Directorate General;
2. The Directorate General of Fish Farming;
3. The Marine and Fishery Research Board (BRKP).

The Directorate General and the Directorate General of Fish Farming are responsible for establishing the classification and status of waters for shellfish farming or catching based on the result of a comprehensive survey and monitoring of shellfish growing areas by BRKP-DKP.

The Directorate General is also responsible for controlling the process of handling, storing, transporting, processing, and labeling shellfish.

To ensure that these activities can be carried out effectively, the Minister should form a central executive team which is made up of representatives from the Directorate General, the Directorate General of Fish Farming and the Marine and Fishery Research Board.

b. Regional Institutes

The Provincial Office and LPPMHP are responsible for verifying the application of Indonesian Shellfish Sanitation System.

1) The Authority of the Provincial Office
   a) Forming and chairing a regional team to report all the results obtained to the Directorate General as an authorized agency;
   b) Coordinating the activities of monitoring the quality and condition of waters, the activities of taking, handling and analyzing samples, and the activities of controlling shellfish growing areas;
   c) Supervising fish processing units, fish landing places, and fish collecting places in accordance with the basic principles of feasibility covering the application of sanitation standard operational procedure (SSOP), good manufacturing practices (GMP) and good handling practice (GHP).
   d) Conducting prevalidation and audit of the application of integrated quality management system (PMMT) based on the Hazard Analysis and Critical Control Points (HACCP) to fish processing units, fish collecting places and fish landing places.

2) The Authority of LPPMHP:
   a) Conducting a quality test on fishery products including shellfish by observing the Technical Guidelines and Administrative Management of LPPMHP and the Guidelines of the National Standardization Board (BSN) No.17025 regarding the authority of test laboratory.
   b) Auditing the application of integrated quality management program based on the HACCP concept.
   c) Issuing health certificates for fishery products including shellfish for and on behalf of the Directorate General.
   d) Conducting monitoring activities based on the national monitoring program drawn up by the Directorate General.

The regional team must make cooperation programs. One of its activities is to hold routine meetings attended by relevant agencies, including the Provincial Office, representatives of the Ministry of Health, the Drug and Food Control Board (BPOM), the Marine and Fishery Research Board, and the Regional Environmental Impact Management Board (BAPEDALDA) assigned in the relevant region.

c. Agenda of Routine Meeting
   The agenda of the executive team's routine meeting are as follows:
   1. Reviewing the classification of the existing shellfish growing areas,
   2. Reassessing all policies, procedures and regulations on the application of the classification of shellfish growing areas.

d. The application of Indonesian Shellfish Sanitation System, covering:
   1. all shellfish growing areas;
   2. shellfish farmers/fishermen;
   3. individuals and/or corporate bodies handling and processing shellfish;
   4. relevant agencies controlling and monitoring shellfish growing areas.

3. Laws and Regulations
   a. Legal Basis for Food Security
      1. Law No.9/1985 on Fishery;
      2. Law No.7/1996 on Food.

   b. Structure of Laws and Regulations
      Based on Resolution of the People's Consultative Assembly (MPR) No.III/MPR/2000 on Legal Sources and Sequence of Laws and Regulations and Letter of the Minister of Justice and Human Rights No.M.UM.01.06-27 dated February 23, 2001, the sequence of laws and regulations is as follows:
      a. 1945 Constitution;
      b. Law;
      c. Government Regulation in lieu of Law;
      d. Government Regulation;
      e. Presidential Decree;
      f. Ministerial Decree;
      g. Regional Regulation.

   c. Relevant regulations
      1) Decree of the Minister of Marine Resources and Fishery No.Kep.01/MEN/2002 on Integrated Quality Management System for Fishery

Products . . . . .

Products (in lieu of Decree of the Minister of Agriculture No.41/Kpts/IK.210/2/98).

2) Decree of the Minister of Marine Resources and Fishery No.Kep.06/MEN/2002 on Requirements and Procedures for Inspecting the Quality of Fishery Products Entering the Territory of the Republic of Indonesia as has been amended by Decree of the Minister of Marine Resources and Fishery No. Kep-43/MEN/2003.

d. Other Regulations

1) Indonesian National Standard on Shellfish No. 02-3919-1995 on Canned Shellfish and No.01-3464-1994 on Frozen Shellfish Meat.

2) Sampling Method, Indonesian National Standard (SNI) or FAO/WHO Code Alimentarius Sampling Plans for Prepackaged Foods (AQL.6.5).

3) Decree of the Minister of Health No.01/BIRHUKMAS/1975, on Requirement and Inspection of Drinking Water.

4) Decision of the Director General of Fishery No.14128/Kpts/IK.130/VII/1998 on Guidelines for Implementing Integrated Quality Management System for Fishery Products.

4. Administrative Procedures

In the Shellfish Sanitation System, the authorized agency carries out the following activities:

a. Classifying potential shellfish growing areas based on sanitation quality and public health security considerations. The authorized agency can declare areas off-limit to shellfish catching.

b. Controlling shellfish catching and farming in the areas declared off-limit. In this regard, the authorized agency is responsible for:

* conducting patrols in shellfish growing areas;
* nabbing and investigating any captor found committing a violation.

c. Arranging and controlling uncultivation, cleaning and purification of shellfish.

d. Preventing shellfish catching or farming in shellfish growing areas which are clearly polluted and/or have the potential of being polluted.

e. Preventing sales, distribution, storing or possession of shellfish that does not meet requirements or is not fit for consuming.

f. Issuing certificates to see if the products meet good handling requirements;

g. Regulating shipment conditions and shellfish labeling requirements and providing accurate initial identification of origin or preventing products from being contaminated.

h. Stipulating technical requirements for the export, import, processing, packing, shipment, storing and repacking of shellfish to prevent consumers from being contaminated and from low quality shellfish.

i. Controlling the depuration of shellfish to prevent the distribution of illegal shellfish, ensure cleanliness, prevent shellfish from being recontaminated, verify the quality of products and the effectiveness of depuration.

j. Stopping processing activities and revoking the certificates of processing units violating good handling practices.

k. Evaluating test laboratories with regard to the requirements set by the Directorate General.

l. Taking samples and conducting necessary microbiological, chemical and physical tests to establish the quality of products and monitor the effectiveness and performance of process.

m. Recommending the export of shellfish whose origin is unclear and banning processing units which have no feasibility certificate of processing (SKP), from carrying out their activities.

E. Certification

Certification is an important requirement to implement the Indonesian Shellfish Sanitation System. In certifying shellfish the following matters should be observed.

1. General Provisions

a. The supplier must complete a letter of guaranty to the processing unit upon the arrival of shellfish. The letter of guaranty covers information on the origin of shellfish, and the shellfish supplier and captor/farmer in the Indonesian waters. The Directorate General must not issue a permit to any processing unit receiving shellfish caught from areas declared off-limit to shellfish catching and farming. In the fish landing place, the quality controller checks whether the shellfish was caught from allowable grounds.

b. The . . . . .

not available or in the waters which have had the level of contamination changed. The sanitation survey is conducted by a central team, namely from the Directorate General. A comprehensive sanitation survey on the classification of shellfish growing area is conducted once every 3 (three) years.

Following are the elements of a sanitation survey:

a. Coastal Sanitation Research

This activity covers:

1) Evaluating all sources which may cause contamination and/or anything which has the potential to become a source of contamination;
2) Identifying the location map of sources of contamination in the waters for catching shellfish;
3) Evaluating the effectiveness of waste handling;
4) Documenting the presence of industrial waste including pesticide and radioactive and its impact on human health;
5) Documenting the presence of human/animal feces albeit in small quantities.

b. Hydrographic Research

This activity is aimed at

1) Establishing the impact of rains, winds, high tides and water currents in spreading pollutant in the waters for catching,
2) Estimating the quantity of water that may dissolve pollutants to achieve an allowable standard,
3) Estimating a period of time needed to spread pollutants from their sources to the waters for catching,
4) Establishing the physical characteristics of water including salinity, temperature and turbidity.

c. Microbiological Observation

This observation is aimed at

1) Establishing the level of faecal contamination (by assuming the number and type of bacteria from human/animal feces)
2) Achieving quantitative data to establish the class of waters,
3) Delineating the border lines of the class of waters.

Table 1. Main Components in Comprehensive Survey

Identification of Sources		Hydrography		Bacteria Research	
A.	Location originating from urban areas	A.	Water flow	A.	Location
1.	Waste treatment center	1.	Previous records	B.	Time
2.	Industrial waste		a. River flow	1.	Seasonal
B.	Sources from coastal environment		b. Rain impact	2.	Consecutive days
1.	Domestic, such as faecal tanks	2.	Survey time	3.	Daily
2.	Human mobilization		a. River flow	C.	Number of samples
3.	Agriculture		b. Rain impact	D.	Interpretation
4.	Animals and wild animals	B.	High tide	E.	Others, such as sediment, shellfish analysis, including pollutant
5.	Others such as the discharge of waste from ships	C.	Current		
		D.	Temperature and salinity		
		E.	Water from land		
		F.	Weather		
		G.	Battymetry		

.. Review

A review of the sanitation quality of shellfish growing area for farming or catching is made periodically at least once every year. The review is needed to see to it that the environmental condition remains unchanged and the already specified classification of waters is still valid.

The review must cover:

a. A review of the previous documents on the status of waters for catching,
b. Recordings for the processing and discharge of industrial waste,
c. A report on the downgrading of contamination originating from the sources of pollution identified in the previous review,
d. Evaluation of new sources of contamination,
e. The taking of samples for microbiological analysis in places that sufficiently represent other places with adequate frequency.

3. Monitoring

a. The Monitoring of Shellfish Growing Area

This monitoring is done by conducting routine inspection, including taking water samples and shellfish for the purpose of microbiological, phytoplankton, mercury, PSP, ASP and DSP analyses.

This monitoring covers:

1) The periodic monitoring of shellfish growing areas and uncultivation areas in order to
   a) prevent all types of activities which deviate from the initial aim of shellfish,
   b) inspect the microbiological quality of shellfish in shellfish growing areas,
   c) inspect the possibility of plankton producing poison in shellfish growing areas and temporary ponds and the possibility of biological toxin content in shellfish,
   d) inspect the possibility of chemical pollution.

   In regard to the aim in letters (c) and (d), a plan to take samples must be stipulated by the authorized agency to inspect the possibility of biological toxin and chemical pollutant, either regularly or case by case.

2) The plan to take samples referred to in point 1a must observe the following matters:
   a) The variation of faecal pollutant in each shellfish growing area and temporary pond,
   b) The possibility of various plankton containing biological toxin in shellfish growing areas and temporary pond.

      Samples must be taken through the following way.

      i. Monitoring:

         Periodical sampling is made to detect a change in the composition of plankton containing toxin and their spreading area.

         Sampling is made once every two weeks.

      ii. Intensive sampling

         The frequency of monitoring is increased by once in a week if there is an indicator of red tide and even as often as possible by increasing the number of sampling points and the number of samples if there is massive death of marine biotas. The marketing of shellfish from the said area must be stopped until the result of a test on hazardous substances is promising.

   c) The possibility of shellfish in shellfish growing areas and temporary ponds being contaminated.

      If the result of a test on samples indicates that the shellfish marketed can endanger human health, the authorized agency must shut down the shellfish growing area until the situation returns to normal.

3) A laboratory test to see if the shellfish accords with the quality of end product referred to in Section V.

b. Supervision and monitoring of processing units

The supervision of processing units is done periodically with a certain interval of time:

This supervision covers:

1) verification to see if the condition of processing units still meet the requirement,
2) cleanliness of place, facility, equipment and health of employees,

3) verification . . . . .

3) verification to see if shellfish is handled and processed properly,
4) application and use of purification system or proper conditioning,
5) inspecting the microbiological quality of shellfish in relation with shellfish growing areas and temporary ponds,
6) inspecting the possibility of plankton producing biological toxin in the shellfish growing area and temporary ponds and the possibility of shellfish containing biological toxin,
7) inspecting the possibility of chemical pollution,
8) proper use of labels,
9) inspecting the condition of storage and transport means to send shellfish.

c. The sanitation quality of waters
To protect the population of shellfish against pollution originating from feces and pollutants discharged into sea, the Government has made and implemented a program to keep down the impact of pollution to the lowest possible level to achieve the quality of shellfish which meets the quality requirement and can be directly consumed by human beings. The quality of shellfish growing areas must meet the requirements specified in Table 2. The frequency and parameter of monitoring to inspect the sanitation quality of waters must be made in such a regular way and the taking of samples can be reduced or stopped if the result of a test on the samples is quite promising. The test is conducted using questionaires. If the observation report indicates evidence of faecal coliform bacteria, mercury, or biological toxin (PSP, ASP, DSP) contamination, the taking of water samples and shellfish products must be done for the purpose of a laboratory test. Data or findings of a laboratory test may change the status of the area in question. If the data or findings of a laboratory test indicate that the allowable area has changed or no longer meets sanitation requirements, reevaluation will be made and the area in question will be declared off-limit.

4. Reevaluation
The reevaluation of shellfish growing areas must be done if the result of a review shows that the sanitation quality of shellfish growing areas has clearly dropped due to a change in potential sources of contamination. The complexity and scope of reevaluation will be specific for each area and may require all elements specified in Table 1 and comprehensive sanitation survey. Remote areas with low potential risks can be evaluated with low frequency and water samples may not be required.
Improvements are intended to return the waters that have changed to the initial condition according to the criteria that meet requirements for shellfish growth. The measures taken depend on the extent to which the waters has not matched the criteria. For its part, there is urgent need to conduct complete identification to investigate the cause.
There are 2 (two) factors causing a decline in the quality of waters, namely:
1. high pollution caused by industrial waste and household waste;
2. surging population of certain microalgae producing biological toxin, such as PSP, DSP and ASP.

SECTION III
CLASSIFICATION AND CLOSURE OF SHELLFISH GROWING AREAS

A. Classification of Shellfish Growing Areas
Shellfish growing areas in the Indonesian Shellfish Sanitation System are classified into 4 (four) classes, namely permissible areas (class), permissible areas with certain condition (class B), limited areas (class C), and off-limit areas (class D). Each of the classes is related to the microbiological quality of waters and the level and potential of pollution due to natural cause or activities in surrounding areas.
Following is the description of each of the classes:
1. Class A (permissible area)
Permissible areas are shellfish growing areas whose shellfish can be directly consumed, does not endanger human health and meets the requirements set forth in SECTION V.
Areas can be classified as class A shellfish growing areas if they meet the following requirements:
* The waters are not contaminated by human feces, toxic substances and biological toxin to the level that endangers human health when consuming the shellfish.
* The average geometrical content of the most possible point (APM) of faecal coliform bacteria in the waters does not exceed 14/100 ml of water and less than 10% of samples contains faecal coliform bacteria of no more than 43/100 ml of water.

2. Class . . . . .

2. Class B (permissible areas with certain condition)
   Permissible areas with certain condition are shellfish growing areas whose shellfish is safe for directly consuming during harvest time which is allowed or meets certain requirements.
   The requirements of a ban on shellfish catching and farming in areas declared as permissible areas must be easily identified with routine measurement and reporting and can be predicted and controlled.
   Areas can be categorized as class B shellfish growing areas if they meet the following requirements:
   The average geometric content of the most possible point (APM) of faecal coliform bacteria in the waters does not exceed 14/100 ml of water and less than 10% of samples contains faecal coliform bacteria of no more than 43/100 ml of water.

3. Class C (limited areas)
   Areas can be categorized as class C shellfish growing areas if the result of a sanitation survey conducted shows the pollution level of feces and toxic substances is fairly low and the application of depuration or removal can make shellfish safe for consuming.
   These shellfish growing areas must have the median average of faecal coliform bacteria from water at 88 per 100 ml, and less than 10% of samples contain no more than 260 faecal coliform bacteria per 100 ml.
   The shellfish grown from this waters cannot be directly consumed but must first be processed through heating or depuration or released to temporary pond or class A shellfish growing areas for at least 2 (two) months.

4. Class D (off-limit areas)
   Areas are declared off-limit to catching by the authorized agency if certain conditions are not met. These areas indicate a high level of faecal pollution or constitute dump sites of feces which are not first processed and contain biological toxin PSP which exceeds the standard level.
   These areas are also declared off-limit if no complete sanitation survey has been conducted there.
   These areas produce shellfish whose biological toxin PSP content is equal to or higher than 80 ug per 100 grams of sample, ASP content is equal to or higher than 20 ug per 100 grams of sample.
   If areas are declared off-limit, all kinds of shellfish catching or other activities are banned in these areas until they meet the requirements of class A, B or C shellfish growing areas.

   Any change in the demarcation of shellfish growing areas and temporary closure or harvest of shellfish growing areas must soon be notified by the authorized agency to relevant agencies through the following mechanism:
   1. The Directorate General notifies a change in demarcation of shellfish growing areas to the Provincial Office,
   2. The Provincial Office notifies new demarcation borders to all producers or captors,
   3. Any change in shellfish growing areas must also be notified to buyers,
   4. The Ministry of Marine and Fishery Affairs and the Provincial Office conduct patrols in areas declared off-limit to catching.

B. CLOSURE OF SHELLFISH GROWING AREAS
   Data or findings obtained from a review or reevaluation may change the status of areas.
   If the result of a review indicates that the sanitation quality of waters in permissible areas changes significantly, particularly the sources of pollution, the areas can be temporarily closed, and if the condition of the permissible areas is deteriorating and does not meet sanitation requirements, the areas will be declared off-limit.
   The closure and reopening of the areas becomes the responsibility of the Director General with the following procedure:
   1. BPPMHP, along with LPPMHP conducts a complete survey and/or reevaluation. If the scientific evidence shows that the criteria of shellfish growing areas are not met, the Director General will inform the Provincial Office of the matter.
   2. The Provincial Office invites all relevant parties, including fishermen, collectors, processors, fish port officers, and patrol officers to a meeting and declares the areas off-limit to catching and farming.
   3. During the closure, LPPMHP must intensively monitor the areas.
   4. If the result of monitoring shows that all the criteria of reopening the shellfish growing areas have been met, the Provincial Office reports it to the Directorate General to reopen the shellfish growing areas.
   5. The Directorate General revises the map of shellfish catching/growing areas.

SECTION IV . . . . . (To be continued)

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INDONESIAN SHELLFISH SANITATION SYSTEM

(Decree of the Minister of Marine and Fishery Affairs No. KEP.17/MEN/2004 dated April 19, 2004)

[Continued from Business News No. 7096 - 7097 pages 2A - 12A]

SECTION IV
CATCHING, FARMING AND POST-HARVEST HANDLING

Post-harvest activities such as handling, collection, processing or distribution of shellfish is one of the very important parts of the Shellfish Sanitation System. This is important for each captor who catches shellfish from clean waters referred to in Section V points 1, 2 and 3. Any piece of information that has the potential to endanger human health must not be gathered, processed or distributed further by consumers.

A. Catching

1. Control of Shellfish Catching

The control of shellfish catching and farming in shellfish growing areas is very important part of the procedure for controlling shellfish catching to ensure that shellfish can only be caught from permissible areas.

The prevention of shellfish from dangerous contamination during handling and catching are made as follows:

a. At a time when there is evidence that hazardous substances or human feces have contaminated the waters to the level that endangers human health and/or poisoning happens to people after consuming shellfish, so that the waters must soon be declared off-limit to all kinds of activities, such as shellfish catching or farming during a certain period of time until the Director General issues a decision to change the status of the waters.

b. Catching areas put under the status of off-limit areas must be routinely monitored and supervised very often by the authorized agency.

c. Catching technique must not cause excessive damage to shellfish and additional contamination to product or reduce significantly the quality of product.

d. Shellfish must not be soaked again in water that may cause additional contamination between catching and landing.

2. Fishing Boat and Equipment

All boats used for catching or transporting shellfish and all equipment used for catching shellfish must be designed, operated and maintained according to hygienic sanitation requirements to prevent recontamination and damage to eggshells. They must be equipped with a good waste water discharging system which can easily be cleaned.

When transporting shellfish in bulk for long distance to a collecting place, temporary pond or processing unit, transportation means must be made in such a way to ensure that shellfish will remain alive.

3. Transport Requirements

The transportation of shellfish from a shellfish growing area to a collecting place, depuration place, temporary pond or processing unit must be equipped with registration documents registered in the landing place. The registration documents are issued by the authorized agency at the request of the captor or farmer.

The documents must contain the following information:

a. identity and address of captor;
b. name and register number of fishing boat;
c. date of catching;
d. location of growing area;
e. classification of growing area (the health status of growing area);
f. type and quantity of shellfish;
g. licence number and processing unit, collecting place, depuration place or temporary pond of destination for shellfish caught in limited areas.

The documents must be given date and serial number and signed by the collector or captor or farmer. The authorized agency must keep a list of registration documents. The documents must be given a stamp and date of departure to the collecting place, depuration place, temporary pond or processing unit, and must be kept by the central or regional operator or UPT unit for a minimum of 12 months.

However, if shellfish is collected by the same staffer in the collecting place, depuration place,

temporary . . . . .

temporary pond or UPI of destination, registration documents can be replaced with permanent transport authorization guaranteed by the authorized agency.

If the shellfish growing area or temporary pond is declared off-limit for the time being, the authorized agency must stop issuing registration documents for the area and soon revoke all registration documents already issued.

Transport means used for carrying live shellfish must be used under the condition that may prevent shellfish from additional contamination and damage to eggshells. The transport means must be equipped with a good waste water discharging system.

4. Requirement for removing shellfish

The requirement for removing shellfish covers:

a. The technique of handling live shellfish for the purpose of removal must make it possible for the shellfish to filter food after being entered into natural waters.
b. Shellfish must be soaked in sea water in the temporary pond for an adequate time which exceeds the time needed to reduce faecal bacteria to a permissible level according to the requirement and standard of product set forth in this decree.
c. An area used for temporary pond must be approved by the authorized agency.
d. The borders of temporary pond must be clearly identified using floats or other permanent means. The distance between one temporary pond to another or between a temporary pond and growing area must be a minimum of 300 meters.
e. Locations within a temporary pond must be separated from one to another properly to prevent one party of products from being mixed with the other. A first in first out (FIFO) system must be used.
f. During the transport of shellfish to a collecting place, depuration place or processing unit, the shellfish must be equipped with registration documents. If the transport of shellfish is carried out by the same employee in the temporary pond and collecting place, depuration place or processing unit, the registration documents are not needed.
g. Permanent recordings from a source of live shellfish, removal time, temporary pond and further destination of a party of products after removal must be kept by the operator of the temporary pond and used by the authorized agency to conduct an inspection.

5. Requirement of Collecting Place

The requirement of collecting place covers:

a. Collecting place must be located in an area which is free from a source of contamination, such as odor, smoke, flood, dust, etc.
b. Building must meet the specified technical requirement.
c. The surface of equipment which is in direct contact with live shellfish must be made of stainless materials which can easily be washed and cleaned repeatedly.
d. Building and equipment must be designed in such a way that ensures the attainment of high level of cleanliness and hygiene and facilitates the operation of the building and equipment.
e. Live shellfish must be washed or cleaned using clean sea water or pressure drinking water, and washing water must not be recirculated.
f. Collecting place can only receive a party of products equipped with registration documents, and originating from permissible growing area or temporary pond.
g. Collecting place must keep the documents issued by the authorized agency as follows:
   * The result of a microbiological test on live shellfish originating from a growing area, temporary pond or permissible area;
   * The date and quantity of live shellfish transported from a collecting place equipped with registration documents;
   * Details of departure from a collecting place including name and address of recipient, date and quantity of live shellfish departed, as well as the number of registration documents.

   The data above must be classified chronologically and kept for a period of time specified by the authorized agency and for a minimum of 12 months.
h. Transport of shellfish from a collecting place
   1) Live shellfish delivered for consumption must be put in closed packs from the collecting place in the same way as when it is sold to a consumer or retailer.

2) The . . . .

2) The transport means used for delivering live shellfish must have the following characteristics:
   a. Inside walls and parts of building which are in direct contact with the product must be made of uncorrosive, fine and easy-to-clean materials.
   b. The transport means must be equipped with materials capable of protecting live shellfish effectively from a drastic change of temperature, contamination of dust or feces, and a damage to eggshells due to friction among shellfish.
   c. Live shellfish must not be transported along with other products that may contaminate the shellfish.
3) Live shellfish must be transported and distributed using a closed vehicle or means capable of maintaining the shellfish at a temperature that does not affect the quality and survival of shellfish.

   The packs of live shellfish transported must not be in direct contact with the floor of the vehicle or container but must be supported by higher surface or other equipment to avoid such contact.

When using ice in the transport of live shellfish, the ice must be made of drinking water or clean sea water.

B. Handling
1. Washing
   a. The newly-caught shellfish must soon be washed to rid it of mud and other manure. If not, the shellfish must be washed at the processing unit upon arrival.
   b. The water used for washing the shellfish must originate from the permissible shellfish growing area or from other source approved by the quality controller.
   c. If the shellfish is washed in the landing place after being caught, the place must meet the specified sanitation and hygienic requirements.

2. Packing and labeling
   a. The packs (boxes or sacks) used for packing shellfish must be clean and be made of permissible materials;
   b. Each party of products must be given a label indicating the origin of material, date of packing, name of product (species) and storage temperature.
   c. Live shellfish must be packed under hygienic condition, while the materials of the pack :
      - must not influence the organoleptic characteristics of live shellfish,
      - must not spread materials hazardous to human health to live shellfish and must be strong enough to protect live shellfish.
   d. Oyster must be packed with eggshells facing downward.
   e. The pack of shellfish must be entirely closed and maintained from the collecting place up to the consumer or retailer.

3. Depuration

Depuration can be done using various deputation instruments, including a repeat circulation system. When using this system, water must be sterilized using ultra violet rays and water must always be clean and thus, a filtering system is needed. To avoid pressure on shellfish and ensure the smoothness of the cleaning system, the following measures must be taken:

a. Before being put into the cleaning instrument, shellfish must be cleaned from mud and other manures using high pressure sprayers.

b. Only live shellfish is entered into clean water.

c. The temperature, salinity and oxygen content of water must be adequate so that shellfish will not come under pressure due to environmental change.

The requirement of depuration

a. The floor and wall of depuration tank and water reservoir must have fine, hard, and watertight surface which can easily be cleaned using brushes or high pressure water. The floor of depuration tank must be fairly slope and be equipped with a liquid waste discharge system according to the work load.

b. Live . . . . .

b. Live shellfish must be washed and clean from mud using clean sea water or drinking water before the depuration process begins. The initial washing can also be made in a depuration tank before the process begins. The water discharge hole must be kept open during the initial washing and later the depuration system must be rinsed off before the process begins.

c. The depuration tank must be supplied with sea water enough for every hour and a certain quantity of live shellfish processed.

d. Clean sea water or cleaned sea water must be used for washing live shellfish. The distance between the incoming (clean) sea water and waste water must meet requirements to avoid contamination. If the treatment of sea water is needed, the process must be approved by the authorized agency after its effective diversification. The drinkable water used as sea water and the structure of its chemical substance must meet the requirement.

e. The operation of depuration system must enable live shellfish to filter food, discharge contamination waste, avoid recontamination, and continue to live after the depuration process and during the packing, storing and transportation process before being marketed.

f. The quantity of live shellfish to be departed must not exceed the capacity of instrument, live shellfish must be constantly departed for an adequate period of time to reduce the bacteria content in accordance with the standard set forth in Section V. This period begins from the time when live shellfish is put into a closed depuration tank until it is taken out of the tank. The depuration place must consider data related to raw materials (type of mollusk, area of origin, micro content, etc.). This is needed to extend the purification period to ensure that the live shellfish meets the standard set forth in Section V.

g. If the depuration tank contains several parties of products, the shellfish species must be the same and be taken from the same growing area or different growing areas which have the same class of growing area.

h. The duration of treatment must be based on the time needed by the party of products which requires the longest depuration period.

The place used for live shellfish in the depuration system must have construction capable of allowing sea water to flow, and the thickness of shellfish must not impede the opening of eggshells during the depuration process.

j. The tank used for depurating shellfish must not contain shrimp, fish or other marine biotas.

k. After the depuration process is over, eggshells must be washed by spraying drinkable water or clean sea water to them. This activity can be done in the depuration tank, if needed. The washing water must not be recirculated.

l. The depuration place must have a laboratory equipped with facilities needed to check the effectiveness of the depuration process using microbiological specifications. When using a laboratory outside the depuration place, there must be prior consent from the authorized agency.

m. The depuration place must regularly keep data on :
- the result of a microbiological test on the incoming water to be used in the purification system,
- the result of a microbiological test on oyster before the purification process,
- the result of a microbiological test on oyster after the production process,
- the date and quantity of live shellfish sent to the purification center using registration document numbers.

- the time of replenishing and emptying the purification system (the duration of purification process), and
- details of product sent after the purification process.

These data must be complete, accurate and clear and be recorded in the main book and must be available at time when the authorized agency conducts an inspection.

n. The depuration place is only allowed to receive parties of products equipped with registration documents set forth in SECTION IV. The depuration place which dispatches live shellfish to a collecting place must give registration documents, licence number and address of the depuration place, duration of depuration process, date of entering and leaving the depuration place and other information needed to identify and trace products.

o. Any pack of already-depurated shellfish must be given a label stating that the shellfish has been depurated.

4. Cold Storage
After being depurated, live shellfish is kept under a temperature that cannot influence the quality of shellfish and endanger its survival. The pack of shellfish must not be in direct contact with the floor of the storage place but must be placed at the higher and cleaner surface. The storage place must be kept clean to avoid cross contamination and only certain people are allowed to enter the storage place. Live shellfish cannot be resoaked or resprayed with water after being packed or leaving the collecting place except if the shellfish is sold by retail in the collecting place.

SECTION V
STANDARD QUALITY OF SHELLFISH

Live shellfish and its processed products used for directly consuming must meet the following requirements:

1. meeting the visual characteristics related to freshness and survival, including eggshells clean from manure, giving a reaction to knock and containing normal intravalvular liquid.

2. faecal coliform content is less than 300 or E.coli is less than 230 per 100 grams of oyster meat based on 5 tubes, 3 dilutions of a MPN test.

3. not containing salmonella in 25 grams of oyster meat.

4. the total PSP content in oyster meat must not exceed 80ug/100g of oyster meat using a bioassay test method.

5. bioassay test method for diarrertic shellfish poison (PSP) must give a negative result.

6. the amnesic content of shellfish poison (ASP) in oyster meat must not exceed 20 ug per gram of domoic acid using a HPLC method.

7. mercury (Hg) content must not exceed 0.5 mg/kg of net weight.

8. lead (Pb) content must be a maximum of 1.5 mg/kg of net weight.

9. cadmium (Cd) content must be a maximum of 1.0 mg/kg of net weight.

SECTION VI
THE MARKING OF DELIVERY PARTY

1. All parties of live shellfish delivery must be equipped with a health label so that the origin of collecting place can be identified during the distribution and transportation of shellfish up to the retailer. The label must contain the following information:
   * the delivering country;
   * the type of shellfish (general name and scientific name);
   * the identification of collecting place (licence number) issued by the authorized agency;
   * the date of packing, containing at least date and month.

2. The label can put on the material of pack or inside the pack. Label using adhesive must not be used, except it cannot be removed. All types of labels can only be used for one time only and must not be transferred to other place.

3. The .....

3. The label must be imperishable and watertight and the information contained in it must be clear, cannot be written off and can easily be understood.

4. The label attached to a party of live shellfish delivery which is not wrapped up in a container for individual consumption must be kept by the retailer in no more than 60 days after it is separated from the party.

SECTION VII
THE MAINTENANCE OF RECORDS

All monitoring activities in the shellfish sanitation system must be recorded and documented in such a way to anticipate the need for recheck and reevaluation in the future, if needed. In documenting the activities, priority must be given to:

a. catching activities covering the date and location of catching, and quantity of shellfish caught,
b. name of shellfish species and name of captor,
c. the result of a microbiological test on the quality of water,
d. the result of a microbiological, chemical and biological toxin test on shellfish,
e. Daily observation of water temperature, salinity, precipitation, oxygen content, turbidity and water's pH.

SECTION VIII
REPORTING PROCEDURE

The regional team must send an official report to the Directorate General once every three months on the monitoring of the implementation of the shellfish sanitation system and the report must reach the Directorate General in no more than the first week of the ensuing quarter.

The result of a test must cover at least the result of analysis of water, phytoplankton and end product.

SECTION IX
ANALYSIS METHOD

The laboratory tests conducted in the shellfish sanitation system consist of microbiological analysis for coliform, E.coli, and salmonella, chemical analysis for mercury, DSP, ASP, and PSP analysis. The analysis methods used are as follows:

A. Phytoplankton Test

1. Sampling Method
   Sampling is made in two ways :
   a. Using a plankton net with a diameter of 31 cm, length 120 cm, and net eye 80 um. The net is pulled horizontally at the sea surface at an average speed of 1 m per minute. The volume of filtered water is measured by a flow meter installed at the net mouth. In the shallow waters samples are taken using a small-sized plankton net with a diameter of 25 cm, length 60 cm, and net eye 20 um. The plankton net is operated vertically at low speed.
   b. Using "Van Dom Sampler" with a capacity of 5 liters which can be sunk beneath the surface to detect phytoplankton at different depths.

2. Preparations for counting cells (sedimentation, filtration)
   a. Preservation method
      Phytoplankton samples are preserved using 4% formalin which was first neutralized with borax for at least 6 hours. If the storage is less than 6 hours, sea water must be added to the sample bottle and kept in the cold box.
   b. Cell counting
      The already preserved phytoplankton is cut into sample fractions using "Sledg wick-Raffer" with 50 mm long, 20 mm wide and 1 mm high (volume 1 ml). Special pipette "stempie pipette" is used to take sample fractions. The samples are refined and identified using a microscope with a 10x40 enlargement.
      Fresh (not preserved) phytoplankton is refined using a settling chamber. To facilitate the refining process, lugol liquid is added to the settling chamber. The settling chamber is later kept conversely below a microscope for refining and identifying.

B. Microbiological Analysis
   * Coliform and E,coil analysis refers to standard analysis method SNI-01-2332-1991.
   * Salmonella analysis refers to standard analysis method SNI-01-2335-1991.

C. Chemical Analysis
   * Mercury content analysis refers to standard analysis method SNI-01-2364-1991.

* Lead . . . . .

* Lead content analysis refers to standard analysis method SNI 01-2368-1991.
* Cadmium analysis refers to standard analysis method SNI 01-2362-1991.

D. PSP and DSP analysis

PSP and DSP analysis is conducted using a biological test which refers to the AOAC method with little modification in the extraction process.

E. ASP analysis

ASP analysis is conducted using HPLC which refers to the AOAC method.

Table 2. The Sanitation Quality of Shellfish Waters

No.	Parameters	Guidelines	Minimum Requirements	Test method/instrument	Minimum frequency of sampling and measurement
1	pH pH unit		7 - 9	Electrometric/pH meter is measured in the place at time of taking samples	Quarter
2	Temperature ^{o} C	Waste influencing waters must not raise water temperature to more than 2 °C and unaffected water temperature		Thermometric/barometer is measured in the place at time of taking samples	Quarter
3	Coloring (after filtration) mg Pt/l		The waste that influences the shellfish waters must not cause the color of water after filtration to deviate more than 10 mg Pt/I from the color of the growing area's waters.	Filtration through filter paper ϕ : 0.45 μm Photometric method, using a platinum/cobalt scale	Quarter
4	Soluble solid matter mg/l		The waste that influences waters must not cause the content of soluble solid matters in the water to exceed 30% of the content in the unaffected water.	Filtration through filter paper ϕ : 0.45 μm, dehydration at the temperature of 105 °C and weighing (at least 5 minutes at an average speed of 2800 to 3200 g, dehydration at the temperature of 105 °C and weighing.	Quarter
5	Salinity $^{0}/_{00}$	12 to 38 $^{0}/_{00}$	- 40 $^{0}/_{00}$ - The waste that influences waters must not cause water salinity to exceed 10% of the salinity of unaffected water.	Conductimetry/salinometer	Every month

6. Saturated . . . .

No.	Parameters	Guidelines	Minimum Requirements	Test method/instrument	Minimum frequency of sampling and measurement
6	Saturated soluble oxygen %	more than 80 %	< 70 % (average value) = individual measurement which indicates the value which is lower than 70 % must be repeated. = individual measurement may not give an indication of the value which is less than 60%, provided there is no risk of danger to the survival of shellfish.	= Winkler method = electrochemical method	Every month, with a minimum of one sample representing the others with low oxygen on the day of taking samples. If large daily variation is found, a minimum of 2 (two) samples must be taken per day
7	Petroleum hydrocarbons		Hydrocarbons must not exist in waters in certain quantities so that they will: = form layers visible to the water surface and/or groups in shellfish. = have a dangerous effect on shellfish	Visual test	6 months
8	Materials undergoing organohalogency	The concentration of each substance in oyster meat must be limited so that it contributes to the high quality of shellfish	The concentration of each materials in waters or oyster meat must not reach or exceed a level that has an adverse impact on shellfish and its larvae.	Chromatography gas after extraction with suitable soluble and purification	6 months
9	Heavy metal Silver Ag Arsen As Cadmium Cd Chromium Cr Copper Cu Mercury Hg Nickel Ni Lead Pb Zinc Zn in mg/l	The concentration of each substance in oyster meat must be limited so that it contributes to the high quality of shellfish	The concentration of each materials in waters or oyster meat must not reach or exceed a level that endangers shellfish and its larvae. The synergic effect of heavy metal must be considered	Atomic absorption spectrophotometry (ASS)	6 months

10. Faecal

No.	Parameters	Guidelines	Minimum Requirements	Test method/instrument	Minimum frequency of sampling and measurement
10	Faecal coliforms/ 100 ml	less than or equal to 300 in oyster meat and intervalvular liquid		The dilution method with deep substrate liquid fermentation, at least 3 dilution tubes. Planting from the positive tube in the confirmation media. Calculate according to the most possible figure = APM. Incubation temperature 44 °C + 0.5 °C	Quarter
11	Matters influencing the taste of oyster meat		The concentration is lower than the concentration that may influence oyster meat.	A test on shellfish is conducted by tasting it if it is believed to have been found in one of the materials.	

THE MINISTER OF MARINE AND FISHERY AFFAIRS,

sgd.

ROKHMIN DAHURI

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