FISH MEDICATION

(The Regulation of Minister of Marine Affairs and Fishery of R.I Number PER.04/MEN/2012, 31 January 2012)

BY THE GRACE OF ONE AND ALMIGHTY GOD

THE MINISTER OF MARINE AND FISHERY

THE REPUBLIC OF INDONESIA,

Considering:

a. that in order to protect fish, environment, and human health resources, it is necessary to review the Decree of Minister of Maritime Affairs and Fisheries Number KEP.26/MEN/2002 concerning Provision, Circulation, Usage, and Supervision of Fish Medicine;
b. that therefore it is necessary to stipulate Minister Regulation concerning Fish Medicine;

In view of:

1. Law Number 16 Year 1992 (BN No. 5292 page 4B-13B) concerning Quarantine of Animals, Fish, and Plants (State Gazette Year 1992 Number 56, Supplementary State Gazette Number 3482);
2. Law Number 31 Year 2004 (BN No 7144 page 7B-12B) concerning Fisheries (State Gazette of Republic of Indonesia Year 2004 Number 118, Supplementary State Gazette of Republic of Indonesia Number 4433), as has been amended with the Law Number 45 Year 2009 (State Gazette of Republic of Indonesia Year 2009 Number 154, Supplementary State Gazette of Republic of Indonesia Number 5073);
3. Law Number 32 Year 2004 (BN No. 7152 page 9B-18B) concerning Local Governance (State Gazette of Republic of Indonesia Year 2004 Number 128, Supplementary State Gazette of Republic of Indonesia Number 4437), as has been amended for the last time with the Law Number 12 Year 2008 (State Gazette of Republic of Indonesia Year 2008 Number 59, Supplementary State Gazette of Republic of Indonesia Number 4844);
4. Law Number 18 Year 2009 concerning Animal Husbandry and Health (State Gazette of Republic of Indonesia Year 2009 Number 84, Supplementary State Gazette of Republic of Indonesia Number 5015);
5. Government Regulation Number 78 Year 1992 concerning Animal Medicine (State Gazette of Republic of Indonesia Year 1992 Number 129, Supplementary State Gazette of Republic of Indonesia Number 3509);
6. Government Regulation Number 15 Year 2002 concerning Fish Quarantine (State Gazette of Republic of Indonesia Year 2002 Number 36, Supplementary State Gazette of Republic of Indonesia Number 4197);

7. Government Regulation Number 38 Year 2007 (BN No. 6776 page 3B-12B) concerning Division of Governmental Affairs Among Government, Province Government and District/City Government (State Gazette of Republic of Indonesia Year 2007 Number 82, Supplementary State Gazette of Republic of Indonesia Number 4737);
8. President Regulation Number 47 Year 2009 concerning Formation and Organization of State Ministry, as has been amended with President Regulation Number 76 Year 2011;
9. President Regulation Number 24 Year 2010 concerning Positions, Duties, and Functions of State Ministry As Well As The Order Of Organization, Duties, And Functions Of Echelon I State Ministry, as has been amended with President Regulation Number 92 Year 2011;
10. Presidential Decree Number 84/P Year 2009, as has been amended with Presidential Decree Number 56/P Year 2010;
11. Regulation of Minister of Marine Affairs and Fishery Number PER.20/MEN/2007 concerning Quarantine Action For Quarantined Fish Pest And Disease Import Media From Abroad And From An Area Into Another Area Within The Territory Of Republic Of Indonesia;
12. Regulation of Minister of Marine Affairs and Fishery Number PER.15/MEN/2010 concerning the Organization and Management of the Ministry of Marine Affairs and Fishery;

D E C I D E D :

To stipulate:

REGULATION OF MINISTER OF MARINE AFFAIRS AND FISHERY CONCERNING FISH MEDICINE.

CHAPTER I

GENERAL PROVISIONS

Article 1

In this Minister Regulation there are definitions as follows:

1. Provision is activity of fish medicine provision or fish medicine raw material done through manufacturing in domestic and/or supply from abroad.
2. Circulation is activity in the framework of distribution ad delivery of fish medicine whether in the framework of trade as well as non-trade.
3. Fish medicine raw material is all chemical materials or substance in the form of active material, additional material, and/or auxiliary material in the form of single component, batch/partially finished product used to make fish medicine.
4. Fish Medicine is preparation that can be used to treat fish, to free from symptoms, or to modify chemical process in the body that includes biological, pharmaceutical, premix, probiotics, and natural medicine.
5. Fish is all types of organism that the whole or part of their life cycle takes place in aquatic environment.
6. Etiquette is direct writing or writing amounted

on container or wrap that contains fish medicine marking.

7. Brochure is sheet made of paper or other material that contains complete marking of fish medicine enclosed in the outer container or wrap.
8. Package is numeral that shows volume or weight or certain amount of a fish medicine preparation in a container whether it is wrapped in or not.
9. Person is an individual person or corporation.
10. Corporation is a well organized group of people and/or wealth in the form of legal entity or non-legal entity.
11. Fish medicine producer is the person who makes fish medicine for commercial purpose.
12. Fish medicine importer is the person who performs fish medicine import from abroad.
13. Fish medicine importer is the person who performs fish medicine import from abroad.
14. Fish medicine distributor is the person who performs fish medicine circulation business from producer or importer to depot and/or to fish medicine shop.
15. Producer Importer Identification Number herein after abbreviated as API-P is producer importer identification number issued by Director General of Foreign Trade of Ministry of Trade to importer who performs goods import for personal use and/or to support production process and is not allowed to be traded or transferred to other party.
16. Fish medicine business license is written license that must be obtained by a person who wants to run fish medicine business.
17. Fish quarantine officer is certain civil servant who is given duty to perform quarantine action based on the laws.
18. Fish Health Expert is someone who gets knowledge concerning fish health through formal education.
19. Minister is the Minister of Maritime Affairs and Fisheries.
20. Director General is Director General of Fish Cultivation.
21. Provincial or Regency/Municipal Office is the office with authorities and liabilities in fisheries field.

Article 2

The scope of this Minister Regulation includes:

a. fish medicine raw material;
b. fish medicine business;
c. purpose of use, preparation, and classification of fish medicine;
b. fish medicine provision;
e. fish medicine registration;
procedures for import of raw material of fish medicine, fish medicine sample, and fish medicine;
g. import and export ports;
h. circulation;
i. re-import; and
j. guidance, monitoring, and supervision.

CHAPTER II

FISH MEDICINE RAW MATERIAL

Article 3

(1) Provision of fish medicine raw material through import from foreign country can only be done by importer with API-P or government/private institution.

(2) Provision of fish medicine raw material by government/private institution as meant at paragraph (1) is done only for research interest.

(3) Fish medicine raw material that comes from foreign country can be entered into the territory of the State of Republic of Indonesia after obtaining Statement Letter of Fish Medicine Raw Material Import.

(4) In order to obtain Statement Letter of Fish Medicine Raw Material Import as meant at paragraph (3), government/private institution or importer must apply written application to Director General that at least contains:
   a. name of fish medicine raw material;
   b. name and the applicant;
   c. name of fish medicine raw material producer;
   d. country of origin of fish medicine raw material;
   e. form of fish medicine raw material;
   f. preparation type of fish medicine raw material;
   g. package size;
   h. purpose of fish medicine raw material import;
   i. amount of fish medicine raw material;
   j. loading port; and
   k. entry port.

(5) Application as meant at paragraph (4), is carried out by attaching the following documents:
   a. Certificate of Analysis (CoA);
   b. Certificate of Origin (CoO) validated by Representative of Republic of Indonesia in the country of origin of fish medicine raw material; and
   c. Certificate of Free Sale.

(6) Director General or official appointed to perform document evaluation within 3 (three) working days since the date of acceptance of the complete documents.

(7) Based on document evaluation as meant at paragraph (6), Director General or appointed official issue:
   a. Statement Letter of Fish Medicine Raw Material Import; or
   b. Rejection Letter of Fish Medicine Raw Material Import, along with reason to reject.

(8) Statement Letter of Fish Medicine Raw Material Import as meant at paragraph (7) point a at least contains:
   a. name of fish medicine raw material;
   b. name and address of importer of government/private institution;
   c. name of fish medicine raw material producer;
   d. country of origin of fish medicine raw material;
   e. form of fish medicine raw material;
   f. preparation type of fish medicine raw material;

g. package size;
h. purpose of fish medicine raw material import;
i. amount of fish medicine raw material;
j. loading port;
k. entry port; and
l. effective term of Statement Letter of Fish Medicine Raw Material Import.

(9) Statement Letter of Fish Medicine Raw Material Import as meant at paragraph (7) point a can only be used for 1 (one) time import and valid for 3 (three) months since the issuance date.

(10) Form and format of Statement Letter of Fish Medicine Raw Material Import are as stated on Attachment I as inseparable part of this Minister Regulation.

Article 4

(1) Exporter who will export fish medicines raw material from the territory of State of Republic of Indonesia must have Statement Letter of Fish Medicine Raw Material Export

(2) In order to obtain Statement Letter of Fish Medicine Raw Material Export as meant at paragraph (1), exporter must apply written application to Director General that at least contains:
a. name of fish medicine raw material;
b. name and address of the applicant;
c. name of fish medicine raw material producer;
d. country of destination;
e. form of fish medicine raw material;
f. preparation type of fish medicine raw material;
g. package size;
h. purpose of fish medicine raw material export;
i. amount of fish medicine raw material; and
k. exit port.

(3) Director General or official appointed to perform evaluation within 3 (three) working days since the acceptance date of complete application.

(4) Based on evaluation result as meant at paragraph (3), Director General or appointed official issues:
a. Statement Letter of Fish Medicine Raw Material Export; or
b. Rejection Letter of Fish Medicine Raw Material Export, along with reason to reject.

(5) Statement Letter of Fish Medicine Raw Material Export as meant at paragraph (4) point a, at least contains:
a. name of fish medicine raw material;
b. name and address of the exporter;
c. name of fish medicine raw material producer;
d. country of destination;
e. form of fish medicine raw material;
f. preparation type of fish medicine raw material;
g. package size;
h. purpose of fish medicine raw material export;
i. amount of fish medicine raw material;
j. exit port; and
k. effective term of Statement Letter of Fish Medicine Raw Material Export.

(6) Statement Letter of Fish Medicine Raw Material Export as meant at paragraph (4) point a can only be used for 1 (one) time export and valid for 3 (three) months since the issuance date.

(7) Form and format of Statement Letter of Fish Medicine Raw Material Export are as stated on Attachment II as inseparable part of this Minister Regulation.

CHAPTER III

FISH MEDICINE BUSINESS

Article 5

(1) Fish medicine business consists of:
   a. fish medicine provision business; and
   b. fish medicine distribution business.

(2) Fish medicine provision business as meant at paragraph (1) point a includes the activity of fish medicine making from preparation of raw material until it becomes fish medicine and/or fish medicine entry from foreign country.

(3) Fish medicine distribution business as meant at paragraph (1) point b includes the activity that related to trade, transportation, and delivery of fish medicine.

Article 6

(1) Every individual who performs fish medicine business, is grouped as:
   a. fish medicine producer;
   b. fish medicine importer;
   e. fish medicine exporter;
   b. fish medicine distributor;
   e. fish medicine depot; and
   f. fish medicine shop.

(2) Provision of fish medicine can be done by government/private institution for research interest.

Article 7

(1) Fish medicine provision business as meant in Article 5 paragraph (1) point a is performed by producer or importer.

(2) Fish medicine distribution business as meant in Article 5 paragraph (1) point b is performed by exporter, distributor, depot, or fish medicine shop.

(3) Every individual who performs fish medicine business as meant in the Article 5 paragraph (1) is obliged to have Fish Medicine Business License.

(4) Extending laws concerning authority, requirements, and procedures of Fish Medicine Business License are regulated with Minister Regulation.

CHAPTER IV

PURPOSE OF USE, PREPARATION, AND CLASSIFICATION OF FISH MEDICINE

Article 8

Purpose of use of fish medicine at least includes:

a. to prevent, to reduce, and to remove fish disease symptoms;
b. to diagnose and to cure fish disease;
c. to help calming and numbing fish;

d. to increase fish reproduction;
e. to overcome deficiency of vitamin and mineral;
f. to beautify color and body of fish;
g. to maintain and/or to increase water quality for aquaculture; and/or
h. to maintain and/or to improve fishery product quality.

Article 9

Fish medicines according to type or preparation are grouped into:

a. biologic;
b. pharmaceutics;
c. premix;
d. probiotics; and
e. natural medicine.

Article 10

(1) Fish medicine of biologic preparation type as meant in Article 9 point a is resulted through biological process in animal or animal tissue to create immunity, to diagnose disease, or to cure disease with immunologic process, namely vaccine, sera (antisera), antigen, and biologic diagnostic material.

(2) Fish medicine of pharmaceutics preparation type as meant in Article 9 point b is resulted from inorganic as well as organic material, and/or chemical synthesis reaction used based on pharmacological work power, namely hormones, antibiotics, antibacterial, chemotherapeutic, anti parasite, anti fungus, anthelmintics, and anesthetics.

(3) Fish medicine of premix preparation type as meant in Article 9 point c is fish medicines used as feed additive and feed supplement given by mixing it with fish feed, consists of feed additive and feed supplement.

(4) Feed additive as meant at paragraph (3) is additional material for feed that naturally does not contain nutrient and the purpose of using is to beautify fish color, to aromatize feed, and to preserve feed.

(5) Feed supplement as meant at paragraph (3) is a substance that naturally exists in the feed, but the amount needs to be increased by adding namely amino acid, vitamin, and mineral into the feed.

(6) Fish medicine of probiotics preparation as meant in Article 9 point d, is resulted from non-pathogenic microbes that naturally exist in water environment and in fish body that work with process of bioremediation, biocontrol of digestive tract and as competitor for pathogenic bacteria, namely Bacillus Subtillis, Lactobacillus, Nitrosomonas, and Nitrobacteria.

(7) Fish medicine of natural medicine preparation as meant in Article 9 point e, is ingredient or concoction of ingredients in the form of original material of plant, animal, mineral, galenic preparation, or mixture of those ingredients without addition of chemical substance with medication power and the benefits are only based on empirical data and there is no complete clinical data, namely meniran leaf extract and sambiloto leaf extract.

Article 11

(1) Fish medicine based on classification of danger that may occur in the use, classified into:
   a. Prescription drugs, is fish medicine that if the use is not in accordance to the rules can cause risk for fish environment, and/or human who consumes the fish;
   b. Limited free drugs, is prescription drugs for fish that treated as free drugs for certain kind of fish provided that it is prepared with certain amount, dose rule, form of preparation, and marked with special warning; and
   c. Over the counter drugs, is fish medicine that can be obtained and used without prescription from veterinarian and/or recommendation from fish health expert.

(2) Extending laws on the fish medicine classification as meant at paragraph (1) are stipulated with Minister Regulation.

CHAPTER V

FISH MEDICINE PROVISION

Article 12

(1) Fish medicine provision is done through domestic manufacturing and entry from aboard.

(2) Fish medicine provision is done by giving priority to domestic manufacturing.

(3) Fish medicine provision through domestic manufacturing is done in accordance to Good Manufacturing Practice (CPOIB).

(4) Extending laws concerning CPOIB as meant at paragraph (3) are regulated with Minster Regulation.

Article 13

(1) Fish medicine prevision with biologic, probiotics, and natural medicine preparation must fulfill the following rules:
   a. fish medicine of biologic preparation type can be done for fish disease types exist in Indonesia;
   b. fish medicine of probiotics in one preparation at maximum contains 5 species of microbes with density of each species at least 106 cfu/ml; and/or
   c. fish medicine of natural medicine preparation in one preparation at maximum contains 5 (five) types of simplicia.

(2) Fish medicine preparation of biologic preparation type for diagnose of disease of non-existent disease in Indonesia, can be done if it does not contain living microbe and/or part of it that carries pathogenic element.

CHAPTER VI

FISH MEDICINE REGISTRATION

First Part

General

Article 14

(1) Fish medicine provided by producer or importer must have Fish Medicine Registration Letter.

(2) Obligation to have Fish Medicine Registration Letter as meant at paragraph (1), is excluded for:

a. fish medicine provided by government/private institution; or
b. natural medicine with simple process, does not contain prescription medicine, and used for own interest.

Second Part

Mechanism

Article 15

(1) In order to obtain Fish Medicine Registration Letter as meant in Article 14 paragraph (1), producer or importer must apply written application to Director General along with:
   a. quality examination result report;
   b. field trial result report, for fish medicine that requires field examination; and
   c. fish medicine technical data.

(2) Application for Fish Medicine Registration Letter for fish medicine from entry from abroad, aside from enclosing requirements as meant at paragraph (1), must be completed with:
   a. copy of Certificate of Origin, and showing the original;
   b. copy of Certificate of Free Sale, and showing the original;
   c. copy of Certificate of Good Manufacturing Practice from authority institution from the country of origin, and showing the original;
   d. copy of Certificate of Non-Genetically Modified Organism, for fish medicine of biologic preparation that is not modified genetically, and showing the original;
   e. copy of Letter of Agency/Distributor Appointment from producer overseas to importer company in Indonesia, and showing the original; and
   f. copy of Statement Letter of Fish Medicine Sample Entry.

(3) Certificate of Good Manufacturing Practice as meant at paragraph (2) point c, is at least equal to CPOIB.

Article 16

(1) Quality examination and field trial as meant in Article 15 paragraph (1) point a and point b are performed on fish medicine sample.

(2) Fish medicine sample that comes from foreign country can be entered into the territory of the State of Republic of Indonesia after obtaining Statement Letter of Fish Medicine Sample Entry.

(3) In order to obtain Statement Letter of Fish Medicine Sample Entry as meant at paragraph (2), importer must apply written application to Director General that at least contains:
   a. trade mark/brand of fish medicine sample;
   b. name and address of the applicant;
   c. name of fish medicine sample producer;
   d. country of origin of fish medicine sample;
   e. composition of fish medicine sample;
   f. form of fish medicine sample;
   g. preparation type of fish medicine sample;
   h. package size;

i. purpose of entry;
j. amount of fish medicine sample;
k. loading port; and
l. entry port.

(4) Application as meant at paragraph (3), is carried out by attaching the following documents:
a. Certificate of Analysis (CoA);
b. Certificate of Origin (CoO) validated by Representative of Republic of Indonesia in the country of origin of fish medicine sample;
c. Certificate of Free Sale; and
d. Certificate of Non-Genetically Modified Organism, for fish medicine of biologic preparation that is not modified genetically.

(5) Director General or official appointed to perform document evaluation within 3 (three) working days since the date of acceptance of the complete documents.

(6) Based on document evaluation as meant at paragraph (5), Director General or appointed official issues:
a. Statement Letter of Fish Medicine Sample Entry; or
b. Rejection Letter of Fish Medicine Sample Entry, along with reason of rejection.

(7) Statement Letter of Fish Medicine Sample Entry as meant at paragraph (6) point a contains:
a. trade mark/brand of fish medicine sample;
b. name and address of the importer;
c. name of fish medicine sample producer;
d. country of origin of fish medicine sample;
e. composition of fish medicine sample;
f. form of fish medicine sample;
g. preparation type of fish medicine sample;
h. package size;
i. purpose of entry;
j. amount of fish medicine sample;
k. loading port;
l. entry port; and
m. effective term of Statement Letter of Fish Medicine Sample Entry.

(8) Statement Letter of Fish Medicine Sample Entry as meant at paragraph (6) point a can only be used for 1 (one) time entry and valid for 1 (one) month since the issuance date.

(9) Form and format of Statement Letter of Fish Medicine Sample Entry are as stated on Attachment III as inseparable part of this Minister Regulation.

Article 17

(1) Quality examination as meant in Article 15 paragraph (1) point a is done by accredited domestic laboratory in accordance to examination rules in Indonesia animal medicine pharmacopeia book, Indonesia pharmacopeia, other pharmacopeias, and/or other medicine analysis standard books.

(2) Field trial as meant in Article 15 paragraph (1) point b is done by competent institution that includes efficacy or benefit test and/or safety test in accordance with fish medicine indications by referring to field trial guidelines.

(3) Field trial as meant at paragraph (2) is performed on:

a. fish medicine that contains active substance that never exists or has no homolog in Indonesia; and/or

b. fish medicine that indications and use have not yet published and have not yet proven with official scientific reference.

(4) Competent institution as meant at paragraph (2), is decided by Director General after fulfilling technical requirements, namely:

a. facilities and infrastructure;

b. human resources; and

c. examination methods.

(5) Extending laws on field trial guidelines as meant at paragraph (2) and technical requirements as meant at paragraph (4) are stipulated with Decree of Director General.

Article 18

(1) Fish medicine technical data as meant in Article 15 paragraph (1) point c is stated on form consists of:

a. trade mark and composition of fish medicine;

b. preparation manufacturing process of fish medicine;

c. examination of fish medicine and raw material used;

d. stability examination;

e. pharmacology power;

f. publication of clinical experiment in the field;

g. information concerning container, wrapper, seal; and

h. information concerning marking, in the form of writing and/or picture put on container wrapper or label and brochure.

(2) Fish medicine technical data form for stability examination as meant at paragraph (1) point d, is not applicable for fish medicine:

a. type of mineral in the form of powder with expiry date less than 1 (one) year;

b. disinfectant; and/or

c. natural materials.

(3) Extending laws on procedures for fish medicine technical form fill out as meant at paragraph (1) are stipulated with Decree of Director General.

Article 19

(1) Director General performs evaluation on document completeness within 2 (two) working days since the acceptance date of application as meant in Article 15 paragraph (1).

(2) Based on the result of document completeness evaluation as meant at paragraph (1), Director General:

a. forwards the documents stated as complete to Fish Medicine Assessment Team to be done technical evaluation upon; or

b. issues rejection letter along with reason of rejection, if the documents are not complete.

(3) Fish Medicine Assessment Team, as meant at paragraph (2) point a perform technical evaluation within 7 (seven) working days.

(4) Technical evaluation as meant at paragraph (3), includes:

a. scientific verification and analysis upon technical data stated in application documents;

b. verification of quality examination result with technical data; and

c. verification of field trial result with technical data.

(5) Technical evaluation result as meant at paragraph (3) is in the form of recommendation and submitted to Director General.

(6) Director General within 3 (three) working days since the acceptance date of recommendation as meant in paragraph (5) must issue:

a. Fish Medicine Registration Letter, for fish medicine that meets requirements; or

b. Fish Medicine Registration Rejection Letter, along with reason of rejection upon fish medicine that does not meet the requirements.

(7) Fish Medicine Registration Letter as meant at paragraph (6) point a contains:

a. fish medicine registration number;

b. fish medicine producer/importer name;

b. fish medicine producer/importer name;

d. fish medicine production address;

e. fish medicine producer name aboard;

f. license grantor name;

g. fish medicine trade mark/brand;

h. fish medicine classification;

i. fish medicine form;

j. fish medicine preparation type;

k. fish medicine composition;

l. package size; and

m. Fish Medicine Registration Letter effective term.

(8) Form and format of Fish Medicine Registration Letter is as stated on Attachment IV as inseparable part of this Minister Regulation.

(9) Extending laws on membership order and duties of Fish Medicine Assessment Team as meant at paragraph (2) are stipulated with Decree of Director General.

Article 20

(1) Fish medicine with same trade mark and composition arrangement is given the same Fish Medicine Registration Letter, even though with different package size.

(2) Fish medicine with different trade mark and/or composition arrangement is given different Fish Medicine Registration Letter.

Article 21

(1) Upon rejected application as meant in Article 19 paragraph (2) point b or paragraph (6) point b, then applicant must retrieve the application documents within 15 (fifteen) working days.

(2) If within 15 (fifteen) working days application documents are not retrieved by applicant, then

application becomes property of Directorate General of Fish Cultivation, Ministry of Marine Affairs and Fishery.

Third Part

Effective Term, Extension, and Replacement

Article 22

Fish Medicine Registration Letter is effective for 5 (five) years since the issuance date.

Article 23

(1) Effective term of Fish Medicine Registration Letter as meant in Article 22 can be extended for the same period.

(2) Extension application for Fish Medicine Registration Letter as meant at paragraph (1) can be done at the latest 3 (three) months prior the expiry date of Fish Medicine Registration Letter.

(3) In order to obtain Fish Medicine Registration Letter extension as meant at paragraph (1), producer or importer must apply written application to Director General along with:

a. copy of Fish Medicine Registration Letter to be extended;

b. latest quality test result report;

c. technical data that includes:

1) trade mark and composition of fish medicine;

2) manufacturing process of fish medicine preparation;

3) examination of fish medicine preparation that includes description, examination method, qualitative and quantitative examination result, attached with analysis certificate;

4) information concerning container, wrapper, seal;

5) information concerning marking, in the form of writing and/or picture put on container wrapper or label and brochure; and

6) duty stamped statement letter from applicant that there is change on composition and indication as well as method of use of fish medicine.

(4) Extension mechanism of Fish Medicine Registration Letter in mutatis mutandis way referring to the provision of Article 19.

Article 24

(1) Fish Medicine Registration Letter can be altered if there is change of administration data that includes:

a. name of producer/importer;

b. address of producer/importer;

c. address of production place;

d. name of license grantor; and/or

e. trade mark/brand name of fish medicine;

(2) In order to obtain Fish Medicine Registration Letter change as meant at paragraph (1), producer or importer must submit application to Director General within 1 (one) month since the change of administration data exists along with:

a. copy of Fish Medicine Registration Letter to be changed; and

b. explanation of reason for administration data change.

(3) Director General within 3 (three) working days since the acceptance date of application for administration data change as meant in paragraph (1) performs document verification.

(4) Based on the result of document verification as meant at paragraph (3), Director General issues:

a. new copy of Fish Medicine Registration Letter; or

b. Rejection Letter, along with reason of rejection.

(5) If new Fish Medicine Registration Letter has been issued, then within the same time applicant must return Fish Medicine Registration Letter on which change has been done.

Article 25

(1) Fish Medicine Registration Letter can be replaced if original Fish Medicine Registration Letter is damaged or lost.

(2) In order to obtain replacement of Fish Medicine Registration Letter as meant at paragraph (1), producer or importer must submit application to Director General and attach original Fish Medicine Registration Letter in case of damaged Fish Medicine Registration Letter, or Statement Letter of Kadit Serse from police in case the Fish Medicine Registration Number is lost.

(3) Director General issues replacement of Fish Medicine Registration Letter within 3 (three) working days since the acceptance date of complete application as meant in paragraph (2).

Article 26

Producer or importer who has had Fish Medicine Registration Letter is obliged to maintain fish medicine quality consistency in accordance to information stated on Fish Medicine Registration Letter.

Article 27

(1) Fish medicine from foreign country can be entered into the territory of the State of Republic of Indonesia after obtaining Statement Letter of Fish Medicine Entry.

(2) In order to obtain Statement Letter of Fish Medicine Entry as meant at paragraph (1), importer or government/private institution must apply written application to Director General that at least contains:

a. fish medicine trade mark/brand;

b. name and address of the applicant;

c. name of fish medicine producer;

d. country of origin of fish medicine;

e. fish medicine classification;

f. fish medicine form;

g. fish medicine preparation type;

h. package size;

i. purpose of fish medicine entry;

j. amount of fish medicine;

k. loading port; and

l. entry port.

(3) Application submitted by importer as meant at paragraph (2), is attached with the following documents:

a. copy of Fish Medicine Registration Letter;

b. packing list that contains type, quantity, and volume/weight unit.

(4) Application submitted by government/private institution as meant at paragraph (2), is attached with the following documents:

a. copy of Certificate of Origin, and showing the original;

b. copy of Certificate of Free Sale, and showing the original;

c. copy of Certificate of Good Manufacturing Practice from authority institution from the country of origin, and showing the original;

d. copy of Certificate of Non-Genetically Modified Organism, for fish medicine of biologic preparation that is not modified genetically, and showing the original;

e. technical data as meant in Article 15 paragraph (1) point c, and

f. packing list that contains type, quantity, and volume/weight unit.

(5) Director General or official appointed to perform document evaluation within 3 (three) working days since the date of acceptance of the complete documents.

(6) Based on document evaluation as meant at paragraph (5), Director General or appointed official issues:

a. Statement Letter of Fish Medicine Entry; or

b. Rejection Letter of Fish Medicine Entry, along with reason of rejection.

(7) Statement Letter of Fish Medicine Entry as meant at paragraph (6) point a at least contains:

a. fish medicine trade mark/brand;

b. name of importer;

c. address of importer;

d. fish medicine registration number;

e. name of fish medicine producer;

f. country of origin of fish medicine;

g. fish medicine classification;

h. fish medicine form;

i. fish medicine preparation type;

j. package size;

k. purpose of fish medicine entry;

l. quantity of fish medicine;

m. loading port;

n. entry port; and

o. effective term of Statement Letter of Fish Medicine Entry.

(8) Statement Letter of Fish Medicine Entry as meant at paragraph (6) point a can only be used for 1 (one) time entry and valid for 3 (three) months since the issuance date.

(9) Form and format of Statement Letter of Fish Medicine Entry are as stated on Attachment V as inseparable part of this Minister Regulation.

CHAPTER VII

ENTRY PROCEDURES FOR FISH MEDICINE RAW MATERIAL, FISH MEDICINE SAMPLE, AND FISH MEDICINE;

Article 28

(1) importer of government/private institution that will enter fish medicine raw material, fish medicine sample, and/or fish medicine into the territory of State of Republic of Indonesia is obliged to report within 1 (one) day prior to arrival and to submit Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry to Quarantine Office on arrival time at entry place.

(2) Quarantine Officer performs examination on Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry as meant at paragraph (1) to find out validity and correctness of Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry.

(3) Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry are stated valid if issued by Director General or appointed official.

(4) Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry are stated correct if conform the physical of goods entered into the territory of State of Republic of Indonesia.

(5) In the framework of examination of Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry as meant at paragraph (4), Quarantine Officer performs physical check in customs area.

(6) Examination of Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry as meant at paragraph (2) s done within 3 (three) working days.

(7) Based on examination of Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry as meant at paragraph (2) and physical examination as meant at paragraph (5). Quarantine Officer issues:

a. Approval Letter of Fish Medicine Raw Material/Fish Medicine Sample/Fish Medicine Exit from Entry Port, if Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry are valid and correct, with copy to Director General of Supervision of Marine Affairs and Fishery Resources; or

b. Rejection Letter of Fish Medicine Raw Material/Fish Medicine Sample/Fish Medicine Exit from Entry Port, if Statement Letter of Fish Medicine Raw Material Entry, Statement Letter of Fish Medicine Sample Entry, and/or Statement Letter of Fish Medicine Entry are not valid and correct.

Article 29

(1) If fish medicine raw material, fish medicine sample, and/or fish medicine are imposed with rejection as meant in Article 28 paragraph (7) point b, then importer or government/private institution are obliged to resend the fish medicine raw material, fish medicine sample, and/or fish medicine to country of origin within 3 (three) days since the rejection takes place.

(2) If within 3 (three) days resending is not done to country of origin, then upon fish medicine raw material, fish medicine sample, and/or fish medicine as meant at paragraph (1) is performed elimination in accordance to provisions in effect.

Article 30

Procedures for fish medicine raw material, fish medicine sample, and/or fish medicine entry of biologic preparation is exceptional from the provision as meant in Article 28 and Article 29, and are regulated with Minister Regulation.

CHAPTER VIII

ENTRY AND EXIT PORT

Article 31

Every fish medicines raw material, fish medicine sample, or fish medicine to be imported into the territory of State of Republic of Indonesia or to be exported from the territory of State of Republic of Indonesia can only be done through entry port and exit port as follows:

a. seaport; Belawan in Medan, Tanjung Priok in Jakarta, Tanjung Emas in Semarang, Tanjung Perak in Surabaya, Soekarno Hatta in Makassar, and Panjang in Lampung;
b. all international airport; and/or
c. Entikong border cross checking post.

CHAPTER IX

FISH MEDICINE DISTRIBUTION

Article 32

(1) Fish medicine distributed in the territory of State of Republic of Indonesia must be packed in airtight container and/or special wrap and mounted with information regarding fish medicine in Indonesian that visible and readable and not easily erased.

(2) Information concerning fish medicine as meant at paragraph (1) at least consists:
   a. fish medicine registration number;
   b. fish medicine producer/importer name and address;
   c. fish medicine trade mark/brand;

d. fish medicine classification;
e. fish medicine form;
f. fish medicine preparation type;
g. fish medicine composition;
h. net weight;
i. allocation/indication and target fish;
j. method of use and storage;
k. production code;
l. expiry date; and
m. withdrawal time, especially for prescription drugs classification.

Article 33

(1) Exporter who will circulate fish medicines to outside the territory of State of Republic of Indonesia must have Statement Letter of Fish Medicine Raw Exit.

(2) In order to obtain Statement Letter of Fish Medicine Exit as meant at paragraph (1), exporter must apply written application to Director General that at least contains:
a. fish medicine trade mark/brand;
b. name and address of the applicant;
c. name of fish medicine producer;
d. country of destination;
e. fish medicine classification;
f. fish medicine form;
g. fish medicine preparation type;
h. package size;
i. purpose of fish medicine exit;
j. fish medicine quantity; and
k. exit port.

(3) Application submitted by exporter as meant at paragraph (2), is attached with the following documents:
a. copy of Fish Medicine Registration Letter; and
b. packing list that contains type, quantity, and volume/weight unit.

(4) Director General or official appointed to perform document evaluation within 3 (three) working days since the acceptance date of complete application.

(5) Based on document evaluation as meant at paragraph (4), Director General or appointed official issues:
a. Statement Letter of Fish Medicine Exit; or
b. Rejection Letter of Fish Medicine Exit, along with reason of rejection.

(6) Statement Letter of Fish Medicine Exit as meant at paragraph (5) point a at least contains:
a. fish medicine trade mark/brand;
b. name and address of the exporter;
c. fish medicine registration number;
d. name of fish medicine producer;
e. country of destination;
f. fish medicine classification;
g. fish medicine form;
h. fish medicine preparation type;
i. package size;
i. purpose of fish medicine exit;
k. quantity of fish medicine;
l. exit port; and

m. Statement Letter of Fish Medicine Exit effective term.

(7) Statement Letter of Fish Medicine Exit as meant at paragraph (5) point a can only be used for 1 (one) time exit and valid for 3 (three) months since the issuance date.

(8) Form and format of Statement Letter of Fish Medicine Exit are as stated on Attachment VI as inseparable part of this Minister Regulation.

Article 34

(1) Everybody is prohibited from circulating fish medicine that unfit for distribution.

(2) Fish medicine that unfit for distribution as meant at paragraph (1) includes fish medicine that:

a. does not have Fish Medicine Registration Letter;

b. experiences physical changes that includes texture, color, and/or smell;

c. already expired; and/or

d. package, container, wrapper and/or seal is damaged.

Article 35

Everybody who does fish medicine business must perform recording upon every distributed fish medicine.

CHAPTER X

RE-ENTRY

Article 36

(1) Every Individual who will do reentry of fish medicine raw medicine or fish medicine originated from Indonesia because rejected by country of importer/country of destination is obliged to report within 1 (one) day prior to arrival to Quarantine Officer and submits the following documents:

a. Statement Letter of Fish Medicine Raw Material Exit or Statement Letter of Fish Medicine Exit; and

b. Goods Export Notification.

(2) Quarantine Officer performs document evaluation as meant at paragraph (1) within 2 (two) working days to find out validity and correctness of documents.

(3) Statement Letter of Fish Medicine Raw Material Exit or Statement Letter of Fish Medicine Exit, and Goods Export Notification are stated valid if issued by authorized institution.

(4) Statement Letter of Fish Medicine Raw Material Exit or Statement Letter of Fish Medicine Exit and Goods Export Notification are stated correct if there is conformity between Statement Letter of Fish Medicine Raw Material Exit or Statement Letter of Fish Medicine Exit and Goods Export Notification with physical of reentry goods into the territory of State of Republic of Indonesia.

(5) In the framework of correctness examination of Statement Letter of Fish Medicine Raw Material Exit or Statement Letter of Fish Medicine Exit, and Goods Export Notification, Quarantine Officer performs physical examination in customs area.

(6) Based on document evaluation result as meant at paragraph (2) and physical examination as meant at paragraph (5), Quarantine Officer issues:
   a. Approval Letter of Fish Medicine Raw Material Exit from Entry Port, if documents are complete, valid, and correct, with copy to Director General of Supervision of Marine Affairs and Fisheries Resources; or
   b. Rejection Letter of Fish Medicine Raw Material/Fish Medicine Exit from Entry Port, if documents are incomplete, invalid, and/or incorrect.

(7) If fish medicine raw material or fish medicine is imposed with rejection act because documents are stated incomplete as meant at paragraph (6) point b, then owner of fish medicine raw material or fish medicine is obliged to complete the lack of documents within 3 (three) working days since the acceptance of Rejection Letter.

(8) If within 3 (three) days since the acceptance of the Rejection Letter as meant at paragraph (6) point b owner of fish medicine raw material or fish medicine can complete the lack of document, then in mutatis mutandis way provisions as meant at paragraph (2), paragraph (3), paragraph (4), and paragraph (5) are in effect.

(9) If within 3 (three) days after the acceptance of Rejection Letter, owner of fish medicine raw material or fish medicine cannot complete the lack of document or fish medicine raw material or fish medicine are imposed with rejection act because documents are stated invalid and/or incorrect as meant at paragraph (6) point b, then fish medicine raw material or fish medicine are imposed with elimination.

(10) Elimination as meant at paragraph (9) is performed by Quarantine Officer.

Article 37

Reentry of fish medicine raw material or fish medicine must through entry port decided as meant in Article 31.

CHAPTER XI

GUIDANCE, MONITORING, AND SUPERVISION

Article 38

(1) Director General and Head of Office perform guidance and monitoring upon provision and distribution of fish medicine in accordance to their respective authority.

(2) Guidance and monitoring as meant at paragraph (1), at least includes:
   a. process of provision and distribution of fish medicine;
   b. facilities and infrastructure of fish medicine storage; and
   c. quality, benefit, and safety of fish medicine.

(3) In implementing guidance and monitoring as meant at paragraph (1), Director General or Head of Office decides Fish Medicine Guidance and Monitoring Team.

(4) Requirements to be member of Fish Medicine

Guidance and Monitoring Team as meant at paragraph (3) must have competency in fish medicine field.

Article 39

(1) in the framework of fish medicine guidance and monitoring as meant in Article 38 paragraph (1), fish medicine producer is obliged to make report every 6 (six) months to Director General concerning:
   a. quantity, type, and origin of raw material;
   b. quantity and type of fish medicine produced; and
   c. medicine quantity that has been distributed and area of distribution.

(2) in the framework of fish medicine guidance and monitoring as meant in Article 38 paragraph (1), fish medicine importer is obliged to make report every 6 (six) months to Director General concerning:
   a. quantity and type of fish medicine that has been reentered into the territory of State of Republic of Indonesia; and
   b. fish medicine quantity that has been distributed and area of distribution.

(3) in the framework of fish medicine guidance and monitoring as meant in Article 38 paragraph (1), exporter is obliged to make report every 6 (six) months to Director General concerning:
   a. quantity and type of fish medicine that has been exited from the territory of State of Republic of Indonesia; and
   b. country of destination.

(4) in the framework of fish medicine guidance and monitoring as meant in Article 38 paragraph (1), fish medicine distributor is obliged to make report every 6 (six) months to Head of Provincial Office concerning:
   a. quantity and type of fish medicine circulated; and
   b. fish medicine distribution business.

(5) in the framework of fish medicine guidance and monitoring as meant in Article 38 paragraph (1), depot and fish medicine shop are obliged to make report every 6 (six) months to Head of Regency/ Municipal Office concerning:
   a. quantity and type of fish medicine distributed;
   b. name of prescription giver veterinarian;
   c. fish medicine distribution area; and
   d. name of fish medicine user for fish medicine in prescription drugs and limited free drugs classification.

Article 40

(1) Head of Regency/Municipal Office submits report of fish medicine guidance and monitoring result to Head of Provincial Office on 10th of the next month.

(2) Head of Provincial Office submits report of fish medicine guidance and monitoring result to Director General at the latest on 20th that contains result of guidance and monitoring he performed

report recapitulation of district/city fish medicine guidance and monitoring.

(3) Guidance and monitoring result as meant at paragraph (2) is used by Director General as material to make policy.

Article 41

Supervision upon fish medicine distribution is performed by Fishery Supervisor.

CHAPTER XII

SANCTION

Article 42

(1) Fish medicine producer or importer who violates Article 26, Article 35, and/or Article 39 is imposed with administrative sanction.

(2) Administrative sanction as meant at paragraph (1) can be in the form of:

a. written warning;

b. freeze of Fish Medicine Registration Letter; or

c. revocation of Fish Medicine Registration Letter.

(3) Administrative sanction as meant at paragraph (2) is given by Director General.

Article 43

(1) Written warning as meant in Article 42 paragraph (2) point a is given to producer or to importer of fish medicine that violates provision as meant in Article 35 and/or Article 39.

(2) Written warning as meant at paragraph (1) is given to producer or importer of fish medicine that does not fulfill obligations 3 (three) times in a row within 15 (fifteen) days for every warning.

Article 44

(1) Administrative sanction in the term of freeze of Fish Medicine Registration Letter as meant in Article 42 paragraph (2) point b is given to:

a. producer or importer of fish medicine as meant in Article 44 paragraph (1) that until the end of time period of third warning does not perform the obligations;

b. producer or importer of fish medicine who violates the provision as meant in Article 26.

(2) Freeze of Fish Medicine Registration Letter as meant at paragraph (1), is carried out for 30 (thirty) days since the sanction imposed.

Article 45

administrative sanction in the form of revocation of Fish Medicine Registration Letter as meant in Article 42 paragraph (2) point c is given to producer or importer that until the expiry date of the freeze of Fish Medicine Registration Letter does not perform the obligations.

CHAPTER XIII

EXPIRY OF FISH MEDICINE REGISTRATION LETTER

Article 46

(1) Fish Medicine Registration Letter as meant in Article 19 at paragraph (6) point a is expired because:

a. revoked because producer or importer of fish medicine until the expiry of freeze of Fish Medicine Registration Letter does not perform the obligations;
b. revoked due to request of the owner of Fish Medicine Registration Letter;
c. revoked because scientifically proven or based on other references the fish medicine is harmful for the health of fish, human, and environment;
d. effective term of Fish Medicine Registration Letter is due and not extended.

(2) Revoked of Fish Medicine Registration Letter as meant at paragraph (1) point a, point b, and point c is performed by Director General.

CHAPTER XIV

OTHER PROVISIONS

Article 47

(1) In emergency condition and/or plague that has been decided by the Minister and there is no fish medicine with Fish Medicine Registration Letter to take care of the emergency condition and/or plague, then fish medicine that fulfills the requirements can be given Temporary Fish Medicine Registration Letter.

(2) In order to obtain Fish Medicine Registration Letter as meant at paragraph (1), producer or importer must submit written application to Director General completed with explanation concerning technical data as meant in Article 15 paragraph (1) point c and requirements as meant in Article 15 paragraph (2) for fish medicine from foreign country.

(3) Director General performs evaluation on document completeness within 1 (one) working days since the acceptance date of application as meant at paragraph (2).

(4) Based on the result of evaluation on document completeness as meant at paragraph (3), Director General forwards documents stated as complete to Fish Medicine Assessment Team to be done technical evaluation upon.

(5) Based on technical evaluation as meant at paragraph (4), within 2 (two) working days, Fish Medicine Assessment Team gives recommendation to Director General that contains approval or rejection.

(6) Director General within 2 (two) working days since the acceptance date of recommendation as meant in paragraph (5) must issue:

a. Temporary Fish Medicine Registration Letter, for fish medicine that fulfills requirements; or
b. Rejection Letter, along with reason of rejection upon fish medicine that does not fulfill the requirements.

Article 48

Fish Medicine Registration Letter as meant in Article 47 at paragraph (6) point a is effective for 1 (one) year.

CHAPTER XV

TRANSITIONAL PROVISIONS

Article 49

(1) In case regulation concerning CPOIB as meant in Article 12 paragraph (4) has not been stipulated, then the manufacturing of fish medicine is referring to Good Animal Medicine Manufacturing Practice (CPOHB).

(2) Fish Medicine Registration Letter that has been issued prior to the stipulation of this Minister Regulation is stated as still effective up to the expiry date.

(3) Application for Fish Medicine Registration Letter submitted and stated complete is processed based on the Decree of Minister of Maritime Affairs and Fisheries Number KEP.26/MEN/2002 concerning Provision, Distribution, Usage, and Supervision of Fish Medicine.

CHAPTER XVI

FINAL PROVISIONS

Article 50

With the stipulation of this Minister Regulation, then Minister of Maritime Affairs and Fisheries Number KEP.26/MEN/2002 concerning Provision, Distribution, Usage, and Supervision of Fish Medicine is revoked and declared null and void.

Article 51

This Minister Regulation starts to take effect since the promulgation date.

For everybody to acknowledge this regulation, ordering the promulgation of this Minister Regulation to be placed in the State Gazette of Republic of Indonesia.

Stipulated in Jakarta

on 31 January 2012

THE MINISTER OF MARINE AFFAIRS AND FISHERY

THE REPUBLIC OF INDONESIA,

Sgnd.

SHARIF C. SUTARDJO

Promulgated in Jakarta

on 1 February 2012

THE MINISTER OF LAW AND HUMAN RIGHTS

THE REPUBLIC OF INDONESIA,

Sgnd.

AMIR SYAMSUDIN

THE STATE GAZETTE OF REPUBLIC OF INDONESIA

YEAR 2012 NUMBER 139

ATTACHMENT I :

THE REGULATION OF MINISTER OF MARINE AFFAIRS AND FISHERY OF REPUBLIC OF INDONESIA NUMBER PER.04/MEN/2012 CONCERNING FISH MEDICINE

STATEMENT LETTER OF FISH MEDICINE RAW MATERIAL ENTRY

NUMBER: .....

In connection with application from..... Number: ..... date .....and based on result of evaluation performed, hereby the Director General of Fish Cultivation of Ministry of Marine Affairs and Fishery of Republic of Indonesia basically approves the entry of fish medicine raw material by:

Name of importer or government/private institution;

Address of importer or government/private institution;

With the following details:

a. name of fish medicine raw material :
b. name of fish medicine raw material producer :
c. country of origin of fish medicine raw material :
d. form of fish medicine raw material :
e. preparation type of fish medicine raw material :
f. package size :
g. purpose of fish medicine raw material entry :
h. quantity of fish medicine raw material :
i. loading port :
j. entry port. :

This Statement Letter of Fish Medicine Raw Material Entry is valid only for 1 (one) time fish medicine raw material entry.

This Statement Letter of Fish Medicine Raw Material Entry is valid for 3 (three) months as of the date of issuance and cannot be transferred to other party.

Jakarta,.....

Director General of Fish Cultivation

.....

Copy to:

1. Director General of Control of Marine Affairs and Fisheries Resources;
2. Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product;
3. UPT Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product.....;
4. Head of Supervision and Service Office of Customs and Excise.....

THE MINISTER OF MARINE AFFAIRS AND FISHERY

THE REPUBLIC OF INDONESIA,

Sgnd.

SHARIF C. SUTARDJO

ATTACHMENT II :

THE REGULATION OF MINISTER OF MARINE AFFAIRS AND FISHERY OF REPUBLIC OF INDONESIA NUMBER PER.04/MEN/2012 CONCERNING FISH MEDICINE

STATEMENT LETTER OF FISH MEDICINE RAW MATERIAL EXIT

NUMBER: .....

In connection with application from..... Number: ..... date .....and based on result of evaluation performed, hereby the Director General of Fish Cultivation of Ministry of Marine Affairs and Fishery of Republic of Indonesia basically approves the exit of fish medicine raw material by:

Name of exporter :

Address of exporter :

with the following details:

a. name of fish medicine raw material :
b. name of fish medicine raw material producer :
c. country of destination :
d. form of fish medicine raw material :
e. preparation type of fish medicine raw material :

f. package size :

g. purpose of fish medicine raw material exit :

h. quantity of fish medicine raw material :

i. exit port :

This Statement Letter of Fish Medicine Raw Material Exit is valid only for 1 (one) time fish medicine raw material exit.

Statement Letter of Fish Medicine Raw Material Exit is valid for 3 (three) months as of the date of issuance and cannot be transferred to other party.

Jakarta,.....

Director General of Fish Cultivation

.....

Copy to:

1. Director General of Control of Marine Affairs and Fisheries Resources;
2. Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product;
3. UPT Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product.....;
4. Head of Supervision and Service Office of Customs and Excise.....

THE MINISTER OF MARINE AFFAIRS AND FISHERY

THE REPUBLIC OF INDONESIA,

Sgnd.

SHARIF C. SUTARDJO

ATTACHMENT III :

THE REGULATION OF MINISTER OF MARINE AFFAIRS AND FISHERY OF REPUBLIC OF INDONESIA NUMBER PER.04/MEN/2012 CONCERNING FISH MEDICINE

STATEMENT LETTER OF FISH MEDICINE SAMPLE ENTRY

NUMBER: .....

In connection with application from..... Number: ..... date .....and based on result of evaluation performed, hereby the Director General of Fish Cultivation of Ministry of Marine Affairs and Fishery of Republic of Indonesia basically approves the entry of fish medicine sample by:

Name of importer :

Address of importer :

with the following details:

a. trade mark/brand of fish medicine sample :
b. name of fish medicine sample producer :
c. country of origin of fish medicine sample :
d. composition of fish medicine sample :
e. form of fish medicine sample :
f. preparation type of fish medicine sample :
g. package size :
h. purpose of entry :
i. quantity of fish medicine sample :
j. loading port :
k. entry port :

This Statement Letter of Fish Medicine Sample Entry is valid only for 1 (one) time fish medicine sample entry.

Statement Letter of Fish Medicine Sample Entry is valid for 3 (three) months as of the date of issuance and cannot be transferred to other party.

Jakarta,.....

Director General of Fish Cultivation

.....

Copy to:

1. Director General of Control of Marine Affairs and Fisheries Resources;
2. Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product;
3. UPT Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product.....;
4. Head of Supervision and Service Office of Customs and Excise.....

THE MINISTER OF MARINE AFFAIRS AND FISHERY

THE REPUBLIC OF INDONESIA,

Sgnd.

SHARIF C. SUTARDJO

ATTACHMENT IV :

THE REGULATION OF MINISTER OF MARINE AFFAIRS AND FISHERY OF REPUBLIC OF INDONESIA NUMBER PER.04/MEN/2012 CONCERNING FISH MEDICINE

DIRECTOR GENERAL OF FISH CULTIVATION

FISH MEDICINE REGISTRATIDN LETTER

NUMBER:.....

Based on technical evaluation result by Directorate General of Fish Cultivation, then fish medicine from:

a. name of fish medicine producer/importer :
b. complete address of fish medicine producer/importer :
c. location address of fish medicine production :
d. Name of fish medicine producer aboard :

e. name of license grantor :

f. trade mark/brand of fish medicine :

g. classification of fish medicine :

h. form of fish medicine :

i. preparation type of fish medicine :

j. composition of fish medicine :

k. package size :

stated

CAN

be provided, be distributed, and be used throughout the territory of Republic of Indonesia.

This Fish Medicine Registration Letter is valid for 5 (five) years as of the date of issuance and cannot be transferred to other party.

Jakarta,.....

Director General of Fish Cultivation

.....

THE MINISTER OF MARINE AFFAIRS AND FISHERY

THE REPUBLIC OF INDONESIA,

Sgnd.

SHARIF C. SUTARDJO

ATTACHMENT V :

to be continued

(A)

FISH MEDICATION

(The Regulation of Minister of Marine Affairs and Fishery of R.I Number PER.04/MEN/2012, dated 31 January 2012)

[Continued from Business News No. 8337 page 19-48]

ATTACHMENT V :

THE REGULATION OF MINISTER OF MARINE AFFAIRS AND FISHERY OF REPUBLIC OF INDONESIA NUMBER PER.04/MEN/2012 CONCERNING FISH MEDICINE

STATEMENT LETTER OF FISH MEDICINE ENTRY

NUMBER: .....

In connection with application from..... Number: ..... date .....and based on result of evaluation performed, hereby the Director General of Fish Cultivation of Ministry of Marine Affairs and Fishery of Republic of Indonesia basically approves the entry of fish medicine by:

Name of importer :

Address of importer :

with the following details:

a. trade mark/brand of fish medicine :
b. number of fish medicine registration :
c. name of fish medicine producer :
d. country of origin of fish medicine :
e. classification of fish medicine :
f. form of fish medicine :
g. preparation type of fish medicine :
h. package size; :
i. purpose of fish medicine entry :
j. quantity of fish medicine :

k. loading port :

l. entry port :

This Statement Letter of Fish Medicine Entry is valid only for 1 (one) time fish medicine sample entry.

This Statement Letter of Fish Medicine Entry is valid for 3 (three) months as of the date of issuance and cannot be transferred to other party.

Jakarta,.....

Director General of Fish Cultivation

.....

Copy to:

1. Director General of Control of Marine Affairs and Fisheries Resources;
2. Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product;
3. UPT Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product.....;
4. Head of Supervision and Service Office of Customs and Excise.....

THE MINISTER OF MARINE AFFAIRS AND FISHERY

THE REPUBLIC OF INDONESIA,

Sgnd.

SHARIF C. SUTARDJO

ATTACHMENT VI :

THE REGULATION OF MINISTER OF MARINE AFFAIRS AND FISHERY OF REPUBLIC OF INDONESIA NUMBER PER.04/MEN/2012 CONCERNING FISH MEDICINE

STATEMENT LETTER OF FISH MEDICINE EXIT

NUMBER: .....

In connection with application from..... Number: ..... date .....and based on result of evaluation performed, hereby the Oirector General of Fish Cultivation of Ministry of Marine Affairs and Fishery of Republic of Indonesia basically approves the exit of fish medicine by:

Name of exporter :

Address of exporter :

with the following details:

a. trade mark/brand of fish medicine :
b. number of fish medicine registration :
c. name of fish medicine producer :
d. country of destination :
e. classification of fish medicine :
f. form of fish medicine :
g. preparation type of fish medicine :
h. package size; :
i. purpose of fish medicine exit :
j. quantity of fish medicine :
k. exit port :

This Statement Letter of Fish Medicine Exit is valid only for 1 (one) time fish medicine exit.

This Statement Letter of Fish Medicine Exit is valid for 3 (three) months as of the date of issuance and cannot be transferred to other party.

Jakarta,.....

Director General of Fish Cultivation

.....

Copy to:

1. Director General of Control of Marine Affairs and Fisheries Resources;
2. Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product;
3. UPT Head of Agricultural Quarantine Agency, Quality Control, and Safety of Fishery Product.....;
4. Head of Supervision and Service Office of Customs and Excise.....

THE MINISTER OF MARINE AFFAIRS AND FISHERY

THE REPUBLIC OF INDONESIA,

Sgnd.

SHARIF C. SUTARDJO

(A)