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## GUIDELINES FOR IMPORTATION AND USE OF HORMONES IN COMMERCIAL FISH PRODUCTION (AQUACULTURE)

### OBJECTIVES:

1. To enhance fish farm yields, efficiency of production and quality of farmed fish products.
2. To ensure safety - environment and to the public (inclusive of consumers and farm personnel using product)
3. To ensure correct use and quality of the hormone used (efficacy).

KEY FEATURES	ISSUES	RECOMMENDATIONS
1. Hormone	Quality, traceability	1.1. The applicant shall obtain recommendation from the Commissioner responsible for Animal Health to NDA for importation of the hormone.
		1.2. Hormone shall be imported from an accredited source. <i>The source should be accredited by the World Fish Centre located in Egypt and Auburn University Alabama, USA.</i>
		1.3. The importer shall follow NDA guidelines for Importation of Drugs and Biological substances into the country.
		1.4. The product shall be clearly labelled in English (indicating brand name, generic name, name and quantity of active ingredients, name and address of manufacturer, manufacturing and expiry dates, batch number and storage conditions).
		1.5. The product shall be clearly labelled <i>for veterinary use only</i> by the manufacturer.
		1.6. The applicant shall register all importations with the Commissioner responsible for Animal Health in addition to the standard requirements by NDA and URA.

		<p>1.7. Importer/user shall log imports as well as their dispatch to the facilities registered to use them. Delivery note/receipts to registered facilities should include log ID to enable traceability.</p> <p>1.8. Returns on the use of the hormone endorsed by the Veterinary Doctor in charge of the farm shall be made to the following:</p> <ul style="list-style-type: none"> <li>• Executive Secretary/Registrar- NDA.</li> <li>• Commissioner responsible for Animal Health</li> </ul>
2. Storage	Maintain quality, restrict access to hormones which are restricted compounds	<p>2.1. Storage shall be done as prescribed by the manufacturer in a manner that safeguards against degradation and/or contamination of the product. This is to ensure safety to the user, public and environment and promote quality of the product.</p> <p>2.2. Stores on the farm shall be secure and have restricted access.</p> <p>2.3. On the Farm: Quantities of the hormones removed from storage shall be logged and tallied to fish batches/lots for which they are used.</p> <p>2.4. The period granted to the facility to store hormones for use shall be six months depending on expiry dates, storage facilities on premises; quantities required each time and their frequency of use.</p> <p>2.5. The maximum quantity that can be stored directly on the registered farm shall be determined by the Commissioner responsible for Animal Health.</p> <p>2.6. Only authorized Veterinary Doctor shall be allowed access to stores holding the hormone and shall be allowed to retrieve it for use on the specified facility and for specified purpose as prescribed in the National Drug Policy and Authority Act, Cap.206.</p> <p>2.7. Disposal of expired hormones shall be as recommended by NDA.</p>
3. Fish farms	Licensing, registration	<p>3.1. Any fish farm on which hormones are to be used shall be licensed by the Commissioner responsible for Animal Health</p> <p>3.2. An application for registration of the fish farm shall be submitted to the Commissioner responsible for Animal Health together with a set of protocols to be used on the farm. The applicant should adhere to the set of prescribed protocols.</p>
4. Personnel	Tracking, proper use, safety	<p>4.1. Personnel managing the use of the product on the fish farm shall keep records/logs correctly.</p>

		4.2. Use and handling of the product on the farm shall be done under the supervision of a registered Veterinary Doctor authorized by the Commissioner in-charge of Animal Health.
4. Use of Hormone on the Farm	Tracking, proper use, safety, quality of farmed product	5.1. Facilities used shall be suitable as recommended in the guidelines (best management practices).
		5.2. The prescribed protocols as presented to the Commissioner in-charge of Animal Health shall be strictly followed. This shall include handling, storage and disposal of hormones (i.e. unused, used or expired).
		5.3. Up to date records shall be kept on the farm.
		5.4. A sample of the fish fingerlings shall be labelled and kept ( <i>i.e. 100 fingerlings</i> ) for future follow up and to determine efficacy. Samples shall be stored in formaline for onward processing in the Laboratory.
		5.5. The fish fingerlings shall be assigned lot numbers that tally with the batch numbers of the hormone used.
		5.6. Samples of sex reversed fish shall be sent to the Commissioner responsible for Animal Health for laboratory analysis
		5.7. Recommended withdrawal periods shall be observed.
6. Record keeping and reporting	Traceability and quality control	6.1. Records of logs are required as listed in Annex 1
		6.2. Report of use of hormones shall be submitted annually to the Commissioner responsible for Animal Health and to NDA (Annex 1)
		6.3. Records pertaining to use, stores and distribution of the hormone or treated fish shall be accessible to relevant authorities for inspection when required (i.e. Commissioner responsible for Animal Health and NDA) who shall inspect the facilities.

**ANNEX 1**

**SAMPLE OF PROPOSED RECORDS/LOG SHEETS FOR TRACEABILITY**

1. Importation Log (for local Importer)

No.	Date	Amount Imported	Source/Supplier	Batch Nos.	Log ID	Signature

2. Disbursement/Sales Loc (for local Distributor) *(could also be as a delivery note)*

No.	Date	Log ID	Batch Nos. Supplied	Total Amount Supplied	Destination	Taken by (and designation)	Name/Signature of recipient	Name Signature of Sales Person

3. On-Farm Stores

Date	Received (Amount)	Log ID and/or Batch Nos. in Stock	Amount in Stock	Amount requested for use	Balance in stock (Amount)	Batch Nos. of Fry	Name and designation	Signature

4. **Sales from Farm:** Receipts should include name of farm, batch number of fish fingerlings, the fact that fish are sex reversed, numbers and average size of fish sold and any other additional information the farm might require.