Department of Fisheries
&
Better Works and Standards (BEST)

Training Program to Field Officers

Interpretation Guidelines

on

National Residue Control Plan (NRCP) Implementation, monitoring and corrective action

National Residue Control Plan- Training manual

2012

Objective

The objective of this training module is to provide the information required for those who are responsible for developing, coordinating, implementing or reporting of NRCP. This gives detailed procedures and guidance on how this can be achieved as stated in yearly NRCP Policy Guidelines..

Participants

Officers of LCA and RCA who are responsible for developing, coordinating, implementing or reporting of NRCP

Background info

Like many developing countries, Bangladesh exports of majority of fish and fishery products to EU. This generates much required foreign exchange revenues and provides employment for rural populations. In order to export fishery products to EU markets, exporting country has to fulfill many requirements or conditions put forth by EU. These exporting countries need to fulfill these requirements to a level at least equivalent to those required within the EU member states (this is called equivalency).

In recent years Bangladesh has implemented seafood control systems like Good Manufacturing Practice (GMP) and Hazard Analysis Critical Control Point (HACCP). But during last few years we have been facing increased presence of chemical contamination in fishery products from either the environment or the use of chemicals to promote growth and health of aquaculture products. This is becoming a major concern for regulators.

EU had issued many Rapid Alert Notifications for many consignments from Bangladesh due to chemical contamination of fishery products, particularly banned drugs and their metabolites. These rapid alert notifications have a significant economic impact for individual exporters, not only with respect to destroyed product, but also loss of customer confidence.

Subsequent to these notifications, Bangladesh has taken many steps such as:

- imposed 100% pre-export testing, self ban for 6 months,
- implementation of NRCP,
- increased monitoring,
- New legislation

Importance of NRCP

To have better access to global markets, it is necessary to meet specific requirements at different points in the supply chain as per EU Directives. To access to EU markets, exporting countries must have proper framework for monitoring and reporting of residues in aquaculture products. Here the 'monitoring' refers to NRCP.

The objective of the National Residue Control Plan is to verify that the appropriate controls and practices are employed to ensure that harmful pharmacologically active or other substances do not enter the food chain from aquaculture products, therefore protecting consumer safety and meeting the requirements of export markets.

As per EU Directive 178/2002/EC the primary responsibility for ensuring the product safety lies with the companies that process fishery products for export, and those persons who handle process or store the product. Then the government or Competent Authority is responsible for verifying that appropriate control measures are implemented by the industry throughout the supply chain to ensure product safety.

Consignments of food which contain residues in excess of EU Maximum Residue Limits (MRLs) for veterinary medicines, Maximum Residue Levels (MRLs) for pesticides and Maximum Levels (MLs) for contaminants e.g. heavy metals, dioxins, etc, or contain residues of substances which do not have a Community MRL or ML may not be legally placed on the EU market and will be rejected.

NRCP means not only sampling and testing of products from various points of supply chain. The final objective of NRCP is to find the source of contaminants and residues and take action to "**prevent"** the entry of those substances into supply chain. No NRCP, No EXPORT.

What are contaminants and residues? How do these contaminants or residues come into the product?

Contaminants in fisheries products refer to hazardous compounds that have found their way into edible parts of the fish or shrimp through polluted water, sediment or the food chain. Typical contaminants are heavy metals such as lead, mercury and cadmium, and organic compounds such as dioxins, PCBs, and pesticides. These chemical contaminants are either non-degradable or highly resistant to breakdown in the environment and their occurrence in fishery products can be unsafe for the consumer.

In most cases contamination is not related to the post harvest handling or processing of the product; rather it is caused by the environmental conditions and treatments to which fishery products are exposed to during their growth, in a farm.

Residues or Pharmacologically active substances may be present in aquaculture products due to various reasons:

- The use of veterinary drugs to control disease;

- Feeds contaminated with these substances either during their manufacture or as a result of using ingredients of animal origin that contain pharmacologically active substances;
- Approved feed additives used to increase growth rates may contain undeclared pharmacologically active substances;
- The illegal use of pharmacologically active substances to increase growth.

Primary objectives of NRCP

The overall objectives of a NRCP plan are

- To produce aquaculture products without any residues of pharmacologically active substances that are harmful to the consumer;
- To have control measures on the supply and use of medicines and pharmacologically active substances;

Specific objectives are:

- To detect illegal use of substances in animal production (hormones, banned subs)
- To detect misuse of authorized veterinary medicinal products
- To control on environmental pollutants
- To implement actions to minimize repeated occurrence of all such residues and contaminants in food

Ultimate objective: To protect consumer health

NRCP Legal background from EU's perspective

Legislation on the control of food in general can be found in a variety of EU legislation on food. **Directive 96/23/EC** ('Residue Control Directive') contains specific requirements in particular for the control of pharmacologically active substances that may be used as veterinary medicinal products in food producing animals (including fish and shrimp). The main purpose of Directive 96/23/EC is to provide an effective and uniform system for the monitoring and control of illegal substances or incorrect use of authorized substances in animal products intended for human consumption. Major requirements of this regulation are:

- Specific enforcement measures to be taken by countries in the case of noncompliant results- investigations on farms, restrictions to the sale of animals;
- Planned sampling and analysis, according to national control plans;
- Provisions related to the authorization of VMPs

Articles 11 to 13 of Regulation 178/2002/EC (Food Law) require that food and feed imported into the EU "shall comply with the relevant requirements of food law or conditions recognized at least equivalent thereto or, where an agreement exists between the EU and the exporting country, with requirements contained therein".

NRCP Legal background from Bangladesh's perspective

Legal basis of national residue monitoring program lies with National legislations namely:

- Fish and Fish Products (Inspection and Quality Control) Ordinance, 1983 (Ord. No. XX of 1983),
- Fish and Fish Product (Inspection and Quality Control) Rules, 1997
- Fish and Fish Product (Inspection and Quality Control) Rules, 1997 (amendment 2008)
- Fish and Fish Product (Inspection and Quality Control) Rules, 2010 (draft)
- Policy Guideline for NRCP (DoF)

What are included in NRCP?

This includes mainly control and monitoring of residues and contaminants in fish and fishery products and at their primary production.

- Residues or pharmacologically active substances: substances that are unwanted traces of medicines or plant protection products or derivatives thereof which remain in the final product.

- Contaminants: Contaminants are substances that can unintentionally enter food during its production or marketing. These can include environmental pollutants, such as dioxins and heavy metals.

Can the presence of residues and contaminants be avoided?

- Residues of substances can be avoided by not using the substance in animal/fish production- Examples: Banned drugs such as Nitrofurans and Chloramphenicol, banned harmones, stilbenes, etc.
- Residues of substances can be avoided by not misusing the substances- Examples: many antibiotics are permitted in aquaculture in Bangladesh, like Tetracyclines. When these are used, the farmers should follow withdrawal period as specified in legislation; if such withdrawal periods are not followed before harvest, higher levels of such substances can be found in products.
- Contaminants are difficult to exclude entirely due to the background level of pollution in the environment. However, responsible means of aquaculture can avoid occurrence of such contaminants.

- "Prevention is better than cure"

The substance groups that are monitored in NRCP:

The Directive 96/23/EC lists those substance groups which have to be tested for in each species. Substances are divided into two main groups:

- Group A – banned or prohibited substances and
- Group B – authorized veterinary medicines and contaminants.

Group A
These substances are not permitted for use in any animals that may enter the food chain (Directive 96/22/EC). Some (e.g. stilbenes and thyrostats) are entirely prohibited; however for some of the others (e.g. androgens, gestagens and beta-agonists) some controlled uses are permitted under strict veterinary control.

Group B
These are the substances with MRLs

Following are the substance groups are monitored under the NRCP program.

- Group A_1- Stilbenes, their salt and esters.
- Group A_3 – Steriods
- Group A_6 –Pharmacologically substances with zero tolerance
- Group B_1- Antibacterial substances, including sulphonomides, quinolones
- Group B_2(a)- Anthalmintices (Anti-helmintics);
- Group B_3(a)- Organochloride pesticids;
- Group B_3(b)- Organophosphate pesticide
- Group B_3(c)- Chemical elements
- Group B_3(d) Micotoxin
- Group B_3(e) Dyes.

EU legislation on monitoring of residues and contaminants in food of animal origin

There is specific EU legislation in place. Council Directive 96/23/EC lays out the requirements. The principal objective of the legislation is to detect illegal use of substances in animal production and the misuse of authorized veterinary medicinal products and to ensure the implementation of appropriate actions to minimize recurrence of all such residues in food of animal origin.

Requirements from countries wishing to export food to the EU:

Articles 29 and 30 of Council Directive 96/23/EC outline residue monitoring requirements for countries wishing to export food of animal origin to the EU.

Residue monitoring plans:

Article 29 (1) of the Directive 96/23/EC states that a third country must submit 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 to Council Directive 96/23/EC

Equivalence (NOT IDENTITY) and guarantee:

Third countries must present guarantees to prove that their residue monitoring systems achieve equivalent levels of protection as that of EU. But this does not mean that controls are weaker. The bottom line remains the same: conditions for prohibited substances and residues apply equally to Member States and third countries.

The legislative framework and the control activities of countries exporting food to the EU are evaluated regularly by FVO mission. Additionally, imports are checked and tested on a random basis at the borders of the EU as part of the responsibilities of the EU authorities for food safety. The guarantees must have an effect at least equivalent to those provided for in the Directive for EU Member States.

What are the guarantees?

Council Directive 96/23/EC:

- Article 4: there must be a centrally coordinated residue monitoring plan in place
- Article 7: legislation governing the authorization, distribution and use of veterinary medicinal products;

- Article 7: legislation governing the authorization, distribution and use of veterinary medicinal products;
- Article 7: the number of samples taken should be in accordance with the sampling levels and frequencies laid down in Annex IV to that Directive;
- Article 11 of 96/22/EC: Prohibits EU from importing from third countries, animals to which stilbenes, thyrostats and estradiol have been administered under any circumstances, or animals to which certain steroid hormones and beta-agonists have been administered.

Submission and approval of residue monitoring plan to EU

Submission every March 31: The residue monitoring plan for the next year should be prepared and submitted by 31 March every year

Once approved by EU, exporting country will be listed in Directive 2010/327/EU, as "eligible to export".

Evaluation process

What happens if we don't comply?

- EU makes favorable evaluation initially based on the guarantees received on paper.
- During subsequent inspection by FVO, if it finds that the paper guarantees cannot be relied upon, the status of the country on the list could be revised.

What does NRCP contain?

- Information on the structure of the competent authority- how it coordinates the whole process; does CA have enough resources- human and financial.
- Legislative framework- like rules on the use of veterinary medicines and pesticides, authorization /use/prohibition of VMP
- A list of approved laboratories for residues controls and the accreditation status of these laboratories;
- Rules covering the collection of official samples;
- Details on measures to be taken in the event of an infringement;

Submission of results; what details to be sent to EU?

- While sending the new NRCP, we need to give the complete details of results of previous year's residue control plan,
- details on its implementation (i.e. numbers of samples taken compared to the number planned)
- actions taken in the event of non-compliant ('positive') results - this gives the EU some indication of how the plan has been implemented.

What should be our approach?

- *Any detection of banned substances shall be followed by an investigation into the source of the substance and appropriate action aimed at the prevention of recurrence in the case of documented illegal use".*
- There is a need for a thorough investigation
- Follow-up action

Implementation of NRCP and Corrective action on non-compliance

Once the NRCP Plans are approved by the Central Competent Authority (CCA), the Local Competent Authority (LCA) and Regional Competent Authority (RCA) decide the sampling program to make the program effective.

Various steps involved in implementation of NRCP are:

- Sampling
- Testing
- Reporting
- Investigation
- Preventive action

Number of samples

DOF has established criteria for the minimum number of samples required for NRCP as 1 sample for each 100 tones of aquaculture product produced in Bangladesh. The estimates of production are based on the previous year's production data.

Bangladesh follows risk-based approach in determining the number of samples.

Even though the size and nature of the sample will be determined by the needs of the laboratory, as a general guideline, it can be assumed that for each analysis a sample should be of 1kg of product.

Conditions for sampling (98/179/EC and Policy Guideline of DOF:

- Sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week.
- Samples should be taken with no prior notice to the facility with respect to the identity of the sampling point or the nature of the analysis to be conducted.
- There should be a surprise in the checks.
- It should be risk-based

There are two sampling approaches. The sampling can be targeted or random.

- **Targeted sampling:** Here the sampling points are previously determined due to suspicion of malpractice, and non-compliances. These methods can be

used only when you have non-compliant results. This type of sampling is not necessarily representative of the industry as a whole.

- **Random** – Here the sampling points are randomly selected to cover all the industry or supply chain. This has the advantage that it provides a good overview of the whole industry.

The timing of samples needs to be evenly distributed throughout the year (or where applicable production season).

Who collects samples (as per Policy Guideline of DOF)

Person who collects the samples need to have been trained for doing such activity. As per current policy guideline, staffs from LCA are authorized to collect samples.

Samples are collected in the presence of the representative of the farm

Sampling procedure (as per Policy Guideline of DOF)

Collect all possible info of farming activity for the current and past cycles of production. History of his farming practice should also be collected. Information on pond preparation, water management, seed stocking, fertilization, feeding, etc are essential data to be collected.

- Collect basic information on farming activities; carry out a monitoring of the farm using check list
- Do random inspection of the farm using checklist;
- Collect samples of fish or shrimp in accordance with instructions given by CA
- Document everything

Samples must include the species of shrimp/fish of all age groups (not only the bigger ones, not only the smaller ones).

Sample collection (as per Policy Guideline of DOF)

- Collect shrimp enough for tests and are placed in an impermeable plastic bag and well sealed.
- The sample bags are numbered.

Sample handling (as per Policy Guideline of DOF)

Samples should be packed in food safe, sealable plastic bags and labeled. Labels should be such that the conditions of transport and storage do not detach, damage or make them illegible

- This sample bag is labeled as follows: the date, the name of the farm, the registration number of the farm, inspector's name, sample number.

Sample transportation (as per Policy Guideline of DOF)

- Samples are transported to CA/Laboratory in cold condition as early as possible (insulated box with ice packs);

Sample testing: to be done in laboratory using validated methods.

What is non-compliance result?

- *Any detection of banned substances (such as nitrofuran derivatives, chloremphenicol, steroids, stilbenes, etc)*

- *Any presence above MRL in case of permitted substances (for example tetracyclines)*

Actions to be taken by CA when residues are detected (as per Policy Guideline of DOF)

When non-compliant results are obtained, it is the responsibility of the CA inspectors to undertake the following activities:

- To conduct investigations at the farm of origin, such us verification of records such as farm record book and other documents, and look for the
    - the cause/source of the contaminant
    - how and when product was contaminated
    - Other potentially contaminated stock.

- To quarantine products at the farm, therefore preventing their distribution or entry into the food chain, until final actions are taken.
- To identify the appropriate actions that should be taken, depending on the risk associated with the identified residue this may include:
    - Harvesting of product, and declaring that these products of animal origin are unfit for human consumption and to ensure that the disposal of such products is such that they do not re-enter the food chain.
    - This should apply to products destined for both the national and export supply chains.

- To increase the control activities (inspection & monitoring) at the farms where noncompliant results were found to ensure that appropriate corrective actions have been implemented and that there is no reoccurrence of the incident

There are two levels of actions to be taken:

1. At the level of RCA
2. At the level of LCA

At the level of RCA:

Where positive results are obtained, the RCA shall follow the following steps without delay:

- All the information of non-complying samples are collected and sent to LCA for taking necessary investigation and actions as per the guideline.
- Local competent authority (LCA) shall carry out an investigation
- The investigation visit shall be unannounced; use farm monitoring checklist
- Determine the reasons for the presence of residues and other contamination- feed, drug, any traces of evidences?
- Document everything

At the level of LCA

Investigation

- All efforts to find the source of contamination should be made through thorough investigation of all possible routes.

LCA- Corrective actions and actions to be taken

When samples contain presence of banned substances or authorized substances above MRL, the stocks of fish or shrimps will not leave the farm of origin.

a) The farm will be harvested in presence of LCA representative and the product is destroyed as per FIQC rule and recorded in pond document and official investigation reports.

b) The affected farm would be prevented from selling fish.

c) These food products would be designated unfit for human consumption and destroyed, as per rules: *It is not allowed to sell fish for general use if it is suspected it will cause illness or poisoning, hence to be judged as unfit for human consumption*.

d) Any aquaculture operation in the same pond will be started only after proper drying and pond preparation in presence of LCA representative.

e) The new operation should use all inputs (feed, fry, etc) from approved sources and documented.

f) Harvesting of next year's crop can be made only on follow-up sampling and on the advice of LCA.

LCA- Follow-up action

Next year: The LCA will take sample and test before harvesting new crop. The product will be marketed only if the results are negative.

If again non-compliance, permission to carry out farming is withdrawn permanently.

What LCA needs to do after investigation?

Detailed investigation report is prepared by LCA with the possible source of contamination with evidences.

Investigation report is sent to RCA

Additional info for reference:

1. Policy Guideline for NRCP of DOF
2. http://ec.europa.eu/food/food/chemicalsafety/residues/third_countries_en.htm
3. Imports of animals and their products from third countries: Provision of guarantees equivalent to EU requirements on residues of veterinary medicines, pesticides and contaminants.
4. 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 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT
5. 2010/327/EU COMMISSION DECISION of 11 June 2010 amending the Annex to Decision 2004/432/EC on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:147:0005:0010:EN:PDF
6. 96/23/EC Commission Directive of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products http://ec.europa.eu/food/food/chemicalsafety/residues/council_directive_96_23ec.pdf