REPORT ON

Preparation of inventory of existing rules and regulations on aqua-inputs in Bangladesh and selected neighboring countries for purposes of identifying areas where new rules would be necessary and consider needed improvement in existing ones where called for in the light of outcome of multi-stakeholders consultation.

under the project

'Work on policy consolidation, improvement in licensing, management process and effective use of aqua inputs'

implemented by

Bangladesh Shrimp and Fish Foundation (BSFF)

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Feed the Future Bangladesh Aquaculture and Nutrition Activity (FtF BANA)

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Acronym

AMP	Aquaculture Medicinal Product
AH	Animal Husbandry
AHCAB	Animal Health Companies Association of Bangladesh
ASEAN	Association of South East Asian Nations
BAPCA	Bangladesh Aqua Product Companies Association
BFSA	Bangladesh Food Safety Authority
BSE	Bovine Spongiform Encephalopathy
BSFF	Bangladesh Shrimp and Fish Foundation
BSTI	Bangladesh Standards and Testing Institution
C/A	Competent Authority
CFR	Code of Federal Regulations (USA)
DAE	Department of Agriculture Extension
DCC	Drug Control Committee
DDGS	Distiller's Dried Grain with Soluble
DDT	Di-chloro Di-phenyle Tri-chloro Ethane
DFO	District Fisheries Officer
DG	Director General
DGDA	Directorate General of Drug Administration
DLS	Department of Livestock Services
DoF	Department of Fisheries
EC	European Commission
EDTA	Ethylene Di-amine Tetra Acetic acid
EEC	European Economic Community
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FGD	Focus Group Discussions
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FIQC	Fish Inspection and Quality Control
FtF BANA	Feed the Future Bangladesh Aquaculture and Nutrition Activity
GMP	Good Management Practice
GMO	Genetically Modified Organisms
GoB	Government of Bangladesh
IRC	Import Registration Certificate
KII	Key Informants' Interview
LAO PDR	Laos Public Democratic Republic
MOC	Ministry of Commerce
MOF	Ministry of Food
MOI	Ministry of Industries
MOFL	Ministry of Fisheries and Livestock
MOHFW	Ministry of Health and Family Welfare
MRL	Maximum Residue Limit
NCL	National Control Laboratory (of DGDA)
NDA	No Data Available
NDAC	National Drug Advisory Council
NOC	No Objection Certificate
NRA	National Regulatory Authority (of Drugs)
NRCP	National Residue Control Plan
PA	Pharmaceutically Active substances
PCB	Poly Chlorinated Bi-phenyle
PI	Proforma Invoice
SRO	Statutory Rules and Orders
TIN	Tax-payers Identification Number
TL	Trade License
USA	United States of America
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USFDA	United States Food and Drug Administration
VAS	Veterinary Assistant Surgeon
VMP	Veterinary Medicinal Products

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Executive Summary

The recent remarkable growth and development in the aquaculture sector of Bangladesh has been the outcome of a combination of policy related initiatives and development interventions taken by the Government as well as development work of multiple stakeholders including inputs suppliers and actual farmers as well as research institutions. The farmers in Bangladesh are also increasingly using aqua-inputs besides fish feed and fertilizer. Bangladesh Shrimp and Fish Foundation (BSFF) is presently working on the project entitled "Work on Policy Consolidation, Improvement in Licensing, Management Process and Effective Use of Aqua Inputs" supported by FtF-BANA. An important component of the project relates to a stock taking of the existing regulatory framework in Bangladesh with particular focus on its adequacy to cover all important governance, regulatory and enforcement related issues in so far as they concern aqua-inputs. The present report summarizes the findings on this important subject with some forward-looking recommendations for future work for feasible improvements.

As part of the exercise, the findings from which are presented in this report, 45 national laws, acts, rules, guidelines and statutory orders were reviewed by the BSFF study team of which 27 were specially found relevant for the study. The study team also reviewed all readily available secondary materials from India, ASEAN Countries, EU, USA and other international organizations to compile useful materials which may come in handy in any future work in Bangladesh on improvement of her regulatory frameworks to adequately cover aqua inputs.

The comprehensive review findings of the BSFF study team indicates that at present Bangladesh has a number of important instruments governing matters relating to fish feed and seed. There are also administrative guidelines and orders dealing with seed, feed and aqua medicinal products. However, no specific reference has been found in these instruments to the expression "aqua-inputs" per se though such inputs including large number of probiotics, prebiotics and some other inputs are increasingly being used in the aquaculture. The examination of relevant rules and regulations indicates that the references to medicines and some specific chemicals and like substances are there in a number of instruments. In the sense that these also form part of the "aqua-inputs", such items are taken care of by the existing instruments. There is, therefore, certainly some well discerned gap here and scope for improvements with inclusion of items which are not presently covered by the existing instruments. There is also no well-defined definition of aqua-inputs to avoid confusion and clarity on substances and medicines with multiple use potentials and which should actually be the competent Bangladesh authority severally or jointly be dealing with regulatory aspects of them.

In the absence of any references to aqua-inputs in specific terms, the coverage of existing regulatory instruments specially the Fish feed and Animal feed Act, 2010 and Fish Hatchery Act 2010 are liberally interpreted and invoked to issue the NOCs by the Department of Fisheries (DoF). With such NOCs, private sector stakeholders are importing aqua-inputs of different types. It is important that some concrete references to aqua-inputs are introduced in the existing instruments with necessary amendments or enactment of all together new additional stand-alone instrument(s). The Government may take a well-considered position on either one of these two options.

Given the nature of some of the aqua-inputs which may be used for both medicinal and other purposes, it is important that such aqua-inputs are clearly identified and an arrangement with provision for coordinated actions by more than one competent authority also deserve to be considered. How these can be done with required change in the legal instruments may be considered by a Government appointed committee.

At the moment the monitoring exercise in terms of testing carried out are of an intermittent nature and are not carried out as a routine exercise on a need-based manner. Future regulatory improvements may also have to focus on this particular issue. From an administrative point, all the competent authorities appear to have genuine needs of well dedicated and well-staffed sections in their respective setups to carry out the regulatory and monitoring activities.

The present report also has useful materials from countries like India, ASEAN member countries; EU and USA which may be used by the Government of Bangladesh in effecting improvements in countries regulatory instrument(s) to adequately cover aqua-inputs.

Section-1
Introduction, Objectives and Methodology

Introduction

The recent remarkable growth and development in the aquaculture sector in Bangladesh has been the outcome of a combination of policy related initiatives taken by the Govt. of the people's republic of Bangladesh which are investment in and introduction of high yielding quality seeds, secure water management technologies, training and targeted extension work and above all initiatives taken by the growers to seize new market opportunities, adopt advanced production processes and use of feed with increase in intensification of production practice especially stocking. Bangladeshi stakeholders are also increasingly using aqua-inputs other than feed and fertilizer to ensure better water management, nutrient administration and avoid diseases for higher production and sustainable growth. The Government has also been working to improve the regulatory framework governing the sector.

2. The project "Work on policy consolidation, improvement in licensing, management process and effective use of aqua-inputs" has been undertaken jointly by BSFF and WorldFish with support from USAID funded FtF-Bangladesh Aquaculture and Nutrition Activity (BANA) project to facilitate development of a comprehensive approach for consideration by the Government of Bangladesh and the stakeholders in the aquaculture sector to affect improvement in the regulatory framework in the country with special focus to bring in the necessary improvements in it which adequately covers aqua-inputs. An inventory of existing rules and regulations on aqua inputs in Bangladesh and drawing useful lessons from selected countries and international sources is an important component of the project. The work on the component has been carried out by a national consultant and the BSFF study team members over a period of 4 months from July to October, 2019. The findings of the consultant and the study team members constitute the contents of the present report on inventory of existing rules and regulations on aqua-inputs in Bangladesh and useful lessons from selected countries and international sources.

1.2 Objectives

3. The work on aqua-inputs under the project "Work on policy consolidation, improvement in licensing, management process and effective use of aqua inputs" was carried out to obtain a comprehensive scenario on the existing regulatory framework of the government of Bangladesh and selected countries and international sources to cover all important governance regulatory and enforcement related issues in the aquaculture sector particularly those relating to production, importation, trade and use of aqua-inputs. Having a detailed information on all relevant laws, acts, rules, regulations, guidelines and SROs in Bangladesh and selected neighboring countries, it is felt, will help the competent authorities in the country to examine whether the existing regulatory instruments in Bangladesh adequately cover the aqua-inputs and if not so what scope for improvements are there to overcome any regulatory deficit and deficiencies in the enforcement arrangements.

1.3 Methodology

4. In carrying out the work on the inventory of existing rules and regulations on aqua-inputs in Bangladesh and selected neighboring countries, the study team mostly focused on collecting and analyzing readily accessible documents and printed materials. The exercise also involved collection of information, details and insight from concerned Ministries, Departments and also relevant stakeholder's associations dealing with various aspects of existing regulatory instruments and the process of issuance of Government orders, No Objection Certificates (NOC) and other related permission. The study team focused both on

collecting primary data and information to the extent possible and qualitative information where considered important and relevant.

5. The information and data gathering exercise as well as obtaining qualitative information and insights were carried out through the followings-

- Desk top research all along the entire period of work in course of the study.
- Collection of information from relevant sources, national and international.
- A preliminary consultation workshop was held with participation from representatives of concerned Ministries, Departments and relevant stakeholders at Dhaka in the months of August, 2019.
- 5 (five) Focus Group Discussions (FGD) were carried out with concerned govt. departments and stakeholder's associations at Dhaka and Cox's Bazar.
- 4 (four) Key Informants' Interviews (KII) held with DLS, Custom's Officials and some BAPCA/AHCAB member stakeholders dealing with aqua-input.

6. The exercise on stock taking on the regulatory instruments also involved preparation of the well-structured guidelines for facilitating FGDs and KIIs. The compilation of information and details on insights obtained during the FGDs and KIIs for analytical purposes were jointly carried out by the National Consultant, BSFF study team, Policy Advisor of the project from BSFF and the Analytical Support Specialist.

Section 2
Review of the relevant conventional Acts, Rules, Policies and Guidelines in Bangladesh

7. As part of stock taking exercise on the regulatory instruments of relevance for the aqua inputs other than feed and fertilizer being used in the aquaculture sector in Bangladesh the BSFF study team examined 85 Acts, Rules, Policies and guidelines etc. (45 National instruments and 40International instruments). The full list of 45 National instruments is enclosed at Annexure-1 of this report. On an scrutiny it was found by the study team that following 27 National (Bangladeshi) instruments were specially examined for their actual or possible relevance for the purpose of the review exercise carried out with focus on aqua-inputs, both to ascertain whether their coverage is comprehensive enough to take care of various regulatory aspects of aqua-inputs being used in Bangladesh or if not so the missing elements in the existing regulatory instruments which needs to be addressed in the future updated regulatory instruments.

1. The Food Safety Act, 2013
2. Food Additives Rules, 2017
3. Food Safety (Contaminants, Toxins and Harmful Residues) Regulations, 2017.
4. Fish and Fish Products (Inspection and Quality Control) Ordinance, 1983.
5. Fish and Fish Products (Inspection and Quality Control) Rules, 1997, amended in 2008.
6. Fish Hatchery Act, 2010.
7. Fish Hatchery Rules, 2011.
8. Fish Feed and Animal Feed Act, 2010.
9. Fish Feed Rules, 2011.
10. Fish Quarantine Act, 2018.
11. National Fishery Policy, 1998.
12. National Shrimp Policy-2014.
13. NRCP Policy Guideline, 2011 (Revision 2012).
14. Guideline for the Control of Aquaculture Medicinal Products AMPs, DoF, January 2015.
15. Compliance Guidelines for Fish Feed Production, Import and Marketing, 2015.
16. Bengal Drugs Rules 1946.
17. The Drugs (Control) Ordinance, 1982.
18. Drugs (Control) (Amendment) Act, 2006.
19. National Drug Policy 2016.
20. Pesticides Act, 2018.
21. Formalin Control Act 2015.
22. Formalin (Import, Production, Transportation, Storage, marketing and Use) Control Rules, 2015.
23. Import Policy Order, 2015-2018.
24. The Environment Conservation Rules, 1997.
25. Bio-safety Guidelines of Bangladesh, 2007.
26. National Environment Policy 2018.
27. The Consumers Right Protection Act, 2009.

2.1.: Findings from Food Safety Act, 2013 of Bangladesh

8. The umbrella instrument of special significance for the present exercise was **Food Safety Act, 2013** which has, among others, detailed provisions regarding "Institutional Structure of Food Safety System in Bangladesh (Chapter-2 of the Act), Formation of the Committees (Chapter-3), Prohibitions related to Food Safety Management System (Chapter-5), Special Responsibilities of Food Business Operators (Chapter-6), Food Analysis and Testing (Chapter-7) and Inspection and Seizure of Food (Chapter-8). It is of interest for the purpose of our analysis that in Chapter-5 of the Food Safety Act, 2013

the following important elements about prohibitions related to food safety management system are mentioned:

Section-23: Use of Poisonous elements

No person shall, directly or indirectly, by himself, use or include in any article of food any chemical or ingredient or substance (such as: Calcium Carbide, Formalin, Sodium Cyclamate), Insecticides or Pesticides (such as DDT, PCB oil etc.), or intoxicated food colour of flavoring matter, whether attractive or not, or any other intoxicated additives or processing aids, which may cause injury or toxicity to human health in any article of food; or shall store, market or sell any such article of food or food ingredient processing such matter.

Section-24: Use of radioactive, heavy metals etc. in excess of acceptable limit

No person shall, directly or indirectly, by himself or by any other person acting on his behalf, use or include in any article of food or food ingredient any radioactive or irradiated matter or naturally of otherwise occurring similar matter or heavy metal in violation of maximum acceptable limit prescribed by regulation or by any other law for the time being in force.

Section-25: Production, importation or marketing of adulterated article of food or food ingredient etc.

No person shall, directly or indirectly, with an intention to sell, by him or by any other person acting on his behalf, produce or import, process, store, supply or sell any adulterated article of food or food ingredient.

Section-26: Production of sub-standard food etc.

No person shall, directly or indirectly, with an intention to sell, by himself or by any other person acting on his behalf, produce or import, process, store, distribute, or sell any article of food or food ingredient which is of sub-standard for human consumption in comparison with the standard prescribed by regulations.

Section-27: Uses of food additives or processing aids

No person shall, directly or indirectly, by himself or by any other person acting on his behalf, use or include in any additive or processing aid in violation of maximum acceptable limit prescribed by regulations in any article of food or food ingredient; or shall import, process, store, distribute or sell such article of food or food ingredient possessing such matter.

Section-28: Keeping of used industrial oil, industrial waste, adulterants, pollutants, etc. in food establishment

No person shall, directly or indirectly, by himself or by any other person acting on his behalf, keep or allow to keep in his food establishment any used industrial oil, industrial waste or adulterants with an intention to mix them with any article of food or food ingredient.

Section-29: Expired article of food or food ingredients

No person shall, directly or indirectly, by himself or by any other person acting on his behalf, import, process, and store, supply or sell any article of food or food ingredient after the date of its expiry.

Section-30: Uses of growth promoters, insecticides, pesticides or drug residues, microbes etc.

No person shall, directly or indirectly, by himself or by any other person acting on his behalf, use or include in any article of food or food ingredient any insecticide or pesticide residue, veterinary or aquaculture drug residue, hormone, antibiotic or growth promoters residue, solvent residue, active ingredients of drugs, microbes or parasites in excess to the maximum residue limit prescribed by regulations or by any other law for the time being in force; or shall store, market or sell any such article of food or food ingredient possess in such matter.

Section-31: Genetically modified food, organic food, functional food, proprietary food, etc.

No person shall, directly or indirectly, by himself or by any other person acting on his behalf, without taking approval in the manner prescribed by regulations or under any other law for the time being in force, produce, import, process, store, distribute or sell any genetically modified or engineered food, organic food, irradiated food, proprietary food, novel food, functional food, foods for special dietary uses, nutraceuticals and any such other food.

Section-32: Food packaging and labeling

No person shall, directly or indirectly, by himself or by any other person acting on his behalf, manufacture, distribute or sell any packaged food or food ingredient which is not packaged, marked and labeled in such manner as may be prescribed by regulations or any other law for the time being in force;

(a) Inscribe any false information or claim, or any mischieving or misleading information on the label mentioned in clause (a)concerning the food contained in the package or concerning the quantity or the nutritive value implying medicinal or therapeutic claims or in relation to the place of origin of the said food;

(b) Manufacture, distribute or sell any packaged food or food ingredient without complying with the obligation of labeling it with are presentation of clear information about the production, packaging and expiry date of food and traceability information in the manner prescribed by regulations; and sell any packaged food or food ingredient by changing or erasing any information inscribed on the label of the packaged food product or food ingredient.

Section-33: Production, sale, etc. of food in unhygienic process regarded as hazardous to human health

No person, by himself or by any other personating on his behalf shall manufacture, import, process or sell any article of food or food ingredient in unhygienic process, in contravention of the conditions and in deviation from the standard process specified by regulations or under any other law for the time being in force, which may cause harm to human health.

Section-34: Sale of diseased or decomposed fish, meat, milk, etc.

No person, by himself or by any other person acting on his behalf, shall produce, store, or sell diseased or decomposed fish or fish product or meat of diseased or dead animals or fowl or decomposed milk or egg or any food products made of such thing.

Section-35: Food serving or catering in hotels, restaurants or food premises

No person, by himself or by any other person acting on his behalf, who render food serving or catering services in a hotel, restaurant or food premises, shall cause hazard to human health through irresponsibility, negligence or carelessness in deviation from the standard prescribed by regulations or by any other law for the time being in force.

Section-36: Manufacture of food by a person suffering from any contagious disease

No person, by himself or by any other person acting on his behalf, shall cause any article of food or food ingredient to be prepared, stored or sold by a person who is suffering from any contagious disease.

Section-37: Manufacture, sale, etc. of misbranded food

No person, by himself or by any other person acting on his behalf shall, directly or indirectly, manufacture, import, store, distribute or sell any misbranded article of food or food ingredient similar or resembling to any article of food or food ingredient marketed in the name of any trade mark or in any trade name registered under the Trademark Act, 2009 (Act No, XIX of 2009).

Section-38: Keeping and exhibiting the name, address and receipt or challan of the concerned parties

Every food business operator or any other personating on his behalf shall, while operating food business, keep the name, address and receipt or challan of all parties involved in

the manufacture, import, processing, storage, distribution or sale of any article of food or food ingredient; and shall be bound to exhibit the information to the Authority or any officer designated by it.

Section-39: Production, sale, etc. of food without registration

No person shall manufacture, import, process, store or sell any article of food or food ingredient without registering a food business which is mandatory under any law for the time being in force.

Section-40: Rendering cooperation to the Authority or any person authorized by it:

Each food business operator or any person acting on his behalf shall, while operating food businesses bound to extend all kinds of cooperation to the Authority or to any officer designated by it at the time of inspection, investigation, sample collection or testing of anything related to food business.

Section-41: False or misleading information in advertisement

No person shall, with the intention of marketing or selling any article of food or food ingredient, cause harm to any consumer by giving any false or misleading information or statement in advertisement in contravention of the conditions for advertisement prescribed by regulations.

Section-42: Making, printing or propagating of false advertisement

(1) No person shall make, print, publish or propagate any advertisement containing false information as to quality, nature, standard etc. of any article of food or food ingredient through which people may be misguided.

(2) In a suit filed under this section, the defendant is to prove for defending himself that-

(a) He was not aware of such false advertisement or he has not come to know despite due diligence, and

(b) He, as a maker, printer, publisher or propagator has made, printed, published or propagated the advertisement in usual course of business.

(3) Where any complaint is lodged against any person under this section in any court, the court shall, unless otherwise proved, presume that such manufacturer or seller has made the endeavor or rendered the assistance to, print, publish or propagate such advertisement.

9. A close scrutiny of the above stipulations of **Food Safety Act, 2013** reveal that they are of a general nature. However, nowhere above the aqua inputs are defined or specifically referred to although many of these reused in the aquaculture sector with important consequences. Only **Section-30 of the Act** may be used to cover aqua-inputs if the section is broadly interpreted.

2.1.2: Food Additives Rules, 2017

10. In the Rule entitled "**Use of Food Additives Rules, 2017**" of the Food Safety Authority, there are details on permissible elements with doses that **<u>can be used</u>** in food or food related products as additives, as described in its scheduleNo-1 under different sections as under

Colouring agents (Part-1), Preservatives (Part-2), Flavor enhancers (Part-3), Anti-oxidants (Part-4), Stabilizers (Part-5), Non-nutritive agents (Part-6), Sweeteners (Part-7, sub-part-1), Acidity regulator (Part-7, sub-part-2), Anti-foam agents (Part-7, sub-part-3), Foaming agents (Part-7, sub-part-4), Firming agents (Part-7, sub-part-5), Thickeners (Part-7, sub-part-6), Anti caking agents (Part-7, sub-part-7), Sequestrates (Part-7, sub-part-8), Gelling agents (Part-7, sub-part-9), Emulsifiers (Part-7, sub-part-10), Bulking agents (Part-7, sub-part-11), Flour treatment agents (Part-7, sub-part-12), Glazing agents (Part-7, sub-part-13), Humectants (Part-7, sub-part-14), Propellants (Part-7, sub-part-15) and Raising Agents (Part-7, sub-part-16).

11. In the schedule No-2 of the same rule, there is a detailed list of the food additives which should be used with maximum precaution.

12. The items of this category can also be specific Colouring Agents (Part-1), Preservatives (Part-2), Flavouring agents (Part-3), Anti Oxidants (Part-4), Stabilizers (Part-5), Non-Nutritive substances (Part-6), Other sweetners (Part-7, sub-part-1), Acidity regulators (Part-7, sub-part-2), Antifoaming agents (Part-7, sub-part-3), Thickeners (Part-7, sub-part-4), Anti caking Agents (Part-7, sub-part-5), Gelling Agent (Part-7, sub-part-6), Emulsifiers (Part-7, sub-part-7), Glazing Agents (Part-7, sub-part-8), Condensing Agents (Part-7, sub-part-9).

13. Some of the above items may be used as aqua-inputs the details of which are not clearly indicated in the above schedule.

2.2: Instruments enforced by The Department of Fisheries (DoF)

14. The Department of Fisheries (DoF) under the Ministry of Fisheries and Livestock (MOFL) is the competent authority on most of the fisheries and aquaculture related subjects enforcing some specific Acts, Rules, Policies and Guidelines at the operational level. The instruments which guide the activities of the department and which are by far the most important are as follows:

1) The Fish and Animal Feed Act, 2010
2) Fish Feed Rules, 2011
3) Fish Hatchery Act, 2010
4) Fish Hatchery Rules, 2011
5) Fish and Fish Products (Inspection and Quality Control) Ordinance, 1983
6) Fish and Fish Products (Inspection and Quality Control) Rules, 1997 amended in 2008
7) Fishery Quarantine Act,2018

15. The following important facts were discerned in these instruments: In the schedules of Rules relevant to these instruments most of the substances used as aqua-inputs are mentioned and DoF used them as their reference points in connection with enforcement activities. These schedules are quite comprehensive requiring minor adjustments or updating to include new substances which have been or are being introduced.

2.2.1: Fish feed and Animal Feed Act, 2010

16. This is the main legal instrument of DoF for management of importation, exportation, production, processing, quality control, marketing, sell, distribution and transportation of fish feed and other aqua-inputs. The main sections in this Act have the following provisions-

Section-2(15): Quality Control Lab related subjects.

Section-4: Relating to restriction on production/processing/import/export/marketing/sale /distribution/other relevant works without taking license.

Section-10: (1) Concerning restriction on maintaining standard limit of ingredients of fish feed and (2) cancellation of license if found non-compliant or presence of any harmful component.

Section-11: Competent authority to test any sample in the laboratory to ensure quality and take action if non-compliant.

Section-12: Concerning restriction on any feed containing harmful ingredients, non-compliant with standards. Requirement for Radiat Compilation of Rules under this Act is still under process. So, there is scope to include compliances regarding importation of Probiotics

and such other aqua-inputs. Ion certificate and fitness certificate of the feed from exporting country.

Section-13(4): Concerning details to be included in the label of name and percentages of all ingredients.

Section-14: Restriction on use of antibiotics, growth hormones, steroids, insecticides and other harmful chemicals in fish feeds.

17. In the Fish Feed and Animal Feed Act, 2010 it appears that section-10, section-12 and section-14 have guiding principles on restricting use of harmful substances in the production and use of fish feed. These guidelines and regulatory requirements are however framed in general terms to apply to all traditional and conventional fish feed without specifically referring to new aqua-inputs which are increasingly being used in the aquaculture sector of Bangladesh.

2.2.2: Fish Feed Rules, 2011

18. In order to ensure the implementation of the Fish Feed and Animal Feed Act, 2010 the Govt. has approved Fish Feed Rule, 2011 which has detailed provisions on the followings:

Rule-6: Standards of ingradients and binders used in fish feed.
Rule-7: list of harmful chemicals in fish feed.
Rule-8: Procedure for detection of standards/nutritive value of feed ingradients.
Rule-9: Procedure for sample collection and testing.
Rule-10: Procedure for seizing.

19. To supplement the above rules which formed the Fish Feed Rules, 2011 the following schedules have been incorporated in these rules.

Schedule-3(A): Highest % of bio-ingredients in fish/shrimp feeds.
Schedule-3(B): Highest % of herbal ingredients in fish/shrimp feeds.
Schedule-3(C): Name and % of traditional/marketable quality ingredients used in fish feed
Schedule-4: List of feed additives usable in fish feed.
Schedule-5: List of appropriate feed binders usable with fish feed.
Schedule-6(A): Standards for prepared feed for carps (dry-wt %).
Schedule-6(B): Standards for prepared feed for cat fishes (dry-wt %).
Schedule-6(C): Standards for prepared feed for koi (dry-wt %).
Schedule-6(D): Standards for prepared feed for Tilapia (dry-wt %).
Schedule-6(E): Standards for prepared feed for fresh water prawn (dry-wt %).
Schedule-6(D): Standards for prepared feed for brackish water shrimps (dry-wt %).
Schedule-7: List of harmful chemicals for fish feed.
Group-A: Anabolizan (Hormons) and prohibited substances.
Group-B: 1. Active Pharmacological (Antibacterial) substances
2. Organo-phosphorus compounds.
3. Environmental contaminants.
4. Chemical substances
5. Micotoxins
6. Anthelmintics
7. Dyes.
Schedule-7(A): List and acceptable limits of antibacterial substances and chemicals in fish feeds(to be used with prior permission of C/A and must test the residue).

20. The general observation on the coverage of aqua-inputs under the existing regulatory instruments noted in the earlier section of the report generally applies in the case of Fish Feed Rules, 2011.

It is however important to note that the specific schedules of Fish Feed Rules, 2011 have important stipulations on non-permissible harmful substances not be used in fish feed and permissible doses in some specific cases.

2.2.3: Fish Hatchery Act, 2010

21. This instrument is the legal framework used by DoF to ensure establishment and monitoring of operation of fish/shrimp hatcheries for production of quality seed/pl to ensure sustainable development of fisheries resources. The Fish Hatchery Act, 2010 has general provision on:

Section-10(1): Power for inspection.
Section-11(1): Restriction on use, power for seizing and disposal of un-approved/restricted commodities.
Section-12: Collection and testing of samples by C/A.

22. The Act is supplemented by the Fish Hatchery Rules, 2011 which have more detailed operational stipulations.

2.2.4: Fish Hatchery Rules, 2011

23. These Rules were adopted in 2011. These are a comprehensive set of rules comprising the followings:

Rule-11: List of approved and un-approved materials, procedure for forfeits and seize of un approved materials.
Rule-12: Procedure for destroying of forfeited materials/chemicals.
Schedule-2:1(b): Guideline on use of permissible aqua medicines and restriction on use of non-approved aqua-medicines.
Schedule-2:7(b): Responsibility of the owner to ensure that the seeds produced are free from restricted drugs/harmful chemicals.
Schedule-2:7(c): Responsibility of the owner to ensure that antibiotics like Nitrofuran, Chloramphenical or any other restricted chemicals are not used.
Schedule-2:7(e): Obligation of the owners to test seeds of each batch for un-approved antibiotics and other harmful chemicals in approved laboratories.
Schedule-2:7(b): Obligation of the owner to not use antibiotics or other chemicals banned by EU/MOFL.
Schedule-2:8(c): Ensuring traceability of all chemicals/aqua-inputs used in the hatchery.
Schedule-2:9(a): Obligation on use of approved antibiotics with withdrawal periods.
Schedule-2:9(b): Matters relating to be the seeds produced to be free from residue of all approved antibiotics and no use of any restricted drugs.
Schedule-3(A): List of banned medicines and chemicals for aquaculture and manufacture of fish products.
Schedule-3(B): List and residue limits of medicines to be used in treatment.
Schedule-3(C): List and dose (as per USFDA approval/21CFR-522-1081) of medicines approved to be used in aquaculture.
Schedule-7: List of approved laboratories for testing of samples (Rule-10).

In case of Fish Hatchery Act, 2010 and the relevant Fish Hatchery Rules, 2011 there is also no specific reference to aqua-inputs.

2.2.5: Fish and Fish Products (Inspection and Quality Control) Rules, 1997, amendment in 2008.

24. Fish and Fish Products (Inspection and Quality Control) Ordinance was promulgated in 1983. Fish and Fish Products (Inspection and Quality Control) Rules, 1997 were adopted as a consequential subsequent step to implement section-3 of the 1983 ordinance. The 1997 Rules are used by FIQC of DoF to ensure compliances of EU and USFDA regulations on non-use of antibiotics, pesticides, hormones and other harmful chemicals in aquaculture. This Rule was amended in 2008. The Rules of this instrument relevant for the purpose of the present study are as follows:

Rule-5(3): Restricted use of any chemical with processed fish which can deteriorate, spoil or contaminate the quality of fish.

Rule-4 & Rule-6: As part of Rule-4 and Rule-6 the relevant Schedule-17 has the following important elements.

Group-A: List of medicines/Chemicals banned for use in aquaculture & Fish products.

Group-B: List of medicines/Chemicals used in animal treatment & their residue.

Group-C: List and dose of medicines/Chemicals approved for use in aquaculture.

Rule-5(7): Restricted use of DDT or any other harmful insecticide with dry fish of any other processed cured fish (Bio-degradable insecticides pesticides, hormone or any other chemical in aquaculture, presence of residue of which can make the quality of fish un-acceptable.

Rule-21(1): Restricted use of any antibiotics.

Rule-21(3): Testing for residual effects of antibiotics, pesticides, hormones or any other chemicals in fish or pond-water whether it is beyond the limit or not.

25. The FIQC Rules are quite comprehensive. However, as a general observation it is worth noting that there is no reference to aqua-inputs in these rules with clarity on their definition or whether the schedules included in them also include some of the new probiotics, prebiotics or other aqua-inputs now in use in Bangladesh.

2.2.6: Fisheries Quarantine Act, 2018

26. Fisheries Quarantine Act, 2018 is a particularly relevant instrument at the disposal of DoF dealing with, specially - import of fish, fish products and beneficial bacteria (Probiotics). It empowers DoF to monitor and control the import of these items. The Act also empowers DoF and Export-Import Authorities of Bangladesh to ban the import of harmful substances falling under these categories permitted by the Imports and Exports Act, 1950 (Act No-XXXIX of 1950). The Fisheries Quarantine Act, 2018 gives DoF the power to have an oversight role on the import of probiotics which according to the definition used in the Section-2(4) of this Act includes fungus, bacteria, nematodes, virus like microorganisms etc. which can be used for managing fish diseases and/or promoting growth and production of fish.

27. The Fisheries Quarantine Act, 2018 does not also have an all-inclusive definition of aqua-inputs, but it takes cognizance of probiotics generally which forms an important component of the basket of aqua-inputs presently used in Bangladesh. Given the Act's limited scope of applications and coverage of some aqua-inputs like Probiotics in the broadest term, there appears to be a significant gap and scope for making relevant Bangladesh regulatory instruments more inclusive.

2.2.7: Guideline for the Control of Aquaculture Medicinal Products AMPs, DoF, January 2015.

28. An umbrella guideline was adopted and issued by the MOFL in 2015 entitled "Policy Guideline for the control of Aquaculture Medicinal Products used in aquaculture: AMPs". This policy guideline includes the following major elements:

Chapter-4: Guidelines on roles and responsibilities of DGDA, DoF and DLS regarding AMPs.
Chapter-5: Guidelines for the control of AMPs.
5.1: Guidelines for obtaining AMPs Registration.
5.2: Guideline for manufacture of AMPs.
5.3: Guideline for Distribution, warehousing, wholesaling and retailing of AMPs.
5.4: Guidelines for Import and possession of AMPs.
5.6: Guidelines for use of AMPs.
Chapter-6: Guidelines for field monitoring of AMPs.
Chapter-7: Implementation of the policy guideline and coordination of the AMPs control program, and
Chapter-8: Validity of the policy guideline.

2.2.8: Notifications/office orders of DoF

29. One interesting finding of the study team has been that, the Government/Ministries or DoF circulate some **notifications/office orders** from time to time to address issues arising out of licensing, management and enforcement activities with regards to feed and aqua-inputs. Such notifications and office orders play important role on the regulatory enforcement processes of the aqua-inputs.

30. There are restrictions on the use of a variety of aqua-inputs in Bangladesh which are framed under the legal frameworks enforced by DoF. Fish Feed Rules, 2011 and Fish Hatchery Rules, 2011 are the legal instruments, where there are specific schedules providing the lists of such restricted inputs, the lists are presented in the Annexure-4 of this report.

2.3: Instruments enforced by The Directorate General of Drug Administration (DGDA)

31. Use of medicines as inputs in the aquaculture sector of Bangladesh is also a very important feature of evolving ground reality of use of verity of inputs. Under the Bangladesh Government Rules of Business the Ministry of Health and more specifically DGDA has the overall responsibility to have the oversight and monitoring responsibility in this important area as well. As such the study team carefully examined the existing reality on regulatory instruments and guidelines being used on aqua medicines.

32. The DGDA enforcement process on aqua medicines (specially the drugs) is guided by a number of important legal instruments. As confirmed during the FGD held with DGDA Officials the main instrument guiding aqua medicines related subjects include The Drug Act, 1940, The Bengal Drug Rules, 1946, The Drug (Control) Ordinance, 1982 and the National Drug Policy 2016.

33. The study team reviewed the **Drug Control Ordinance, 1982** and **National Drug Policy 2016**, which are very important instruments to control the management systems of drugs in the country. These instruments are enforced by the Directorate General of Drug Administration (**DGDA**). There are some relevant sections in these two instruments which are also important for aquaculture sector. A short review about these two instruments reveals the followings:

2.3.1: Drug Control Ordinance, 1982

34. This instrument imposes control on manufacture, import, distribution and sale of Drugs (in addition to and not in derogation of The Drug Act, 1940). Followings are the important sections under this Act:

Section-4: Govt. specified Drug Control Committee (DCC).
Section-5(1): Drug should be registered by the licensing authority for production/importation/distribution/sale.
Section-5(2): The DCC should recommend for the registration
Section-5(3): Conditions should be imposed by the licensing authority for registration.
Section-5(5): Duration of registration is 5 years.
Section-9(1): No Drug or parent raw materials should be imported out of schedule.
Section-9(2): NOC must be taken from licensing authority before importation.
Section-9(2)(ii.(i): The authority will fix the highest retail price of the imported drug.
Section-13(1): Manufacture of medicines other than Ayurved, Unani and Homeo must be done under supervision of registered Pharmacist.
Section-13(2): Medicines must be retailed under the supervision of registered Pharmacist.
Section-24(1): The Govt. will form National Drug Advisory Council.
Section-24(2): This council will advise the Governmentt about-

a) Measures of adopting National Drug Policy.
b) Take necessary actions on local manufacture, importation etc.
c) Importation of medicines and pharmacological raw materials.
d) Coordination with other Ministry, Organization or person about manufacture, importation, distribution and marketing of drugs.

2.3.2: National Drug Policy 2016

35. The National Drug Policy, 2016 is imposed to ensure safe, effective and good quality drugs at affordable price, rational and safe use of drugs and proper dispensing, achievement in self-sufficiency in manufacture of drugs and raw-materials by providing services and facilities on a priority basis to all local drug manufacturing industries, expand the export of drugs manufactured locally and establish an effective surveillance system of drugs. This is the 3rd National Drug Policy, the 1st Policy was compiled in 1982 and the 2nd in 2005. The main articles of the policy relevant with the management of aqua-inputs in the country are as follows:

Article-4.4(a): Selection of drugs for registration.
Article-4.4(b): Standards for registration.
Article-4.4(c): Registration for importation.
Article-4.6: National Regulatory Authority (NRA) of drugs.
Article-4.8: Drug selection, quality determination, collection, stocking and distribution system.
Article-4.9: Advertisement and publicity of drugs.
Article-4.10: Transparent and rational pricing of drugs.
Article-4.14: Skilled Human Resource in Drug manufacturing industries.
Article-4.16: National Control Laboratory (NCL).
Article-4.22: Clinical trial and Bio-equivalence studies of drugs.
Article-4.26: Drugs used in treatment of fish/livestock

a. Appropriate quality control measures as per GMP guideline for manufacturing.
b. Indications of use should be specified on the label, literature and packet; Drugs used in livestock should be discouraged to use in fishes.

c. In addition to discouraging use of VMPs instruction will be given to the pharmaceutical companies to increase the production of AMPs for treatment purpose.

36. The Article-4.26 of the National Drug Policy, 2016 has the following stipulations. It may be seen that reference to aqua medicines in the section is of a very general one.

Article-4.26: Drugs used in treatment of fish/live stock

a. Appropriate quality control measures as per GMP guideline for manufacturing
b. Indications of use should be specified on the label, literature and packet, Drugs used in livestock should be discouraged to use in fishes.
c. In addition to discouraging use of VMPs instruction will be given to the pharmaceutical companies to increase the production of AMPs for treatment purpose.

37. Discussion with the DGDA Officers by the study team was able to conclude into few important massages regarding the management of aqua-inputs in Bangladesh, most important of them are as follows-

1. DGDA has no separate guidelines to control the management of aqua-drugs, but the same instruments as those for veterinary drugs are used for the purpose.
2. In the registration of any drug or medicine, if there arises any confusion about any aqua-input, then the DGDA take consent from DoF about this, and the same is done by DoF in a similar case.
3. There are two committees in the management chain of Drug registration by DGDA authority. One is DCC (Drug Control Committee) headed by Secretary of MOH and constituted with specialists and professionals, formed according to Section-4 of Drugs (Control) Ordinance, 1982 and Article-4.6 of National Drug Policy 2016, which functions for giving opinion/recommend for registration through evaluation of safety, efficacy and usefulness of all applied drugs for locally manufacture or for importation. Final decision is taken by licensing authority in a local committee headed by the DG of DGDA based on the proposals from DCC. None of the committees include any representative from DoF.
4. There is another National Drug Advisory Council formed as perSection-24 of Drugs (Control) Ordinance, 1982, which is formed by the Government to advise about the measures to be taken on 1) implementation of the national drug policy, 2) for production and supply of essential drugs for local demand of the country, 3) import of drugs and raw materials and 4) co-ordination with various ministries, agencies and persons concerned with manufacture, import, distribution and sale of drugs.
5. As per recommendation of DCC, the DGDA has banned and cancelled the registration of a lot of Antibiotics, Medicines and their preparation combinations used in human and animal treatment which should be withdrawn from the market within next December/2019. The official order is presented in the Annexure-5 of this report.

2.4: Import Policy Order, 2015-2018

38. Given that most of the aqua-inputs presently used in Bangladesh are imported. The study team closely examined the "Import Policy Order, 2015-2018" of Bangladesh to see its various provisions which may have relevance for import and management of use of aqua-inputs in Bangladesh. It was found by the study team that, following important provisions of the Import Policy Order may be of relevance for the regulatory regime of aqua-inputs.

Article-17(1): In case of importation, of fish feed/poultry of dairy feed, Radiation certificate, fitness certificate, level of Sizium-137 per KG during shipping should be provided by the importer as provided by the exporting country,

Article-17(2)(a): Obligation to provide certificate on absence of Chloramphanical, Nitrofuran and other harmful medicine hormone melamine & steroid

Article-17(2)(b): In case of dairy & poultry feeds, declaration of absence of these on the label, certificate on absence of GMO, certificate from local specific laboratory of testing Cloramphanicle, Nitrofuransand Antibiotics after import.

Article-17(2)(c): Obligation to provide date of manufacture and expiry for all imported fish/dairy/poultry feeds.

Article-17(4): Meat & bone-meal should be imported by prior permission from DLS. Must confirm absence of antibiotics/swine meat/chromium and melamine. Certificates regarding these should be submitted.

Article-17(8): The conditions of Article-17(4) should be met and mentioned in the LC for importation of fish/poultry/animal feed.

Article-17(11): In case of fish importation, the exporting country should produce a certificate to the customs authority regarding absence of formalin in the imported fish.

Article-17(14): Imported commodities must provide certificates for the absences of "Bovine Spongiform Encephalopathy (BSE)" and Avian Influenza from the C/A of the exporting country.

Article-29(2)(b)(12): Restricted items for importation: Following items are restricted for importation under Stochholm Convension on Persitant Organic Pollutants (POPs): Aldrin/Clorodon/DDT/Di-Aldrin/Andrin/Heptachlor/Mirex/Tocsafen /Hexa-chloro benzin/Policlorinatedbi-phenyle (PCB).

The list of prohibited goods mentioned in Part-B of Annexure-1 of the Import Policy Order 2015-2018 is presented in the Annexure-3 of this report.

39. The Import Policy has also attached schedules of permissible items of Controlled list, Prohibited list, The study team checked both the lists and found that there are scopes for improving them to include aqua-inputs which the experts may consider harmful.

2.5: Inventory and Review of other local legal instruments

40. Inventory and review of the Laws, Acts, Rules, Regulations and Guidelines related with governing the management activities of Department of Livestock Services (DLS), Department of Agricultural Extension (DAE) and Ministry of Commerce (MOC) etc. are presented in the Annexure-2 of this report.

Section 3
Inputs from regional and international relevant materials

41. The BSFF study team considered and examined to the extent possible the legal instruments and guidelines in India, ASEAN member countries, EU and USA to collect reference materials which might be of use for the Bangladesh authority in any exercise to improve on the existing regulatory frameworks in Bangladesh with regards to aqua-inputs.

3.1: Review of relevant materials from India

42. In India there is not a single stand-alone regulatory instrument or an all comprehensive definition with regards to aqua-inputs other than feed. All the regulatory and enforcement related guidance are included in multiple instruments and governmental instructions. The study team found the following among these instruments and guidelines which could be of interest for Bangladesh.

3.1.1: Coastal Aquaculture Authority Rules, 2005

43. Coastal Aquaculture Authority Rules, 2005 of the Indian Ministry of Agriculture, Department of AH, Dairying and Fisheries have several elements which were found relevant for the present purpose.

Rule-5: The Coastal Aquaculture Authority has empowered to: (v): Fix standards for all costal aquaculture inputs like seed, feed, growth supplements, chemicals/medicines, for maintenance of the water bodies & the organisms reared there-in & other aquatic lives.

Rule-8(1): Empowers C/As to take sample of water, soil & the farmed animals to detect residue of banned chemicals, antibiotics & other pharmacologically active compounds & to adopt appropriate procedures for collection, analysis, reporting & follow-up actions.

Rule-8(4) empowers authorized laboratories to carry-out analysis of water, soil and farmed animals to detect residue of banned chemicals, antibiotics or other PA substances.

Annexure of the Coastal Aquaculture Authority Rules, 2005 provides Guidelines on the followings which can be taken into note by the GOB in any review exercise.

11.0: Regulations about use of chemicals and drugs.

11.3: Chemicals should be avoided in shrimp ponds for prevention or treatment of diseases, as food additives, disinfectants, removal of other fishes, treatment of soil or water, in hatcheries, entry of chemicals from hatcheries to the environment should be monitored carefully and must be removed from waste-waters.

11.5: Directive about chemical pesticide.

11.6: Directive about chemo-therapeutants.

11.7: Table-5: Elaborates prohibition of use of 20 items of Antibiotics and other PA substances banned for use in shrimp aquaculture.

11.8: Standards to be followed by the farms and input-providers on the MRL of drugs and antibiotics.

3.1.2: Drugs and Cosmetics Act, 1940 (amended up to 31/12/2016)

44. Drugs and Cosmetics Act, 1940 (amended up to 31/12/2016) of India imposes regulation on import, manufacture, distribution and sale of drugs and cosmetics in the country. This Indian instrument may also be considered by GoB as reference material. The sections of the Act found relevant for the present study are:

Section-7: The Drug Consultative Committee which is to provide advice to the government on any matter tending to secure uniformity.

Section-10: Prohibition of import of some drugs/cosmetics.

Section-18: Prohibition of manufacture & sale of drugs/cosmetics.

3.1.3: Drugs and Cosmetics Rules, 1945 (As amended up to 31/12/2016)

45. The Drugs and Cosmetics Rules, 1945 (as amended up to 31/12/2016) of India, especially the following sections in the instruments have details on authorization and licensing related procedures.

Rule-23: Requirement of import license of the drugs/aqua-inputs.

Rule-24(A)(1): Application for registration certificate of drugs is to make in specific form with specific fees.

Rule-26: Conditions for import license: (1): All conditions of Form-9 should be complied and (2): Inspector should be permitted for store inspection, sample collection & sending for test.

Rule-28: Duration of import license fixed at 3 years.

Rule-29(A): Duration of registration certificate fixed at 3 years.

Rule-30(A): Prohibition of import of date expired drugs (Schedule-C or C (1) and 30(B): No drug should be imported which is restricted for production, sale or distribution in the exporting country.

Rule-31: Prohibition of import of drugs which do not match with local standard (Schedule-F (1).

Rule-32: Prohibition of import of drugs without packing labeling as per Part-IX & X or Schedule-F (1).

Rule-38: Requirements to have names of drug producers & amount of import.

Rule-39: Need for declaration statement to be produced to the Customs Collector with other important documents.

Rule-40: Customs Collector having doubt can collect samples, send to specific lab and can hold the consignment till getting positive report. But the collector can release the product if the importer gives undertaking not to sale/distribute commodities before permission of the Collector or return the consignment to the exporting country.

Rule-43(A): Land port/Railway ports are specified to import drugs from some specific countries

3.2: Review of materials from ASEAN Countries

46. According to the information collected and reviewed from the ASEAN countries there are wide range of instructions and guidelines which are generally enforced on all aqua-inputs including feed. The ASEAN countries jointly developed the 2013 ASEAN "Guidelines for the use of chemicals in aquaculture and measures to eliminate the use of harmful chemicals". The member states comprised Brunei Darussalam, Indonesia, Malaysia, Myanmar, Philippine, Singapore, Thailand, Vietnam, Cambodia and LAO PDR. The purpose of the Guidelines was to minimize adverse impacts on human health and the aquatic environment. The present observations on the Guidelines are presented below:

47. The Guidelines lay emphasis on monitoring and regular updating of the sections by the respective CAs which are multiple in the member countries reflecting the allocation of business among their concerned ministries and departments and the guidelines also has stipulations on list of prohibited chemicals, maximum residue limits (MRL) of chemicals, withdrawal periods and dosages.

48. As regards the ASEAN guideline the followings are also worth noting

Section-5: Terms and Definitions: In this section there is no separate or standalone definition of aqua-inputs. However, in other sections the terms "chemicals and drugs" and "chemicals" are used interchangeably to define major elements (and compounds) of aqua-inputs (Section-11 and Appendix-II). Therefore, based on earlier review of some national and international legal instruments and literature on aqua-inputs, it

may appear that, the term "chemicals and drugs" is widely accepted and used to define aqua-inputs.

Appendix-II: List of chemicals used in aquaculture of ASEAN member states. This Appendix groups the chemicals into seven categories, which are 1) Antibiotics/Antimicrobials, 2) Disinfectants, 3) Chemo-therapeutants, 4) Pesticide, 5) Hormones, 6) Anesthetics and 7) Culture system preparation. Under each category there is a list of aqua elements (and compounds). As an example, lime and zeolite are listed under the culture system preparation category. Furthermore, all elements (and compounds) in each category are classified as either PROHIBITED (totally banned) or No (currently no use) or NDA (no data available) or YES (allowed to be used with recommended maximum residual limits and withdrawal period).

Section-7: This section spells out the role and responsibilities of C/As manufacturers and traders and aqua culturists. There is no separate reference to the importers or the import process. It is likely that the section does not cover import since such aqua-inputs are locally available or manufactured. However, another possibility is that the term traders includes importers as well as may be the case for the relatively less advanced countries such as Cambodia or LAO PDR, Myanmar, Vietnam.

Appendix-I: Competent Authority (ies) in ASEAN countries regulating and monitoring the use of chemicals in aquaculture. This appendix presents in a matrix from the C/As in each of the ten ASEAN member states responsible for 1) regulation of chemicals used in aquaculture, 2) Veterinary drugs, 3) Pesticides. In nine out of the ten member states the Department of Fisheries (DoF) is responsible for item 1).

3.3: Relevant materials from European Union (EU)

49. There is a specific obligation for EU countries to ensure food safety by adoption of standards and in implementation of residue monitoring plans for legal control on the use or misuse of authorized veterinary medicines, drugs and other aqua-inputs in food producing animals including fish/shrimp and investigate the reasons for residue contamination. There is also an obligation for the aquaculture production business to ensure that such treatments are recorded. All authorized/licensed products for aquaculture, which contain pharmacologically active substances, should be in line with Commission Regulation (EU) 37/2010. Almost all member states usually follow the regulation to keep the maximum residue limits for aquaculture samples within its maximum level. The EU mainly imposes legal frameworks for official controls on the use of VMPs/aqua-inputs in aquaculture among the member states rather than importation.

50. The study team found that EU legislations and regulatory instruments on VMP have 3 main components covering matters relating to-

1) Control of manufacture,
2) Control of place in the market and
3) Post approval monitoring.

51. They follow from the regulations and directives mentioned below:

- Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.
- Directive 2001/82/EC on the Community code relating to veterinary medicinal products. amended by Directive 2004/28/EC of the European Parliament.
- Regulation (EC) No 726/2004/EC laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

- Council Regulation (EEC) No 2377/90/EEC laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin.
- Commission Directive: 2001/12/EC of 26 February 2001 (amending Council Directive 91/440/EEC).

52. From FGDs conducted by the study team it appears that Bangladesh Government has tried to accommodate all the above requirements in the schedules of FIQC Rules Fish Feed Rules and Fish Hatchery Rules.

53. For importation from third countries the member countries follow EU Council Directive 96/23/EC of 29, 1996, Article 29 of Chapter VI of this directive is about:

- Inclusion and retention on the lists of third countries from which member states are authorized to import animals and animal products covered by this Directive shall be subject to submission by the third country concerned of a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I (list of substances having anabolic effect and unauthorized substances, veterinary drugs and contaminants); the plan must be updated at the request of the Commission.
- Compliance with the requirements of and adherence to the guarantees offered by the plans submitted by third countries shall be verified by means of the checks referred to in Article 5 of Directive 72/462/EEC (1) and the checks provided for in Directives 90/675/EEC (2) and 91/496/EEC (3).
- Member States shall inform the Commission each year of the results of residue checks carried out on animals and animal products imported from third countries, in accordance with Directives 90/675/EEC and 91/496/EEC.

3.4: The inputs from USA

54. The BSFF study team, while reviewing materials from US, found that the US Govt. has a comprehensive "Guide to Drugs, Vaccine and Pesticide use in Aquaculture" revised in April 2007. According to it multiple agencies have jurisdictions on drugs, vaccines and pesticides used in aquaculture

55. Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) of US share some areas of mutual regulatory responsibility. **A memorandum of understanding** sets forth the responsibilities of each agency under The Federal Food, Drug, and Cosmetic Act (FFDCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The memorandum also provides guidance in the area of aquaculture, particularly as to which agency has jurisdiction over a particular substance for its intended use. As regards jurisdiction over disinfectants, EPA is the C/A for sanitizers, and aquatic treatments used solely for the control of algae or bacterial slime and over any other aquatic treatments used solely for pest control that do not include claims for control of parasites or diseases of fish.

56. The jurisdiction over new animal drugs lies with FDA with its jurisdictions also covering products intended to treat or prevent parasites or diseases of fish, anesthetize aquatic species, and alter the sex or regulate the reproduction of aquatic species. Some state regulatory agencies also have their due role to play State Departments of Agriculture or other designated state agencies may also register federally approved pesticides to permit their legal distribution and sale within a state or territory. States may have additional regulatory requirements, including additional data and/or additional restrictions on use and licensing. These requirements can affect the distribution and use of pesticides that are purchased from a distributor in one state for intended use in another. States can provide registration for additional uses of federally registered pesticides to meet special local needs under section 24(c) of FIFRA. Products

registered for special local needs under section 24(c) are listed separately in each table of EPA-registered products in Appendix B.

57. The study team, following its review of US specific inputs, is of the view that the Bangladesh Government may benefit from taking due note of the classification and grouping of drugs, biologics and chemicals used in aquaculture in the US as reflected in the guide for using drugs, biologics and other chemicals in aquaculture of the American Fisheries Society for any exercise on arriving at **a comprehensive definition** for incorporation in the relevant regulatory instruments in Bangladesh. The guide is also rich in details on **a) Approved and conditionally approved drugs, b) Low regulatory priority drugs, c) Deferred regulatory status drugs, d) Approved Biologics, e) Disinfectants, f) Pesticides and g) Best Management Practices and similar relevant practices.**

Section 4
The regulatory regime and enforcement arrangements in Bangladesh

58. On a review of the regulatory arrangements in Bangladesh, it was found that presently entities dealing with fish feed & aqua-inputs have to have 4 specific types of licenses. i.e. a) Category-1: License for production, b) Category-2: license for import, 3) Category-3(a): License for whole sale transactions and 4) Category-3(b): License for retail transactions. These licenses are issued by DFOs to be renewed annually (stakeholders have reported during FGD that they are facing difficulties off late in getting such licenses – the difficulties arising out of the need to get NOC from more than one sources i.e. BSTI &Department of Environment). A representative License of category-2 (for import) issued by DoF is presented in the Annexure-9 of this report.

59. In case of import, all the importers are supposed to have IRC from the Chief Comptroller of Imports. Having IRCs by themselves do not ensure that import of specific items can be carried out without meeting further requirements. Importers have to submit Proforma Invoice (PI) with details on product, their source, price, quantity & volume, pack size, port of exit & entry etc. The importers are also supposed to submit NOCs from DoF which DoF issues following consideration of the analytical certificate from the exporters to the affect that the products do not contain elements not permissible by the Bangladesh authorities namely for reasons of radioactive contents, presence of harmful drugs, swine, BSE, avian influenza, steroid & hormones. The DoF NOCs are issued in favour of the applicant importers with copies to concerned Commissioner, Customs in charge of the relevant port of entry with copies to concerned DFOs. A representative NOC issued by DoF can be seen in the Annexure-6.

60. On multiple purpose aqua-inputs which can be used for medicinal, therapeutic & general production purposes, DoF usually refers such cases to DGDA for their clearance. Upon the receipt of DGDAs clearance on no objection DoF issues the final NOC which are also forwarded to the Customs authority. During the FGD it was widely emphasized by most private sector importers that lack of clarity on the definition of aqua-inputs and what needs to be done with regards to multi use aqua-inputs the process of issuance of NOCs become complex and time consuming. A representative NOC issued by DGDA can be seen in the Annexure-7.

61. Presently, the Aquaculture Section in the DoF issues the NOCs for import of the aqua-inputs. The aquaculture section in the DoF is headed by the Deputy Director (Aquaculture) and is in overall charge of his section supported by his staff members. During the FGDs it was informed that workload in the section is quite demanding requiring adequate permanent support staffs. Unlike in other concerned Govt. departments, presently there is no dedicated committee at DoF working on this subject.

62. At the DGDA, under a Director three Deputy Directors are responsible for the managements of Registration & Quality Control of drugs, Inspection & Licensing of the drug and management of the testing laboratory respectively. The Director issues NOCs processed by the section of the corresponding Deputy Directors. During the FGDs the BSFF study team was informed that additional staffs deploy in these sections will help speed up work. DGDA is the sole authority to enforce the legal instruments dealing with management practices of all drug and other related inputs and their ingredients. DGDA enforces Drug Control Ordinance, 1982, the National Drug Policy, 2016 and other related instruments for the purpose. In these legal frameworks, not only licensing, but also registration of the input (drug or the ingredients) is a legal obligation for importation, manufacture or any other management process. Registration of drugs by DGDA is controlled by two committees. The first one is the Drug Control Committee (DCC)formed by the Ministry of Health and Family Welfare (MOHFW) according to the Section-4(1) of Drug (Control) Ordinance, 1982. DCC recommends drugs for registration and/or cancellation. Another committee is the Standing Committee for Import of Pharmaceuticals formed by the MOHFW to make recommendations for

DCC. *There is no representative in the DCC from DoF.* But the SCIP have representative from DG-DLS/DG-DoF (whenever applicable).

63. The Administration section of DLS issues the NOCs for importation of the inputs. The Director (Admin and Animal health) is the chief of the section. The Assistant Director (Training) issues the NOCs with consent from him. Fish and Animal Feed Act, 2010, Animal Feed Rules, 2013, Livestock Quarantine Act, 2005 etc. are the main instruments of enforcement by DLS.A representative NOC issued by DLS can be seen in the Annexure-8.

64. Department of Agriculture Extension (DAE) is the enforcement organization of the legal instruments related with importation of pesticides. These pesticides are very rarely used as aqua-inputs, but the management system of importation, storage, distribution and usage of the pesticides were considered by the BSFF team for review. Registration and licensing of the pesticides for importation and other distribution process is done by the section of Director (Plant Protection Wing) of DAE which are made by taking the proper approval of the Pesticide Technical Advisory Committee. Pesticides Act, 2018 is the principle instrument to control the management of pesticide in Bangladesh by DAE.

Section 5
An overall overview and scope for future improvements

65. The comprehensive review undertaken by the BSFF study team on the regulatory instruments indicate that at present Bangladesh has a number of important instruments governing matters relating to feed, seed and fertilizer. There are also administrative guidelines and orders dealing with feed, seed and fertilizer. However, no specific reference has been found in these instruments to the expression "aqua-inputs" per se though such inputs including large number of prebiotic and probiotics are increasingly being used in the aquaculture sector. The examination of relevant rules and regulations indicates that the references to medicines and some specific chemicals and like substances are there in a number of instruments. In the sense that these also form part of the "aqua-inputs", such items are taken care of by the existing instruments. There is, therefore, certainly some well discerned gap here and scope for improvements with inclusion of items which are not presently covered by the existing instruments. There is also no well-defined definition of aqua-inputs to avoid confusion and clarity on substances and medicines with multiple use potentials and which should actually be the competent Bangladesh authority (CA) should severally or jointly be dealing with regulatory aspects of them.

66. In the absence of any references to aqua-inputs in specific terms, the coverage of existing regulatory instruments specially the Feed and Hatchery Acts is liberally interpreted and invoked to issue the NOCs by the Department of Fisheries (DoF). With such NOCs, private sector stakeholders are importing aqua-inputs of different types. It is important that some concrete references to aqua-inputs are introduced in the existing instruments with necessary amendments or enactment of all together new additional stand-alone instrument(s). The Government may take a well-considered position on either one of these two options.

67. Given the nature of some of the aqua-inputs which may be used for both medicinal and other purposes, it is important that such aqua-inputs are clearly identified and an arrangement with provision for coordinated actions by more than one competent authority also deserve to be considered. How these can be done with required change in the legal instruments may be considered by a Government appointed committee.

68. At present, several levels of coordination and monitoring mechanisms are envisaged in the relevant legal and regulatory instruments. Activating them and making them inclusive in terms of participation in their activities of representative of all relevant competent authorities can be a major improvement affected in course of the consolidation of the coverage and effective coordination in future.

69. At the moment the monitoring exercise in terms of testing carried out are of an episodical nature and are not carried out as a routine exercise on a need-based manner. Future regulatory improvements may also have to focus on this particular issue. From an administrative point, all the competent authorities appear to have genuine needs of well dedicated and well-staffed sections in their respective setups to carry out the regulatory and monitoring activities.

Section 6

Conclusion

70. The review exercise on the regulatory regime and legal and administrative instruments relevant for the aqua-inputs production, importation, trade and use reveal that there are significant scopes for future improvement in them both in term of developing a comprehensive definition of aqua inputs for use in all relevant future regulatory instruments, details as to how authorization for their production, trade and use deserving particular attention for regulatory and enforcement purposes and improvements needed to facilitate better and effective coordination at all relevant levels. The present exercise and its outcome reflected in the present report, it is hoped, will serve as a useful basis for future planned work and initiative on policy consolidation for effective use of aqua inputs in Bangladesh with necessary improvement in the regulatory regime in the relevant field with special focus, among others, licensing, management process and monitoring of effective implementation of relevant national laws, rules, guidelines and regulations.

Section 7

References

Bangladeshi materials reviewed

1. Fish and Fish Products (Inspection and Quality Control) Ordinance, 1983.
2. Fish and Fish Products (Inspection and Quality Control) Rules, 1997, amendment in 2008.
3. Fish Hatchery Act, 2010.
4. Fish Hatchery Rules, 2011.
5. Fish Feed and Animal Feed Act, 2010.
6. Fish Feed Rules, 2011.
7. Fisheries Quarantine Act, 2018.
8. National Fishery Policy, 1998.
9. NRCP Policy Guideline, 2011 (Revision 2012).
10. National Shrimp Policy-2014.
11. Guideline for the Control of Aquaculture Medicinal Products (AMPs), DoF, January, 2015.
12. Compliance Guidelines for Fish Feed Production, Import and Marketing, 2015.
13. Codes of Conduct for Selected Segments of the Shrimp Aquaculture Industry in Bangladesh, Department of Fisheries (DoF), Edited by Global Aquaculture Alliance (GAA)/The Best Aquaculture Practices (BAP) Program (Formerly known as Aquaculture Certification Council (ACC), July 2011.
14. Animal Disease Act, 2005.
15. Animal Disease Rules, 2008.
16. Fish and Animal Feed Act, 2010.
17. Animal Feed Rules, 2013.
18. Bangladesh Animal and Animal Product Quarantine Act, 2005.
19. National Poultry Development Policy, 2008.
20. Bengal Drugs Rules 1946.
21. The Drugs (Control) Ordinance, 1982.
22. Drugs (Control) (Amendment) Act, 2006.
23. National Drug Policy 2016.
24. The Drug (Control)(Amendment) Ordinance, 1984.
25. Annual Drug Report of Bangladesh, 2013, Department of Narcotics Control Ministry of Home Affairs Government of the People's Republic of Bangladesh.
26. Bangladesh Pharmaceuticals in Health Care Delivery Draft Mission Report 24 October - 3 November 2010 30th November 2010 Kathleen A Holloway Regional Advisor in Essential Drugs and Other Medicines World Health Organization, Regional Office for South East Asia, New Delhi.
27. Business Analysis of Pharmaceutical Firms in Bangladesh: Problems and Prospects Md. Anamul Habib, Md. Zahidul Alam, Volume–VI, Number–01, January-June, 2011.
28. Management & Marketing Practices & Problems of Pharmaceuticals Industry In Bangladesh Masters of Business Administration, BRAC University
29. National Guideline on the Pharmaco-vigilance System in Bangladesh, Directorate General of Drug Administration Ministry of Health and Family Welfare
30. New Product Registration Procedure, Applicant User Guide April 27, 2017
31. Supply Chain Management in Pharmaceutical Industries: A Study on Eskayef Bangladesh Ltd A Dissertation submitted to BRAC Institute of Governance and Development (BIGD) in Partial Fulfillment of the Requirements for the Degree of Masters in Procurement and Supply Management, BRAC Institute of Governance and Development BRAC University April 15, 2016
32. Pesticides Act, 2018
33. Pesticide Rule, 1985

34. Plant Quarantine Act, 2011
35. Plant Quarantine Rules, 2018
36. Formalin Control Act 2015
37. Formalin (Import, Production, Transportation, Storage, marketing and Use) Control Rules, 2015
38. Import Policy Order, 2015-2018
39. Authorized Economic Operator (Accreditation) Rules, 2018: SRO No-214-Law/2018/37/Customs: Read with Customs Act, 1969 (Act No. IV of 1969, section 219).
40. Customs Act, 1969 (ACT No. IV OF 1969) [8th March, 1969]
41. The Environment Conservation Rules, 1997.
42. Bio-safety Guidelines of Bangladesh, 2007.
43. National Environment Policy 2018
44. The Food Safety Act, 2013
45. Use of Food Additives Rules, 2017
46. Safe Food (Chemical pollution, Toxin and harmful residue) Rules, 2017.
47. Food sample collection, Testing and Analysis Rules, 2017.
48. Safe Food (Technical Committee) Rules, 2017; SRO No-270-Law/217, 27 August, 2017.
49. Safe Food (Food ceasing and Administrative procedure) Rules, 2014; SRO No-249-Law/2014, Date-23 October, 2014.
50. Consumer Right Conservation Act, 2009.

Relevant materials from India

1. The Indian Veterinary Council Act, 1984
2. The Coastal Aquaculture Authority Rules, 2005
3. The Drug and Cosmetics Act, 1940 (As amended up to the 31st December, 2016)
4. The Drug and Cosmetics Rules, 1945 (As amended up to the 31st December, 2016)
5. The Drug Rules, 1945 (Under The Drugs Act, 1940), December, 1946
6. Procedure for import of livestock products into India, New Delhi, the 7th July, 2001
7. Responsible use of Antimicrobials in Indian Aquaculture, Opportunities and Challenges, 7th December, 2016.
8. The use of Chemicals in Aquaculture in India, Pathak SC; Ghosh SK; &Palanisamy K Published by SEAFDEC
9. Status of Aqua-medicines, Drugs and Chemicals Use in India: A Survey Report; Mishra SS, Das R, Das BK, Choudhary P, Rathod R, Giri BS, Debbarma J, Sahoo SN, Barua A, Sahu A, Patil PK, and SwainP.
10. Antibiotics in Aquaculture: An Overview, R. Vignesh, B.S. Karthikeyan, N. Periyasamy and K. Devanathan, South Asian Journal of Experimental Biology, Vol-1, Issue-3, 2011
11. Aquaculture Medicine and Aquatic Animal Health Management, Edited by: IS Bright and YS Yadava, Aquaculture Authority, Ministry of Agriculture, Department of Animal Housbandry, Dairying and Fisheries, Channai, Tamin Nadu, India and National Center for Aquatic Animal Health, Cochin University of Science and Technology, Kochi, Kerala, India, November 2005.
12. Status of Aqua-medicines, Drugs and Chemicals Use in India: A Survey Report, Mishra SS, et al., J Aqua Fisheries 2017, 1: 004 HSOA Journal of Aquaculture & Fisheries
13. The Use of Chemicals in Aquaculture in India, S.C.Pathak, S.K.Ghosh, and K. Palanisamy, Technical Services Department National Bank for Agriculture and Rural Development, Bombay, India, 2000.
14. Antibiotic Use in Food Animals: India Overview, S. Sivaraman, ReAct Asia-Pacific, Christian Medical College, Vellore, Tamil Nadu, India, 2018
15. BOBP - Overview on INDIAN AMPs
16. Form-B: Application for Permit to Import Live-stock products for Trading/Marketing.
17. Drug Act, B.E. 2510"

Relevant inputs from ASEAN Countries

1. Guidelines for the use of Chemicals in Aquaculture and Measures to Eliminate the use of Harmful Chemicals, The ASEAN Secretariat, Jakarta, Indonesia, December 2013.

Reference materials from EU

1. Overview Report of a series of Fact-Finding Missions carried out in 2014 and 2015 on the implementation of the Rules on Finfish Aquaculture, EC Directorate General for Health and Food Safety.
2. EC General Food Law Regulation 178/2002: Guidence Notes on the Food Safety Act 1990 (Amendment) Regulations 2004 and the General Food Regulations 2004.
3. REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
4. COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.
5. Better Training for Safer Food: Feed Law, Executive Agency for Health and Consumers, European Commission.

Relevant inputs from USA

1. Federal Food, Drug, and Cosmetic Act (FD&C Act) (As amended through December 31, 2004).
2. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
3. FDA Food Safety Modernization Act (Public Law 111–353, January 4, 2011).
4. A comprehensive Guide to Drugs, Vaccine and Pesticide use in Aquaculture, Revised in April 2007 (Texas Agricultural Extension Service Publication No.: B-5085, 1994), Prepared by The Federal Joint Subcommittee on Aquaculture Working Group on Quality Assurance in Aquaculture Production
5. Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture (Guide) American Fisheries Society Fish Culture Section, July 2016.

Additional reference materials

1. The Use of Chemicals in Aquaculture in Thailand (a SEAFDEC publication), Kamonporn Tonguthai, AAHRI, Department of Fisheries Kasetsart University Campus Bangkok, Thailand
2. Food Act, B.E. 2522
3. Hazardous Substances Act, B.E. 2535
4. Agricultural Standards Act, B.E. 2551 (2008)
5. The Royal Ordinance on Fisheries B.E. 2558 (2015)
6. Animal Feed Quality Control Act, B.E. 2558
7. Animal Epidemics Act, B.E. 2558 (2015)
8. Fisheries Law (Law No. 17/2003/qh 11), National assembly of socialist republic of Vietnam Legislature XI, 4th session (from 21 October to 26 November 2003)
9. Current Fisheries and Aquaculture Policies Relevant to RFLP in Viet Nam, Vietnam Institute of Fisheries Economics and Planning (VIFEP), ThuaThien Hue, January 2010
10. The Enhancement and Conservation of National Environmental Quality Act, B.E. 2535."
11. Wildlife Preservation and Protection Act, B.E. 2535 (1992)"

12. Thai Agricultural Standards, TAS 9003-2004, Pesticide Residues: Extraneous Maximum Residue Limits, National Bureau of Agricultural Commodity and Food Standards Ministry of Agriculture and Cooperatives, Thailand.
13. Monitoring Antibiotics Use and Residue in Freshwater Aquaculture for Domestic Use in Vietnam; Dang Kim Pham, Jacqueline Chu, Nga Thuy Do, Francois Brose, Guy Degand, Philippe Delahaut, Edwin De Pauw, Caroline Douny, Kinh Van Nguyen, Ton Dinh Vu, Marie-Louise Scippo and Heiman F.L. Wertheim, Januaru 6, 2015.
14. Vietnam Fisheries and Aquaculture Sector Study (Final Report), Ministry of Fisheries and The World Bank, February 16, 2005
15. Current Fisheries and Aquaculture Policies Relevant to help in Viet Nam, Nguyen DzungThi Phuong, Vietnam Institute of Fisheries Economics and Planning (VIFEP), ThuaThien Hue, January 2010
16. Fisheries Law, Law No. 17/2003/qh 11, National assembly of socialist republic of Viet Nam.
17. Implementing Rules and Regulations of Republic Act No-10611, February 20, 2015, Republic of the Philippines, Department of Agriculture and Department of Health joint DA-DOH Administrative Order No-2015-0007, 20 February 2015
18. Universally Accessible Cheaper and Quality Medicines Act of 2008, Republic Act N0-9502, Philippines, July 23, 2007.
19. Rules and Regulations to Implement Prescribing Requirements for the Veterinary Drugs and Products, Republic of the Philippines, Department of Health, Office of the Secretary, 15 October 1991.
20. The New Food and Drug Administration (FDA) of the Republic of the Philippines, Agnette de Perio Peralta and Maria Cecilia Credo Matienzo, Center for Device Regulation, Radiation Health, and Research, Food and Drug Administration, Department of Health, Manila-1003, Philippines
21. Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices, Administrative Order No.20l5- 0053, Office of the Secretary, Department of Health, Republic of the Philippines, December 21, 2015
22. Aquatic resources in the Philippines and the extent of poverty in the sector, Rebecca Rivera, Environmental Science Program, University of the Philippines, May 2002
23. The use of chemicals in aquaculture in the Philippines, Cruz-Lacierda, Erlinda R.; De la Peña, Leobert. &Lumanlan-Mayo, Susan. A SEAFDEC publication, Date published: 2000
24. Responsible Use of Antibiotics in Aquaculture, FAO Fisheries Technical Paper 469, Rome 2005.
25. Antimicrobial Use in Aquaculture and Antimicrobial Resistance, Joint Report of FAO/OIE/WHO, Seoul, 13-16 Jznuary, 2006.
26. Aquaculture Initiatives on Prudent and Responsible use of Veterinary Medicines, Rohana P. Subasinghe and Melba B. Reantaso, FAO Fisheries and Aquaculture Department, OIE Glibal Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals, Paris, France, 13-15 March, 2013.
27. OIE Standards, Guidelines and Resolution on antimicrobial resistance and the use of antimicrobial agents
28. Manual of Diagnostic Tests for Aquatic Animals - 28/06/2019.
29. Heavy use of Antibiotics in Aquaculture: Emerging Human and Animal Health Problem – A Review, Pathmalal M. Manage, Dept. of Zoology, University of Sri Jayewardenepura, Sri Lanka, 2018.
30. Drug Approval System of Malaysia, May 2016.
31. Code of Practice for Fish and Fishery Products (CAC/RCP, 52-2003).
32. CODEX ALIMENTARIUS COMMISSION, Procedure Manual.
33. Antibiotics in Aquaculture: A (Fish) Veterinarian's Perspective, Hugh Mitchell, MS. DVM, Aqua tactics Fish Health, Kirkland, WA.
34. Addressing the Issue of Antimicrobial Resistance in Tilapia Aquaculture: A Guidance Note

35. Drugs and Chemicals used in Aquaculture Activities for Fish Health Management in the Coastal Region of Bangladesh, Md. RajibSharker, KanijRukshana Sumi, Md. Jahangir Alam, Md. Mokhlesur Rahman, Zannatul Ferdous, Mir Mohammad Ali and Md. Reza Chaklader, Intrernational Journal of Life Science Biotechnology and Pharma Research, Vil-3) October 2014,
36. Use of Chemicals and biological products in Asian aquaculture and their potential environmental risks: a critical review, Andreu Rico, KriengkraiSatapornvanit, Mohammad M. Haque, Jiang Min, Phuong T. Nguyen, Trevor C. Telfer, and Paul J. Van Den Brink, Reviews in Aquaculture: Vol-4, pp 75-93, 2012.
37. Preliminary review of the legal framework governing the use of chemicals in aquaculture in Asia, A SEAFDEC Publication, Van Houtte, Annick, 2000
38. Use of Aqua-Medicines and Chemicals in Aquaculture in Shatkhira District, Bangladesh, M. Ashraful Alam and M. Mamnur Rashid, Department of Aquaculture, Bangladesh Agricultural University, Mymensingh,Journal of Pharmacy and Biological Sciences (IOSR-JPBS)e-ISSN: 2278-3008, p-ISSN:2319-7676. Volume 9, Issue 6 Ver. V (Nov-Dec. 2014), PP 05-09
39. Environmental Risks of Veterinary Medicinal Products Used in Aquaculture, Boris Kolar, Nation Laboratory of Health, Environment and Food, Slovenia.

Section 8
Annexure

Annexure-1

List of 45 Bangladesh legal instruments and guidelines

1.	Bangladesh Food Safety Authority	1.	The Food Safety Act, 2013.
2.		2.	Use of Food Additives Rules, 2017.
3.		3.	Safe Food (Chemical pollution, Toxin and harmful residue) Rules, 2017.
4.		4.	Food sample collection, Testing and Analysis Rules, 2017.
5.	Department of Fisheries (DoF)	1.	The Tank Improvement Act, 1939.
6.		2.	East Bengal Protection and Conservation of Fish Act, 1950.
7.		3.	The Protection and Conservation of Fish Rules, 1985.
8.		4.	Marine Fisheries Ordinance, 1983.
9.		5.	Marine Fisheries Rules, 1983.
10.		6.	Shrimp Culture Tax Act, 1992.
11.		7.	Shrimp Culture Tax Rules, 1993.
12.		8.	Fisheries Quarantine Act, 2018.
13.		9.	Fish and Fish Products (Inspection and Quality Control) Ordinance, 1983.
14.		10.	Fish and Fish Products (Inspection and Quality Control) Rules, 1997, amended in 2008.
15.		11.	Guideline for the Control of Aquaculture Medicinal Products (AMPs), DoF, January, 2015.
16.		12.	Fish Hatchery Act, 2010.
17.		13.	Fish Hatchery Rules, 2011.
18.		14.	Fish Feed and Animal Feed Act, 2010.
19.		15.	Fish Feed Rules, 2011.
20.		16.	National Fishery Policy, 1998.
21.		17.	National Shrimp Policy-2014.
22.		18.	NRCP Policy Guideline, 2011 (Revision 2012).
23.		19.	Guideline for the Control of Aquaculture Medicinal Products AMPs, DoF, January 2015.
24.	DGDA	1.	The Drugs (Control) Ordinance, 1982.
25.		2.	The Drug (Control) (Amendment) Ordinance, 1984.
26.		3.	Drugs (Control) (Amendment) Act, 2006.
27.		4.	Bengal Drugs Rules 1946.
28.		5.	National Drug Policy 2016.
29.	MOC	1.	Import Policy Order, 2015-2018.
30.		2.	Formalin Control Act 2015.
31.		3.	Formalin (Import, Production, Transportation, Storage, marketing and Use) Control Rules, 2015
32.	DLS	1.	Animal Disease Act, 2005.
33.		2.	Animal Disease Rules, 2008.
34.		3.	Fish Feed and Animal Feed Act, 2010.
35.		4.	Animal Feed Rules, 2013.
36.		5.	Bangladesh Animal and Animal Product Quarantine Act, 2005.
37.		6.	National Poultry Development Policy, 2008.
38.	DAE	1.	Pesticides Act, 2018.
39.		2.	Pesticide Rule, 1985.
40.		3.	Plant Quarantine Act, 2011.
41.		4.	Plant Quarantine Rules, 2018.
42.	Directorate of Consumer Right	1.	Consumer Right Conservation Act, 2009.
43.	Department of Environment	1.	The Environment Conservation Rules, 1997.
44.		2.	National Environment Policy 2018.
45.		3.	Bio-safety Guidelines of Bangladesh, 2007.

Annexure-2

Review of the relevant sections of Laws, Acts, Rules, Regulations and Guidelines related with governing the management activities of DLS, DAE and Ministry of Commerce (MOC).

1. Animal Disease Act, 2005

Impose restriction on spreading and control of animal diseases.

Section-16(1) Without Licensing, restriction on-

a. Establishment, operation of animal hospital & treatment.
b. Establishment, operation of cattle farm or poultry.
c. Establishment, operation of animal product processing factory.
d. Collection or preservation of sperms for AI
e. Establishment, operation of animal farm for broods

Section-17: The VAS is authorized for inspection & information collection for Registration.

Section-18:

1) DG-DLS or Veterinary Officer is authorized for registration of those in Section-16.
2) Specific system/steps, conditions and fees payment should be followed.
3) Considerations for registration:
   a) Financial status,
   b) Whether relevant or not,
   c) Whether relevant for public health and/or environment conservation.

2. Animal Disease Rules, 2008

Imposes the functional procedure of "Animal Disease Act, 2005" for its proper implementation.

Rule-18: 1) Specific form to apply for registration.
2) Conditions of Schedule-7 should be fulfilled.
3) Inspection for justifying the information in the application.
4) Registration if conditions are fulfilled.

Rule-19: 1) Duration of registration is 1 year.
2) Application for renewal before 3 months prior to over the duration.
3) If failure, more 3 months is allowed if applied for.

Schedule-7: a) Milk should be free from.
1.2: c) Un-approved harmful chemicals.
d) Residue of antibiotics or pesticides.

3. Fish and Animal Feed Act, 2010

Legal framework for monitoring production, processing, quality control, import, export, marketing, sell, distribution and transportation of fish and animal feed.

Section-2(15): QC Laboratory defines 11 laboratories for testing.

Section-4: Restriction on production/processing/import/export/marketing/sale/distribution/other relevant works without taking license.

Section-10: (1) Restriction on maintaining standard limit of ingredients of feed and (2) cancellation of license if found non-compliant or any harmful component.

Section-11: Govt. will test any feed in the laboratory to ensure quality and take action if non-compliant.

Section-12: Ensure restriction on any feed containing harmful ingredients, non-compliant with standards. So, radiation certificate and fitness certificate of the feed from exporting country must be submitted with shipping documents.

Section-13(4): Ensure listing of name and % of all ingredients on the label.

Section-14: Restriction on using antibiotics, growth hormones, insecticides in the feeds.

Section-15: Empowered for inspection.

Section-16: Empowerment for seizing and destroy of adulterated feed.

4. Animal Feed Rules, 2013

Imposes the functional procedure of "Fish Feed and Animal Feed Act, 2010" for proper implementation.
Rule-3: 1) Application in prescribed form.
2) Fees for application.
Rule-4: 3 categories of License.
Schedule-3: Conditions and list of documents for license.

5. Pesticides Act, 2018

Impose control on Import, production, packing, re-packing, storage, distribution, marketing, advertisement and use of insecticides.
Section-4: Registration is compulsory.
Section-5: Application and registration (also with Section-9 and Section-10)
Section-6: Duration of registration is 3 years.
Section-7: Renewal of registration, application 30 days before ending duration.
Section-19: Formation of Pesticide Technical Advisory Committee to advice the Govt. regarding technical issues.
Section-21: Analyst appointed for testing sample of pesticides.

6. Formalin Control Act, 2015

Impose control on Import, production, transportation, storage, marketing and usage of Formalin and check its miss-handling.
Section-4: Licensing is compulsory.
Section-5: License by the Government for import & production and by concerned DC for transportation, storage, sale and use.
Section-9: Formalin Control Committees: District committee & Upazilla committee.
Section-32: Establishment of laboratories, appointment of analyst and reporting for examining types, quantity, dose & ingredients of Formalin.

7. Formalin (Import, Production, Transportation, Storage, marketing and Use) Control Rules, 2015

Functional procedure of "Formalin Control Act 2015" for its proper implementation.
Rule-3: Import license by MOC, production license by MOI.
Rule-4(1): Prescribed forms for 5 categories of Licenses.
Rule-4(2): Papers required: Nationality certificate/NID/BD/Bank certificate for economic solvency/TIN/TL/Deed copy of Joint stock company/Company papers/Demand assessment report of MOI for production/Design & papers of vehicles for transportation.
Rule-6: Procedure for license.
Rule-7: Duration 1 year.
Rule-14: District Formalin Control Committee: 15 Members
Rule-15: Jurisdiction of District Committee.
Rule-17: Upazilla Formalin Control Committee: 16 Members
Rule-18: Jurisdiction of Upazilla Committee.

List of banned inputs in the Import Policy Order 2015-2018

IMPORT POLICY ORDER 2015-2018
Ministry of Commerce
Government of the People's Republic of Bangladesh

ANNEXURE-1

List of Prohibited Goods
Part-B
The following goods shall not be importable, namely:

(1) Maps. charts and geographical globes which do not indicate the territory of Bangladesh in accordance with the maps published by the Department of Survey, Government of the People's Republic of Bangladesh;

(2) Horror comics, obscene and subversive literature including such pamphlets, posters, newspapers, periodicals, photographs, films, gramophone records and audio and video cassette tapes etc.;

(3) Books, newspapers, periodicals, documents and other papers, posters photographs, films, gramophone records, audio and video cassettes, tapes etc. containing matters likely to outrange the religious feelings and beliefs of any class of the citizens of Bangladesh;

(4) Unless otherwise specified in this order, goods of secondary or sub-standard quality or below ~standard or old, used, reconditioned goods or factory rejects and goods of job-lot/stock-lot;

(5) Reconditioned office equipment, photocopier, type-writer machine, telcx9 phone, and fax, old computer, old computer accessories, old electrolytic goods

(6) Goods (including their containers) bearing any words or inscriptions of any religious connotation the use or disposal of which may injure the religious feelings and beliefs of any class of the citizens of Bangladesh;

(7) Goods (including their containers) bearing any obscene picture, writing inscription or visible representation;

(8) Import of live swine and any item prepared from swine;

(9) All kinds of industrial sludge and fertilizer & any other. products produced from sludge; and

(10) Unless or otherwise specified in this order, all kinds of waste;

(11) Horn up to 75 decibel capacity in order to control sound pollution under the Sound Pollution Control Rules, 2006; and

(12) Following chemical, insecticides and industrial chemicals under the Stockholm Convention on Persistent Organic Pollutants (pops)

Aldrine, Chlordane, DDT, Dielldrin endrin, heptachlor, mirex, toxaphene, hexachlorobenzene, polychlorinated biphenyl (PCB).

List of banned inputs in the legal instruments of DoF

সংক্ষিপ্ত শিরোনাম ।মৎস্যখাদ্য বিধিমালা, ২০১১।

তফসিল-৭: বিধি ৭ দ্রষ্টব্য :

মৎস্যখাদ্যে ক্ষতিকর রাসায়নিক দ্রব্যাদির তালিকা:

Group A:

(1) Anabolizan (Hormones) and prohibited substances:
   a) All stilbens, substances produced from stilbens, their salts and esters.
   b) Steroids, anabolic steroids.

(2) Antibiotics and Pharmacologically active substances
   a) Chloramphenicol
   b) Chloroform
   c) Chlorpromazine
   d) Colchincine
   e) Depsone
   f) Dimefridiazole
   g) Metronidazole
   h) Nitrofurans, Including metabilies
   i) Ronodazone

Group B:

1. **Active Pharmaclogical Substances** (Antibacterial Substances)
   (a) Sulphonamides, All substances belonging to the sulphonamide group:
   (b) Diamino prymidine derivatives: Trimethoprim, Amoxicylin: Ampiciline, Benzylpenicline, Cloxacillin, Dicloxacillin, Oxacillin:
   (c) Quinolones: Flumequine, Sarafloxacin:
   (d) Tetracyclines: Tetracycline, Chlortetraycycline, Oxytetracycline.
2. **Organophospherus Compound:** Azamethiphos, Diazinon, Acephate, Fenitrothion, Malathion, Quinalphos.
3. **Environmental contaminations:** Organochloirnes, DDT, Aldrin, Endrin, Dieldrin, Heptachlor, Endosulphan, PcBs.
4. **Chemical substances:** Lead, Mercury, Cadmium, Chromium, Arsenic
5. **Micotoxin:** Aflatoxin (Group B1, B2, G1, G2)
6. **Antherlmintics:** Flubendazole
7. **Dyes:**
   (a) Malachite green:
   (b) Leucomalachite green:
   (c) Crystal violet
   (d) Leucocrystal violet

তফসিল-৭ (ক) : বিধি ১০ দ্রষ্টব্য:

মৎস্যখাদ্যে এন্টিব্যাক্টেরিয়াল সাবষ্ট্যান্স ও রাসায়নিক পদার্থ ব্যবহার এর গ্রহণযোগ্য মাত্রা সম্বলিত তালিকা যাহা অত্যাবশ্যক প্রয়োজন হেতু ক্ষমতাপ্রাপ্ত কর্মকর্তার লিখিত অনুমতি সাপেক্ষে ব্যবহার করিতে হইবে এবং উক্ত এন্টিব্যাক্টেরিয়াল সাবষ্ট্যান্স ও রাসায়নিক পদার্থ এর অবশিষ্টাংশ (Residue) এর উপস্থিতি পরীক্ষা করিতে হইবে।

১। গ্রুপএ, : স্টীলবিনসএবংতাহারসহযোগীয়লবনওএ্যাস্টারঃ

সাবষ্ট্যান্সের নাম	গ্রহণযোগ্য মাত্রা

ডাই ইথাইল ষ্টীলবেসটারোল	০০ পিপিবি

২। গ্রুপ এ৩ : স্টেরয়েড ও এনাবোলিক স্টেরয়েডঃ

সাবষ্ট্যান্সের নাম	গ্রহণযোগ্য মাত্রা
(ক) টেষ্টোষ্টারোন	০০ পিপিবি
(খ) ১৯ - - নর টষ্টোষ্টারোন	০০ পিপিবি
(গ) ১৭ - - ইষ্ট্রাডায়ন	০০ পিপিবি

৩। গ্রুপ A_6 : নিষিদ্ধ এন্টিবায়োটিক
(ফারমাকোলজিক্যালি একটিভ সাবষ্ট্যান্স)

সাবষ্ট্যান্সের নাম	গ্রহণযোগ্য মাত্রা
(ক) ক্লোরামফেনিকল-	০০ পিপিবি
(খ) ফুরজোলডিন মেটাবোলাইট (AOZ)	০০ পিপিবি
(গ) ফুরালটাডন মেটাবোলাইট (AMOZ)	০০ পিপিবি
(ঘ) নাইট্রোফুরানটয়েন মেটাবোলাইট (AHD)	০০ পিপিবি
(ঙ) নাইট্রোফুরাজন মেটাবোলাইট (SEM)	০০ পিপিবি

৪। গ্রুপ B_1 : এন্টিব্যাক্টেরিয়াল সাবষ্ট্যান্সঃ

সাবষ্ট্যান্সের নাম	গ্রহণযোগ্য মাত্রা
(ক) টেট্রাসাইক্লিন	১০০ পিপিবি
(খ) অক্সিটেট্রাসাইক্লিন	১০০ পিপিবি
(গ)ক্লোরটেট্রাসাইক্লিন	১০০ পিপিবি

৫। গ্রুপ B_2 (এ): এ্যানথালমিনটিক্স (এন্টিহেলমিনটিক্স):

সাবষ্ট্যান্সের নাম	গ্রহণযোগ্য মাত্রা
(ক) ফ্লুবেনডাজোল	০৫ পিপিবি
(খ) মেবেনডাজোল	০৫ পিপিবি

৬। গ্রুপ B_3 (এ): অর্গানোক্লোরাইড পেষ্টিসাইড:

সাবষ্ট্যান্সের নাম	গ্রহণযোগ্য মাত্রা
(ক) অলড্রিন	০.০০৫ পিপিএম
(খ) ডিডিটি	১.০০০ পিপিএম
(গ) হেপ্টাক্লোর	০.০০৫ পিপিএম
(ঘ) এন্ড্রিন	০.০১০ পিপিএম

৭। গ্রূপ বি৩ (সি): কেমিক্যাল ইলিমেন্টঃ

সাবষ্ট্যান্সের নাম	গ্রহণযোগ্য মাত্রা
(ক) লেড	০.০৫ পিপিএস (চিংড়ী)
	০.৩০ পিপিএম (মাছ)
(খ) ক্যাডমিয়াম	০.৫০ পিপিএম (চিংড়ী)
	০.০৫ পিপিএম (মাছ)
(গ) মারকারী	০.৫০ পিপিএম (চিংড়ী ও মাছ)
(ঘ) ক্রোমিয়াক	০.১০ পিপিএম (চিংড়ী ও মাছ)
(ঙ) আর্সেনিক	১.০০ পিপিএম (চিংড়ী ও মাছ)
(চ) কপার	৫.০০ পিপিএম (চিংড়ী ও মাছ)
(ছ) জিং	৫০.০০ পিপিএম (চিংড়ী ও মাছ)

৮। গ্রুপ বি৩ (ডি):

সাবষ্ট্যান্সের নাম	গ্রহণযোগ্য মাত্রা
(ক) আফলাটক্সিনস (গ্রুপ B_1)	২.০০ পিপিবি
(খ) আফলাটক্সিন (গ্রুপ $B_1 B_2$, $G_1 G_1$,)	৪.০০ পিপিবি

৯। গ্রুপ বি৩ (ই): ডাইসঃ

সাবষ্ট্যান্সের নাম	গ্রহণযোগ্য মাত্রা
(ক) ম্যালাকাইট গ্রীন	০০ পিপিবি
(খ) লিউকো ম্যালাকাইট গ্রীন	০০ পিপিবি
(গ) ক্রিষ্টাল ভায়োলেট	০০ পিপিবি
(ঘ) লিউকো ক্রিষ্টাল ভায়োলেট	০০ পিপিবি

সংক্ষিপ্ত শিরোনাম । মৎস্য হ্যাচারি বিধিমালা, ২০১১ :

তফসিল-৩: ধারা -১১:

গ্রুপ- এ : মৎস্য চাষ ও মৎস্য পণ্য উৎপাদনে নিষিদ্ধ ঘোষিত ঔষধ ও রাসায়নিক দ্রব্যের তালিকা

১। স্টীলবিন্স এবং তার সহযোগী লবণ ও এ্যাস্টার (গলদা ও বাগদা হ্যাচারির জন্য উক্ত দ্রব্যাদি পরীক্ষা করতে)

২। স্টেরয়েড

৩। ইসি নির্দেশিক ২৩৭৭/৯০, ২৬ জুন ১৯৯০ এর সংযুক্তি ৪ এ উল্লেখিত ড্রাগসমূহ

(ক) ক্লোরামফেনিকল
(খ) ক্লোরোফর্ম
(গ) ক্লোরো প্রমাজিন
(ঘ) কোলছিসিন
(ঙ) ডেপসন
(চ) ডাইমেট্রিডায়াজল
(ছ) মেট্রোনিডায়াজল
(জ) নাইট্রোফিউরান এবং
(ঝ) রোনোডাজন।

হ্যাচারিতে উপরোক্ত ১, ২ ও ৩ ক্রমিকে বর্ণিত দ্রবাদির উপস্থিতি সম্পর্কে হ্যাচারী মালিক বছরে একবার পরীক্ষা করতঃ তার প্রতিবেদন খামারে সংরক্ষণ করবেন।

গ্রুপ-বি : প্রাণির চিকিৎসার জন্য ব্যবহৃত ঔষধ এবং তার অবশিষ্টাংশঃ

১। এন্টি ব্যাকটেরিয়াল দ্রব্য সমূহ, সালফোনিমাইডস এবং কুইনোলনস

২। (ক) অন্যান্য পশু বা প্রাণীর চিকিৎসায় ব্যবহৃত ঔষধ

(খ) এ্যাসথালমিনটিকস

৩। অন্যান্য দ্রব্য এবং পরিবেশ হতে মিশ্রিত অবশিষ্ঠাংশ-

৩ (এ) P_cB_s সহ অরগানোক্লোরিন যৌগ।
৩ (বি) অরগানো ফসফরাসের যৌগ।
৩ (সি) রাসায়নিক পদার্থ।
৩ (ডি) মাইকোটক্সিন।
৩ (ই) রং।

হ্যাচারিতে উপরোক্ত ৩ (এ), (বি), (সি), (ডি), (ই) ক্রমিকে বর্ণিত দ্রবাদির উপস্থিতি সম্পর্কে হ্যাচারী মালিক বছরে একবার পরীক্ষা করতঃ তার প্রতিবেদন খামারে সংরক্ষণ করবেন

গ্রুপ-সি : মৎস্য চাষে ব্যবহার করা যাইবে এমন ঔষধের তালিকা এবং তাহার ব্যবহার মাত্রা ইউএসএফডিএ এবং এন এফ আই অনুমোদিত)

(২১সিএফআর -৫২২-১০৮১)-

(ক)

ক্র নং	দ্রবণ/যৌগের নাম	ব্যবহার
১।	ক্রোনিক গোনাডোট্রপিন	স্পনিং কার্যক্রম উন্নয়নের জন্য ব্রুড এর ক্ষেত্রে ব্যবহার করা যাইবে। (২১ সিএফআর -৫২২-১০৮১)।
২।	ফরমালিন দ্রবণ	প্রোটোজোয়া এবং মনোজেনেটিক &&ট্রমাটোড এবং ফাংগি (fungi) নিয়ন্ত্রণে ব্যবহার করা যাইবে (২১ সিএফআর -৫২৯-১০৩০)। খাদ্য হিসাবে ব্যবহৃত হইবে এমন কোন মৎস্য বা তাহার মাংসল অংশে ব্যবহার করা যাইবে না।
৩।	ট্রাইকেইন-মিথেন সালফোনেট	ক্যাটফিস, &ট্রাউট, স্যালমন, পাইক, পার্চ এর ক্ষেত্রে খুবই স্বল্প পরিমাণে হ্যাচারীতে ব্যবহার করা যাইবে। ব্যবহারের ২১ দিনের মধ্যে কোন মৎস্য ধরা যাইবে না (২১ সিএফআর -৫২৯-২৫০৩)।
৪।	অক্সিটেট্রাসাইক্লিন	চিংড়ি ও মাছ এর ক্ষেত্রে ব্যবহার করা যাইবে। ব্যবহারের কমপক্ষে ৩০ দিন পর মৎস্য ধরা যাইবে (২১ সিএফআর ৫৫৮- ৪৫০)।
৫।	সালফাডাইমিথোক্সিন বা আরমেট্রপিন যৌগ	চিংড়ি ও মাছ জাতীয় মৎস্যে ব্যবহার করা যাইবে। ব্যবহারের কমপক্ষে ৪২ দিন পর মৎস্য ধরা যাইবে। মৎস্যের মাংসল অংশে এর গ্রহণযোগ্য মাত্রা ০.১ পিপিএম (২১ সিএফআর ৫৫৬- ৬৪০)।

খ) বিভিন্ন রাসায়নিক পদার্থের গ্রহণযোগ্য মাত্রা হ্যাচারিতে নিম্নে বর্ণিত রাসায়নিক দ্রবাদির উপস্থিতি সম্পর্কে হ্যাচারী মালিক বছরে একবার <u>পরীক্ষা করতঃ তার প্রতিবেদন খামারে সংরক্ষণ করবেন।</u>

১. লেড
২. মারকারী
৩. ক্যাডমিয়াম
৪. কপার
৫. আর্সেনিক
৬. জিংক

<u>গ) বিভিন্ন কীটনাশকের গ্রহণযোগ্য মাত্রা</u>

১.	অরগানো -ক্লোরিন	৫০.০ মা.গ্রা./কেজি পানিতে
২.	পিসিবিএস (PCBs)	৫০.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৩.	এলড্রিন	০.০২ মা.গ্রা./কেজি মৎস্যের মাংসে।
৪.	ডিডিটি	২.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৫.	হেপ্টাক্লোর	২.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৬.	ডাইএলড্রিন	২.০ মা.গ্রা./কেজি মৎস্যের মাংসে।

ঘ) বিভিন্ন এন্টিব্যাকটেরিয়াল দ্রব্যের গ্রহণযোগ্য মাত্রা

১.	টেট্রাসাইক্লিন	৫০.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
২.	অক্সিটেট্রাসাইক্লিন	৩০.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৩.	সালফা মিথোক্সিন	২৫.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৪.	সালফা ডাইমিথোক্সিন	২৫.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৫.	সালফা ডায়াজিন	২৫.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৬.	সালফা থায়াজিন	২৫.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৭.	এমোক্সিসিলিন	২৫.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৮.	অক্সিলিনিক এসিড	৫.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
৯.	ডাইফ্লক্সিন	১০.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
১০.	ক্লোরটেট্রাসাইক্লিন	৩০.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
১১.	সালফোনিলামাইডস	৫০.০ মা.গ্রা./কেজি মৎস্যের মাংসে।
১২.	কোইনোলনস	৫০.০ মা.গ্রা./কেজি মৎস্যের মাংসে।

ঙ) রোগ প্রতিরোধে হ্যাচারীতে ব্যবহৃত রাসায়নিক দ্রব্যাদি ও ঔষধপত্রের নাম নিম্নে দেওয়া হলো

1. ব্লিচিংপাউডার (৬০-৬৫% ক্লোরিন)
2. সোডিয়াম হাইপো-ক্লোরাইড (তরল)
3. ফরমালিন (ল্যাব গ্রেড)
4. ফরমালিন (কমার্শিয়াল গ্রেড)
5. সোডিয়াম থায়োসালফেট
6. সোডিয়াম বাই-কার্বনেট
7. অক্সি-টেট্রাসাইক্লিন
8. ট্রেফলন
9. প্রিফুরান
10. ইডিটিএ (Ethylene Di-amino Tetra acetic Acid)
11. এ্যাকোয়াকালচার প্রোবায়ো&&টক্স
12. জুথামসাইড/প্রোটোজোয়াসাইড
13. মিথিলিন ব্লু
14. ভিটামিন প্রিমিক্স/মাল্টিভিটামিন/ভিটামিন-সি
15. এমএস-২২২, চেতনা নাশক
16. কুইনালডিন, চেতনা নাশক
17. কোলভ অয়েল, চেতনা নাশক
18. খাবার লবণ, ছত্রাকনাশক ও জীবাণুনাশক

মৎস্য প্রজননে ব্যবহৃত হরমোন

চ) হরমোন /প্রণোদক

1. প্রাকৃতিক প্রণোদক: পি.জি., এল.আর.এইচ. (L.R.H) এবং এফ.এস. এইচ. (FSH)
2. সিনথেটিক প্রণোদকঃ ওভাপ্রিম, এইচ.সি.জি. (H.C.G), ওভাক্লিন
3. H.C.G. - গ্লাইকোপ্রোটিন, ৪০-১২০ দিনের গর্ভবতী মহিলার প্রস্রাব হতে প্রস্তুতত
4. পি.জি.- মাছের মাথার খুলির মধ্যে থাকে।

List of banned veterinary drugs by DGDA

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা-১২১২
www.dgda.gov.bd

স্মারক নং: ডিজিডিএ/২৯-০২/০৯/৩৩৬৩

তারিখ: ০৭/০৫/২০১৯

বিজ্ঞপ্তি

সর্বসাধারণের অবগতির জন্য জানানো যাচ্ছে যে, Antimicrobial Resistance বাংলাদেশসহ ও সারা বিশ্বের জন্য একটি মারাত্মক সমস্যা। অ্যান্টিবায়োটিকের অযৌক্তিক ও অপব্যবহার রোধকল্পে ইতঃপূর্বে নিষিদ্ধিত অ্যান্টিবায়োটিকসমূহ ঔষধ নিয়ন্ত্রণ অধিদপ্তর ২৫০তম সভা কর্তৃক পুনর্মূল্যায়নপূর্বক প্রদত্ত সুপারিশের ভিত্তিতে প্রাণি ও মানব চিকিৎসায় ব্যবহৃত নিম্নবর্ণিত অ্যান্টিবায়োটিকসমূহের রেজিস্ট্রেশন বাতিলের সিদ্ধান্ত গৃহীত হয়।

প্রাণি চিকিৎসায় ব্যবহৃত রেজিস্ট্রেশন বাতিলকৃত ঔষধের তালিকা:

১. Colistin-এর সকল অভিনেশনের রেজিস্ট্রেশন ।
২. প্রাণি চিকিৎসায় ব্যবহৃত Colistin-এর Single Preparation এর সর্বনিম্ন ১ (এক) লিটার বিশিষ্ট Oral Solution এবং Injectable dosage form ব্যতীত বাকী সকল dosage form এর রেজিস্ট্রেশন ও pack size।
৩. Fosfomycin এর সকল Dosage form এর রেজিস্ট্রেশন।
৪. Ciprofloxacin এর সাথে সকল Combination এর রেজিস্ট্রেশন।
৫. Olaquindox Powder (Vet) -এর রেজিস্ট্রেশন।

৬. প্রাণি চিকিৎসায় ব্যবহৃত নিম্নবর্ণিত ঔষধসমূহের রেজিস্ট্রেশন বাতিল:
ক. Azithromycin,
খ. Amoxicillin Trihydrate+Bromhexine Hydrochloride+Vitamin A,
গ. Amoxicillin Trihydrate + Cyproheptadine Hydrochloride + Guaiphenes + Lysozyme Hydrochloride + Vitamin A

৭. নিম্নোক্ত Veterinary Antibiotic Combination Preparation এর রেজিস্ট্রেশন বাতিল:

SL NO	Generic Name
1.	Amoxicillin 1.25 gm + Cloxacillin 1.25 gm/vial Injection
2.	Amoxicillin Trihydrate 10% + Bromhexine Hydrochloride 2% + Vitamin A 500000 IU/KG Powder
3.	Doxycycline 1 gm + Oxytetracycline 2 gm Powder
4.	Doxycycline 1 gm + Oxytetracycline 2 gm/100 gm Powder
5.	Doxycycline 10% + Neomycin Sulphate 10% Powder
6.	Doxycycline 10% + Oxytetracycline 20% Powder
7.	Doxycycline 10% + Tylosin 20% Powder
8.	Doxycycline 100 mg + Trimethoprim 100 mg/gm Powder
9.	Doxycycline 100 mg + Tylosin 200 mg Sachet
10.	Doxycycline 150 mg + Neomycin Sulphate 150 mg/gm Powder
11.	Doxycycline 20 gm + Tylosin 23 gm/100 gm Powder
12.	Doxycycline Hydrochloride 10% + Gentamicin 10% Powder
13.	Gentamicin 2.5% + Neomycin Sulphate 20% Powder
14.	Gentamicin 3 gm + Sulphadimidine 12.5 gm + Trimethoprim 2.5 gm/100 ml Injection
15.	Neomycin Sulphate 5% + Procaine Penicillin 8.3333% Ointment
16.	Oxyclozanide 1.4 gm + Tetracycline Hydrochloride 2 gm Bolus
17.	Procaine Benzylpenicillin 4 Lac IU + Streptomycin 500 mg/vial Injection
18.	Streptomycin 250 mg + Sulfadiazine 1.583 gm + Sulfadimidine 1.583 gm + Sulfapyridine 1.583 gm Bolus
19.	Streptomycin 313 mg + Sulfadiazine 1.583 gm + Sulfadimidine 1.583 gm + Sulfapyridine 1.583 gm Bolus
20.	Sulfaclozine 300 mg + Vitamin K 20 mg/gm Powder
21.	Sulphachloropyridazine Sodium 100 mg + Trimethoprim 20 mg + Vitamin K .8 mg/gm Powder
22.	Amoxicillin Trihydrate 5% + Cyproheptadine Hydrochloride 1% + Guaiphenesin 3.5% + Lysozyme Hydrochloride 1% + Vitamin A 2500% Powder
23.	Ciprofloxacin 20 gm + Trimethoprim 50 gm Sachet
24.	Erythromycin 50 mg + Sulphadimethoxine Sodium 125 mg + Trimethoprim 25 mg/ml Injection
25.	Guaiphenesin 1.8% + Roxithromycin 1% + Tylosin 1% Powder
26.	Kanamycin 10000 IU/gm + Rofaxanide 2% Powder
27.	Loperamide 1 gm + Norfloxacine 25 gm + Trimethoprim 25 gm + Zinc Oxide 20 gm/KG Oral Powder

৮. নিম্নোক্ত Human Fixed Dose Antibiotic combination এর রেজিস্ট্রেশন বাতিল:
1. Benzyl Penicillin 1 Lac IU + Procaine Penicillin 3 Lac IU Injection
2. Benzyl Penicillin 2 Lac IU + Procaine Penicillin 6 Lac IU Injection

মেজর জেনারেল মোঃ মোস্তাফিজুর রহমান
মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর
ফোনঃ ৯৮৮০৮০৩
E-mail: dgda.gov@gmail.com

Sample NOC issued by DoF

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
মৎস্য অধিদপ্তর,বাংলাদেশ
মৎস্য ভবন, রমনা, ঢাকা
www.fisheries.gov.bd

পত্র নং : ৩৩.০২.০০০০.১২০.০৭.০০৭.১০(৫ম খণ্ড)- ৫৮৪ তারিখঃ ০৬/০৭/২০১৯ খ্রি.

বিষয় : চিংড়ি পোনার খাদ্য আমদানির অনাপত্তি পত্র প্রদান প্রসংগে।

সূত্র - ০১ : মৎস্য ও প্রাণিসম্পদ মন্ত্রণালয়ের পত্র নং-৩৩.০০.০০০০.১১৮.১৬.৪৪৫.১৬-৩৫০, তারিখ : ১৮/০৫/২০১৭ খ্রি.

সূত্র -০২ : এম কে হ্যাচারী এর ০২/০৭/২০১৯খ্রি. তারিখের পত্র নং-MKA 13/06/2019।

উপর্যুক্ত বিষয় ও সূত্রের প্রেক্ষিতে নির্দেশক্রমে জানানো যাচ্ছে যে, সরকারের প্রচলিত আমদানির বিধি বিধান অনুসরণপূর্বক এসআরও নং-২১৪-আইন/২০১৭/৫২/কাস্টমস, তারিখ-০১/০৭/২০১৭খ্রি.মোতাবেক উল্লিখিত GOLD ADVANCE PRAWN FEEDS চিংড়িখাদ্য আমদানির বিষয়টি বিবেচনা করা যেতে পারে।

আমদানিযোগ্য পণ্য

ক্রঃ নং	পণ্যের নাম	উপাদানের নাম	উল্লিখিত পণ্য উৎপাদনে ব্যবহৃত উপকরণের নাম	ইনভয়েস নং ও তারিখ :	উৎপাদনকারী দেশ	প্যাক সাইজ (কেজি/প্যাক)	পরিমান (কেজি)
1	GOLD ADVANCE PRAWN FEEDS	Crude protein-39.12%, Moisture-9.67%, Ash-8.42%, Crude fat-7.05%, Crude fiber-1.40%	Fish meal, Squid liver powder, Soybean meal, Wheat flour, Vitamins, Minerals, Preservatives	Invoice no -MKA/001/2019-GCST, Date 27.06.2019, H.S. Code no-2309.90.90	Thailand	820bagx25kg	20,500
						Total=	20,500

শর্তাবলীঃ

১। সরকারের প্রচলিত আমদানির বিধি-বিধান মোতাবেক শুল্ক বিভাগ কর্তৃক আরোপিত শুল্ক পরিশোধের প্রমাণক মৎস্য অধিদপ্তরে অবশ্যই দাখিল করতে হবে।

২। আমদানিকৃত পণ্য খালাসের পূর্বে সংশ্লিষ্ট জেলা মৎস্য কর্মকর্তা/উপজেলা মৎস্য কর্মকর্তার উপস্থিতিতে আমদানিকৃত পণ্যের নমুনা সংগ্রহ করে ক্ষতিকররেসিডিউ এর উপস্থিতি ও জীবাণুমুক্ততা এবং পুষ্টিমান সম্পর্কে সরকার কর্তৃক অনুমোদিত ল্যাবরেটরিতে পরীক্ষাপূর্বক প্রতিবেদন অত্র দপ্তরে দাখিল করতে হবে। এ সংক্রান্ত সকল ব্যয়ভার সংশ্লিষ্ট আমদানিকারক/স্বত্বাধিকারী বহনকরবেন।

৩। আমদানিকৃত মৎস্য খাদ্য এন্টিবায়োটিক, Pesticide, টোমারী উপজাত, মেলামিন, শূকর এবং প্রানিজ উপজাত (Procine and Bovine)মুক্ত হতে হবে।

৪। আমদানিকৃত পণ্যটি মৎস্য অধিদপ্তরের দায়িত্বপ্রাপ্ত কর্মকর্তার উপস্থিতিতে গুদামজাত করতে হবে।

৫। আমদানিকৃত পণ্যটি মৎস্যচাষে ব্যবহারের জন্য কোথায় কি পরিমান সরবরাহ করা হয়েছে তার প্রতিবেদন যথাযথ কর্তৃপক্ষের মাধ্যমে মৎস্য অধিদপ্তরে প্রেরণ নিশ্চিতকরতে হবে।

৬। আমদানিকৃত পণ্য অবশ্যই মৎস্য উৎপাদনে ব্যবহার করতে হবে।

৭। আমদানিকৃত পণ্যের প্যাকেটের গায়ে পণ্যের নাম, পণ্যের উপাদানসমূহ, কোম্পানী, উৎপাদনকারী দেশের নাম(Country of Origin) ও উৎপাদনে তারিখ স্পষ্টাকারে উল্লেখ থাকতে হবে।

৮। আমদানিকৃত পণ্য রিপ্যাকিং করা যাবে না।

৯। আমদানির নিমিত্ত এই এনওসি ১ (এক) বৎসর বলবৎ থাকবে।

১০। পণ্য আমদানি সংক্রান্ত কোন ভুল/অসত্য তথ্য প্রদানের দায়-দায়িত্ব আমদানিকারক প্রতিষ্ঠান বহন করবে।

১১। কর্তৃপক্ষ ইচ্ছা করলে আমদানিকৃত পণ্যের যে কোন ধরনের পরীক্ষা করতে পারবেন।

১২। ভুল/অসত্য তথ্য প্রদানের পাশাপাশি কোন তথ্য গোপন করা হলে ইস্যুকৃত NOC বাতিলসহ ভবিষ্যতে এ ধরনের NOC প্রদান স্থায়ীভাবে বন্ধ করা হবে।

১৩। উপরোক্ত শর্তগুলো পালনে ব্যর্থ হলে এবং এতদসংক্রান্ত অন্যান্য সরকারি বিধি বিধান অনুসরণ করা না হলে NOC বাতিল বলে গণ্য হবে।

মহাপরিচালকের পক্ষে
০৬/৭/১৯
(ড. মো: জিল্লুর রহমান)
উপপরিচালক (মৎস্যচাষ)
ফোন:০২-৯৫৬১৫৯২
ই-মেইলঃ ddaqua@fisheries.gov.bd

জনাব মঈন উদ্দিন আহমদ
প্রোপাইটর,
এম কে এ হ্যাচারী
বাড়ি নং:নি/১৭৫, রোড নং:২৩ , নিউএইচ এস , মহাখালি, ঢাকা-১২০৬ ।
হ্যাচারী: সোনারপাড়া হ্যাচারী জোন, জালিয়াপালং , উখিয়া, কক্সবাজার ।

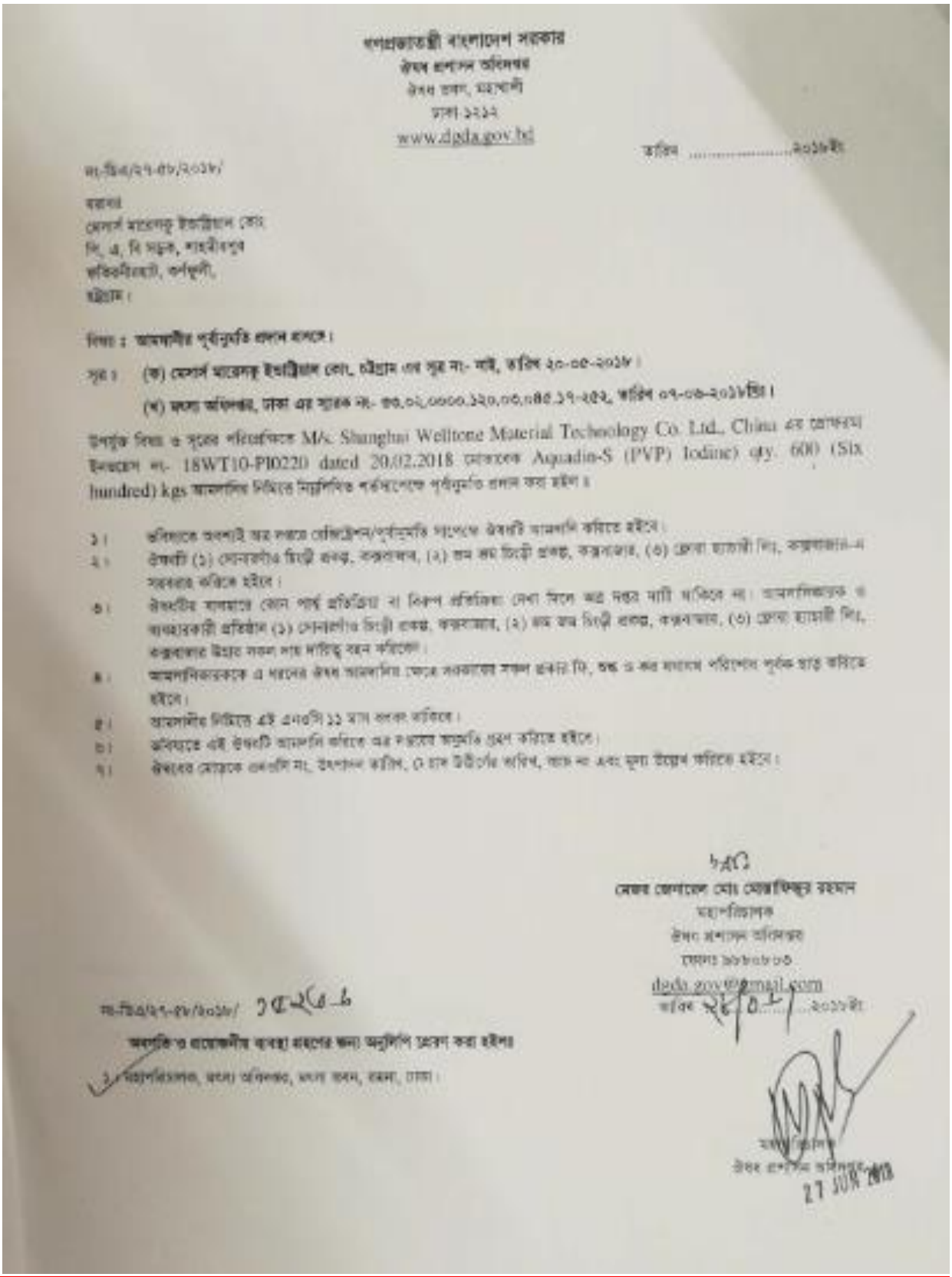
পত্র নং : ৩৩.০২.০০০০.১২০.০৭.০০৭.১০(৫ম খণ্ড)- ৫৮৪/১ (৪) তারিখঃ ০৬/০৭/২০১৯ খ্রি.

সদয় অবগতি ও কার্যার্থে অনুলিপি প্রেরণ করা হলোঃ

১। কমিশনার (কাস্টমস), কাস্টমস হাউজ, চট্টগ্রাম বন্দর, চট্টগ্রাম।
২। উপপ্রধান, আইসিটি শাখা , মৎস্য অধিদপ্তর , মৎস্য ভবন , ঢাকা (ওয়েব সাইটে প্রকাশের অনুরোধ করা হলো)।
৩। জেলা মৎস্য কর্মকর্তা, সদর, কক্সবাজার অথবা তার মনোনীত প্রাথী (পণ্য খালাস ও নমুনা পরীক্ষার নিমিত্ত কাস্টমস এর চাহিদামত স্থলবন্দরে উপস্থিত থাকা ও গুদামজাতকরণের পরিদর্শন ও নমুনা পরীক্ষার প্রতিবেদন প্রেরণ নিশ্চিত করবেন)।
৪। দপ্তর নথি।

০৭/০৭/২০১৯
(মো: জুয়েল শেখ)
প্রধান মৎস্য সম্প্রসারণ কর্মকর্তা
ফোনঃ ০২-৯৫৬৭২২০
ই-মেইলঃ cfeo@fisheries.gov.bd

Sample NOC issued by DGDA



গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী
ঢাকা-১২১২
www.dgda.gov.bd

তারিখ .....২০১৮ইং

নং-ডিএ/২৭-৪৮/২০১৮/

বরাবর
মেসার্স শাহেদস্থ ইন্টারন্যাশনাল কোং
দি, এ, বি সড়ক, শহীদবন্দর
ফতিকন্দিরহাট, বন্দরপুর,
চট্টগ্রাম।

বিষয় : আমদানীর পূর্বানুমতি প্রদান প্রসঙ্গে।

সূত্র : (ক) মেসার্স শাহেদস্থ ইন্টারন্যাশনাল কোং, চট্টগ্রাম এর সূত্র নং- নাই, তারিখ ২০-০৫-২০১৮।

(খ) ফরম অধিদপ্তর, ঢাকা এর স্মারক নং- ৩৩.০২.০০০০.১২০.০৩.০৪৫.১৭-২৫২, তারিখ ০৭-০৬-২০১৮ইং।

উপরোক্ত বিষয় ও সূত্রের পরিপ্রেক্ষিতে M/s. Shanghai Welltone Material Technology Co. Ltd., China এর প্রোফরমা ইনভয়েস নং- 18WT10-PI0220 dated 20.02.2018 মোতাবেক Aquadin-S (PVP Iodine) qty. 600 (Six hundred) kgs আমদানির নিমিত্তে নিম্নলিখিত শর্তাধীনে পূর্বানুমতি প্রদান করা হইল।

১। তালিকাভুক্ত অথবা অত্র দপ্তরে রেজিস্ট্রেশন/পূর্বানুমতি গ্রহণপূর্বে ঔষধটি আমদানি করিতে হইবে।
২। ঔষধটি (১) সোনারগাঁও ডিস্ট্রী প্রকল্প, কক্সবাজার, (২) রূপ রস ডিস্ট্রী প্রকল্প, কক্সবাজার, (৩) ক্রোকা হাসানী লিঃ, কক্সবাজার-এ সরবরাহ করিতে হইবে।
৩। ঔষধটির ব্যবহারে কোন পার্শ্ব প্রতিক্রিয়া বা বিরূপ প্রতিক্রিয়া দেখা দিলে অত্র দপ্তর বরাবর লিখিতে হবে। আমদানিকারক ও ব্যবহারকারী প্রতিষ্ঠান (১) সোনারগাঁও ডিস্ট্রী প্রকল্প, কক্সবাজার, (২) রূপ রস ডিস্ট্রী প্রকল্প, কক্সবাজার, (৩) ক্রোকা হাসানী লিঃ, কক্সবাজার উহার সকল দায় দায়িত্ব বহন করিবেন।
৪। আমদানিকারককে এ ধরণের ঔষধ আমদানির ক্ষেত্রে সরকারের সকল রুলস লিঃ, শুল্ক ও কর যথাযথ পরিশোধ পূর্বক ছাড় করিতে হইবে।
৫। প্রদানকৃত লিটারে এই এলসি ১১ মাস বলবৎ থাকিবে।
৬। ভবিষ্যতে এই ঔষধটি আমদানি করিতে অত্র দপ্তরের অনুমতি গ্রহণ করিতে হইবে।
৭। ঔষধের মোড়কে এলসি নং, উৎপাদন তারিখ, ও হার উল্লেখের অধিক, ব্যাচ নং এবং মূল্য উল্লেখ করিতে হইবে।

মেজর জেনারেল মোঃ মোস্তাফিজুর রহমান
মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর
ফোনঃ ৯৮৮৪৮৬৩
dgda.gov@gmail.com
তারিখ ২৪/৬/২০১৮ইং

নং-ডিএ/২৭-৪৮/২০১৮/ ৩৫২৫-৮

অবগতি ও প্রয়োজনীয় কার্যক্রম গ্রহণের জন্য অনুলিপি প্রেরণ করা হইলঃ

১। মহাপরিচালক, ফরম অধিদপ্তর, ফরম ভবন, রমনা, ঢাকা।

27 JUN 2018

Sample NOC issued by DLS

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
প্রাণিসম্পদ অধিদপ্তর
কৃষি খামার সড়ক, ফার্মগেট, ঢাকা-১২১৫।
www.dls.gov.bd

স্মারক নং- ৩৩.০১.০০০০.১১১.২২৩৭ তারিখ-২৪/১০/২০১৮ইং।

প্রাপক

মারেসকু ইন্ডাষ্ট্রিয়াল কোং
পি.এ.বি. সড়ক, শাহমীরপুর,
ফকিরনীরহাট কর্ণফুলী, চট্টগ্রাম।

বিষয়ঃ- পশুখাদ্য/ভেটেরিনারি ঔষধ সামগ্রী আমদানির অনাপত্তি সনদ (NOC) প্রদান প্রসঙ্গে।

উপর্যুক্ত বিষয়ে আপনার ১৯/০৯/২০১৮ইং তারিখের আবেদনের প্রেক্ষিতে পশুপুষ্টি উপকরণ ও ভেটেরিনারি ঔষধ সামগ্রী আমদানি অনাপত্তি সনদ (NOC) প্রদান কমিটির ০৭/১০/২০১৮ তারিখের সভার সিদ্ধান্ত মোতাবেক নিম্নবর্ণিত পণ্য বর্ণিত শর্তসাপেক্ষে China থেকে আমদানির জন্য অনাপত্তি সনদ প্রদান করা হল।

আমদানিযোগ্য পণ্য

ক্র: নং	পণ্যের বিবরণ	প্রফরমা ইনভয়েস নং	তারিখ	উৎপাদনকারী দেশ	প্যাক সাইজ	পরিমান
1.	Yeast Beta Glucan (G 100)	GSY1809063	10/09/2018	China	25kg	25 kg
2.	Yeast Beta Glucan (G 80)			Do	25kg	75 kg
3.	Yeast Beta Glucan (G 20)			Do	25kg	250 kg
4.	Vitamite			Do	25kg	25 kg
5.	Vitamax			Do	25kg	50 kg
6.	Ascorbic Acid			Do	25kg	200 kg

শর্তাবলীঃ-

১। আমদানিতব্য পণ্য অবশ্যই পোল্ট্রিখাদ্য/পশুখাদ্য হিসেবে ব্যবহার করতে হবে।
২। কমিটির সদস্যগন ও ক্ষমতাপ্রাপ্ত কর্মকর্তা কর্তৃক সময় সময় ওয়ার হাউজ, ব্যবসা প্রতিষ্ঠান ও বাজার পরিদর্শনে এবং বিধিমোতাবেক ব্যবস্থা গ্রহণে প্রয়োজনীয় সহযোগীতা করতে হবে।
৩। আমদানিতব্য পণ্য রিপ্যাকিং করা যাবে না এবং পশুখাদ্য/পোল্ট্রি খাদ্য ব্যতীত অন্য কোনভাবে ব্যবহার করা যাবে না।
৪। এই ছাড়পত্রের মেয়াদ ইস্যুর তারিখ হতে **১ (এক) বৎসর** পর্যন্ত বলবত থাকবে।
৫। সরকারের প্রচলিত আইনের ব্যত্যয় ঘটলে NOC বাতিল বলে গন্য হবে এবং আইন অনুযায়ী ব্যবস্থা গ্রহণ করা হবে।
৬। পশুখাদ্য বিধিমালা-২০১৩ এবং আমদানি নীতি আদেশ ২০১৫-২০১৮ এর ধারা ১৭ তে উল্লেখিত বিষয়াদি অনুসরণ করতে হবে।

(ড. মোঃ আবু সুফিয়ান) ২৪/১০/১৮
সহকারী পরিচালক (প্রাণিস্বাস্থ্য ও প্রশাসন)
পক্ষে, মহাপরিচালক
প্রাণিসম্পদ অধিদপ্তর, বাংলাদেশ, ঢাকা।
ফোন-০২-৯১১৫৯৬৮
e-mail:adhealthdls@gmail.com

অনুলিপিঃ-

১। কমিশনার, কাস্টমস হাউস, চট্টগ্রাম, বাংলাদেশ।
২। সহকারী পরিচালক, প্রাণিসম্পদ কোয়ারেনটাইন স্টেশন, চট্টগ্রাম, বাংলাদেশ।
৩। সভাপতি, এ্যানিমেল হেলথ কোম্পানিজ এসোসিয়েশন অব বাংলাদেশ (আহকাব), সেন্টার পয়েন্ট, ইউনিট-১২ ডি, ১৪/এ, তেজকুনীপাড়া, ফার্মগেট বা/এ, তেজগাঁও, ঢাকা-১২১৫।

Annexure-9

Sample Export/Import License issued by DoF

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
জেলা মৎস্য কর্মকর্তার কার্যালয়
মোটেল রোড, কক্সবাজার।

ফরম-৪
[বিধি-৩ দ্রষ্টব্য]

মৎস্যখাদ্য উৎপাদন ও প্রক্রিয়াজাতকরণ/মৎস্যখাদ্য আমদানি ও রপ্তানি/মৎস্যখাদ্য সংরক্ষণ ও বিক্রয় এর

লাইসেন্স

১। লাইসেন্স নম্বর ঃ ম.খা.আ/কক্স-২৮, প্রদানের তারিখ ঃ ২৪/১১/২০১৫ খ্রিঃ।

২। ব্যক্তি/প্রতিষ্ঠানের নাম ঃ এগ্রোকেয়ার লিমিটেড।
হোটেল সি-ভিউ, হলিডে মোড়, কক্সবাজার।

৩। ব্যক্তি/প্রতিষ্ঠানের ধরন ঃ ব্যক্তি মালিকানাধীন।

৪। ব্যক্তি/প্রতিষ্ঠানের স্বত্বাধিকারীর তথ্যাদি ঃ

(ক) নাম ও পদবী ঃ জুবায়ের আবদুল্লাহ জামান, ব্যবস্থাপনা পরিচালক।

(খ) পিতার নাম ঃ মরহুম চৌধুরী নাদেরুজ্জামান।

(গ) মাতার নাম ঃ মনোয়ারা।

(ঘ) বর্তমান ঠিকানা ঃ হোটেল সি-ভিউ, হলিডে মোড়, কক্সবাজার।

(ঙ) স্থায়ী ঠিকানা ঃ ১২৭/২, শাহ আলী বাগ, মীরপুর-১, ঢাকা-১২১৬।

৫। লাইসেন্সের ক্যাটাগরি ঃ ক্যাটাগরি-২ (মৎস্যখাদ্য উপকরণ আমদানি, রপ্তানি ও সংরক্ষণ)।

৬। বার্ষিক মৎস্যখাদ্য আমদানি-রপ্তানির পরিমাণ ঃ ২,০০০ (দুই হাজার) মে.টন।

৭। লাইসেন্সের মেয়াদ ঃ ০১/০৭/২০১৫ খ্রিঃ হইতে ৩০/০৬/২০১৬ খ্রিঃ পর্যন্ত।

তারিখ ঃ ২৪/১১/২০১৫খ্রিঃ।

ক্ষমতাপ্রাপ্ত কর্মকর্তার নাম, পদবী ও স্বাক্ষর
(সীলমোহর)

প্রযোজ্য শর্তাবলী ঃ

১। লাইসেন্স হস্তান্তরযোগ্য নহে।

২। লাইসেন্স গ্রহীতা মৎস্য খাদ্য ও পশুখাদ্য আইন, ২০১০ এবং মৎস্য খাদ্য বিধিমালা, ২০১১ মানিয়া চলিতে বাধ্য থাকিবেন।

নবায়ন ঃ

নবায়নের মেয়াদ			নবায়নের তারিখ	ক্ষমতাপ্রাপ্ত কর্মকর্তার নাম, পদবী ও স্বাক্ষর
হইতে	পর্যন্ত			
		নবায়ন করা হইল		
		নবায়ন করা হইল		
		নবায়ন করা হইল		
		নবায়ন করা হইল		

Annexure-10

Details on Focus Group Discussions (FGD) and Key Informants Interviews (KII)

A. List of Focus Group Discussions (FGD)

No	FGD No.	Participants	Venue	Date
1.	FGD-1	Officers from Department of Livestock (DLS), importers and distributors of aqua-inputs(mainly for shrimp sub-sector), aqua-input users (members of SHAB and shrimp hatchery owners), representatives from Chemist and Druggist Association.	Office of the Aqua Supplier's Association, Hotel Saikat, Main Road, Cox's Bazar.	20/07/2019
2.	FGD-2	DG, DoF, DD (Aquaculture), DD (Shrimp), Assistant Chief (Shrimp), Assistant Director (Legal), Senior Asst. Director (FIQC), Chief Fisheries Ext. Officer and other Officers of DoF	Matshya Vaban, DoF, Dhaka.	28/08/2019.
3.	FGD-3	President, BAPCA, Secretary General, BAPCA, Joint Secretary, BAPCA, Member, BAPCA and the members of BSFF-FtF-BANA Team.	BSFF Conference Room, Bonani, Dhaka.	10/10/2019.
4.	FGD-4	Officers of Department of Agriculture Extension (DAE)	Office of the Deputy Director (Import), Plant Quarantine Wing, DAE, Khamar bari, Farm gate, Dhaka.	23/10/2019.
5.	FGD-5	Assistant Directors of DGDA, Assistant Chief of DGDA, Superintendent of Drags at DGDA, Government Analysts of DGDA	Office of the Directorate General of Drug Administration (DGDA), Mohakhali, Dhaka.	29/10/2019.

B. List of Key Informants Interviews (KII)

No	No. of KII	Name of the Participants	Organization	Date
1.	KII-1	Zubaier A Jaman	Agrocare Ltd, Dhaka.	29/07/2019
2.	KII-2	Md. Kamal Uddin	ABESTA, Chittagong.	12/09/2019
3.	KII-3	Md. Jahangir, Customs	Customs House, Chittagong.	15/09/2019
4.	KII-4	Dr. Pallab Kumar Datta	DLS, Dhaka.	23/10/2019

Annexure-11

Guidelines used for FGDs

Work on policy consolidation, improvement in licensing, management process and effective use of aqua inputs.

Implemented by: Feed the Future (FtF) Bangladesh Aquaculture and Nutrition Activity (BANA)- BSFF Component.

Bangladesh Shrimp and Fish Foundation (BSFF)
House # 3, Level # A5, Road # 4, Block # F, Banani, Dhaka-1213

Name of the Organization:…….……

Date of Discussion:……Time:……..……..

For purpose of facilitation of FGD the following broad questions may be discussed:

Q-1: Are you aware that with modernization of the aquaculture sector grass rout level farmers are using aqua inputs of various types and commercial sellers and major suppliers are marketing them? Can you share your assessment on the nature of growth in the use of aqua-inputs in Bangladesh?

Q-2: Locate roles does your organization play in monitoring the use of these aqua-inputs and what are the regulatory instruments do you use for the purpose?

1. Aqua inputs.
2. Aqua medicines.
3. Drugs/Antibiotics.
4. Probiotics/Prebiotics.
5. Disinfectants/Sterilizers.
6. Other aqua chemicals.
7. Growth Hormones/Growth Stimulators/Growth promoters.
8. Insecticides/Pesticides.
9. Feed ingredients.
10. Feed additives.
11. Others……

Q-3: Can you share your organization's precise role with uproots to the followings?

1. Licensing for manufacture.
2. Licensing for Importation/Exportation.
3. NOC for importation.
4. Distribution (Dealership/Retailer ship).
5. Marketing.
6. Storage.
7. Testing of the commodities (parent component/Residue).

Q-4: What role does your organization/department play in the licensing process of importation of the aqua medicine's drugs?

Q-5: What is the Legal basis of your organization's work (Please name the corresponding Act/Rule/Regulation/Policy).

1. ……
2. ……
3. ……
4. ……
5. ……

Q-6: What are the Legal provisions in rules and regulations Act/Rule/Regulation/Policies?

Q-7: Are there any standard list of permissible products/inputs/ingredients in the regulations?

Q-8: If there is no such standard list, then how do you process the request for NOC/Permission?

Q-9: Do you have standardized forms/formats for issuing license/NOC or any related work or purpose?

Q-10: Does your organization issue any NOC/permission to import any Aqua inputs?

Q-11: Name the types of inputs for which your organization issue NOC/permission for importation Aqua inputs.

Q-12: Do you have any list of banned aqua inputs which you take into account before issuing the NOC/license?

Q-13: If there is such a list, please give the details.

Q-14: Are there any standard list of products/ingredients specific for particular species of fish/shrimp farming (applicable for DoF only)?

Q-15: If there is no species-specific product, are these equally beneficial for generalized use (applicable for DoF only)?

Q-16: Are there products which are commonly used in human/crop/livestock/aquaculture for which you are also giving license/NOC? Please name them.

Q-17: What are the specific pre-requisites needed by your organization for issuance of NOC and licenses?

1. ---------
2. ---------
3. ---------

Q-18: Does your organization requires "pre-tests of the aqua-inputs" prior to issuance ofNOC?

Q-19: If the response to above question is affirmative, then which labs are preferred or referred by you for testing?

Q-20: Does your organization have own testing laboratory to conduct the required tests?

Q-21: Do you carry out any random check for monitoring of the aqua-inputs?

Q-22: Do the Bangladesh regulatory instruments have specific requirements for monitoring and surveillance of product quality in the regulation?

Q-23: Mention the specific provision for compliance criteria for importers/dealers/retailers in marketing chain.

Q-24: What are the limitations in the existing Acts, Rules and Regulations with which you are working with? Do you think that, present laws, acts, rules and regulations are sufficient to meet the presentrequirement?

Q-25: Do you have any suggestion for improvement for present legal instruments?

Q-26: Is there any focal point or designated official in your dept. working on aqua inputs?

Q-27: Do you have any coordination with other departments/organizations also dealing with aqua-inputs?

Q-28: If yes, what are the arrangements for coordination and how effective is the correlation mechanism?

Q-29: Do you have regular coordination meetings with other concerned ministries, Departments and Govt. agencies in preparing and updating the list and using them for enforcement purposes?

Q-30: Have you any concrete suggestion for capacity building and institutional strengthening for your dept. to be able to deal with aqua inputs?

1. Training
2. Funding
3. Manpower
4. Up-dating regulations
5. -------------------------

THE END