

INDIA

MILK PRODUCT

RESIDUE MONITORING PLAN
(RMP)

YEAR 2018-19



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EIC'S RESIDUE MONITORING PLAN (RMP)
Milk Products 2018-19

EIC/RMP/MP/2018-19, Rev.1

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1. Introduction

Government of India enacted the Export (Quality Control and Inspection) Act, 1963, for the sound development of the export trade of India through quality control and inspection and for matters connected therewith. Export Inspection Council (EIC), a statutory body, set up by the Government of India under Section (3) of the Export (Quality Control and Inspection) Act, 1963, for implementation of the Act.

The residues of pharmacologically active substances, pesticides and other environmental contamination in the food chain meant for exports is a concern of EIC to meet the importing country's requirements. In the WTO regime, EIC is committed to ensure food safety and quality of the products for the export purpose and therefore establishing Residue Monitoring Plans (RMPs) to provide equivalent guarantees to importing countries.

2. Purpose

Establish official control measure to provide equivalent guarantees to European Commission by implementing Residue Monitoring Plan (RMP) in line with the Council Directive 96/23/EC dated 29th April 1996 and relevant EC requirements for import of Milk Products from India and effectively minimize or prevent introduction / contamination of substances that have health hazards and of the concern of European Union, enhancing trust and confidence in the food safety.

3. Objectives

To detect any illegal treatment (s) / abuse of substances in the production of food of animal origin

To comply with the Maximum Residue Limits (MRL) for Veterinary drugs, pesticides and other pharmacologically active substances and the Maximum Limits (ML) for heavy metals and other environmental contaminants in the food of animal origin as per EU requirements.

To communicate and carry out follow-up actions in the event of detection of illegal treatment (s) of pharmacologically active substances or the detection of residues higher than the acceptable limits, in food of animal origin.

4. Scope

The raw milk production (primary producer / farm / suppliers of primary producers) and procurement for processing of milk products and the approved establishments those processing the milk products meant for export to European Union.

5. Legal Base

The Export (Quality Control and Inspection) Act, 1963, and amendments thereof, for the sound development of the export trade of India through quality control and inspection and for matters connected therewith

Order No. S.O. 2719 dated 16.12.2000 notifying Milk Products for quality control and inspection prior to export.

S.O. 2720 dated 16.12.2000 called as the Export of Milk Products (Quality Control and Inspection and Monitoring) Rules, 2000 and amendments thereof.

Any other order, direction or instruction which may, from time to time, be made, issued or given by Central Government or the Director, EIC.

6. Monitoring

Export Inspection Agencies (EIAs) located at Chennai, Delhi, Kochi, Kolkata and Mumbai and their field offices called as Sub-Offices are carrying out Quality Control, Inspection and Certification including implementation of RMP to ensure food safety of the Food Commodities meant for export to all countries including EU. The controls measures are based on the legal provisions stated above and HACCP based Food Safety Management System of the approved processing establishments (Food Business Operators). The HACCP implementation is being monitored through a surveillance mechanism. Each EIA is supported by state-of-art laboratories and qualified officials for the purpose. The EIA officials are imparted with various trainings to keep them updated and improve their professional skills to meet food safety requirements of importing countries including EU.

7. Laboratory Services

Each EIA is supported by state-of-art laboratories. The laboratories have implemented Quality Management System and are accredited as per ISO/IEC 17025:2005. The laboratories have validated test methods as per international standards and EU requirements. Unless otherwise mentioned, the methods described in manual / Journal of Association of Official Analytical Chemists or the methods prescribed by the Community Reference laboratories will be followed. The external laboratories approved by Export Inspection Council, New Delhi, are also utilized for testing of residues and contaminants in food products. The laboratories are approved for analysis based on the assessment for compliance as per ISO 17025:2005 requirements and their capability and competency to test residues and contaminants as per the EU requirements given in Commission Decision 2002/657/EC, and other specific Community legislation like Document No. SANCO/12571/2013, Commission Regulation (EC) No 836/2011, Commission Regulation (EC) No 401/2006, Commission Regulation (EC) No 252/2012, etc. as applicable where more specific rules have been laid down, ensuring that the analytical methods are fit for purpose. The approved laboratories shall participate in Proficiency Testing programmes, recognised or organised by the national or international PT providers, on regular basis to ensure their competency. The approved laboratories shall also participate in the trainings and inter-laboratory testing programmes organized by EIC or other institutions. These laboratories are accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL), of India, which are the members of APLAC & ILAC. The laboratories are under the obligation to provide access, on demand, to their testing facilities, methods of analysis and records (including chromatograms) to the authorized officials of EIC and EIAs, their representatives and officials from importing countries including EU countries.

8. Sampling Plan (Level and Frequency)

The establishments are approved to process the food of animal origin for export to EU from the identified population of animals or primary production sites. There are limited numbers of establishments approved to process food of animal origin for export to EU.

Every year sampling plan is reviewed and revised in line with EU requirements, to provide equivalent guarantees to EU. As per the EU document, Version 2 (2 Oct 2009), the number of samples to be taken is planned based on the animals/products from the farms eligible for processing or the total throughput of the approved establishments for export to the EU. The sampling plan is given in Annex 1. The parameters to be tested in the samples are planned based on the EU requirements and the substances being used / likely to be present in the specific animal production in India. The Regulatory Residue Control Programme designed as per the EU guidelines is given at Annex 3.

The numbers of samples to be drawn and tested are allotted to the EIAs in proportion to the animals/products from the farms eligible for processing or the total throughput of the approved establishments for export to the EU in their jurisdiction.

In turn each EIA shall draw monthly schedule by allotting the number of samples in proportion to the animals/products from each of the farms eligible for processing or the total throughput of the each of the approved establishments for export to the EU in their jurisdiction, which shall be spread over the whole year based on the season and production. A copy of the plan shall be sent to EIC, immediately before implementing the plan, for information and record. EIAs may re-allocate the samples to reduce or increase the number of samples to be drawn from the existing approved establishments, with prior permission from EIC, whenever there is addition or deletion of the approved establishment. The re-allocation of the samples shall be in proportion to the production as stated above.

EIA shall not inspect and certify the product under the consignment wise inspection (CWI) system for export to EU countries.

9. Sampling Procedure

- 1) The sampling shall be unforeseen, unexpected, in variable intervals, not at fixed time or on a particular day of the week, and with an element of surprise.
- 2) The EIA concerned shall ensure that suitable sampling tool, suitable clean food grade sample containers, sealing wax, official seal, thread, disposable gloves, labels, cloth, etc. are arranged for the sampling and transportation of the samples.
- 3) Only one sample at a time shall be drawn from a single producer. Multiple samples shall not be drawn from one producer / farm. In subsequent sampling from the same producer, the samples shall be tested for different set of parameters and testing of same set of parameters in the samples from the same

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producer shall be avoided, unless there is doubt and targeted to detect illegal treatment or abuse of a particular substance.

- 4) The samples shall be drawn at primary production or at the different stages of handling primary produce like farming, storage, transportation, receipt at processing establishment, etc. No sample shall be drawn from the intermediate or final product at the establishment or finished product store.
- 5) Samples from the matrix specified in the Regulatory Programme, traceable to the source, shall be drawn by EIA as per planned schedule to achieve the objective stated above. The sample shall be homogenized and be representative of the lot or batch with uniform characteristics based on the source / production and traceable to the individual primary producer / farmer / farm. No composite sample shall be taken from the different sources.
- 6) The sample shall not be treated / processed by any physical or chemical treatment except chilling and freezing, to prevent deterioration. No preservative shall be added to any sample.
- 7) Keeping in mind the objective, random sample, suspected sample and targeted sample shall be drawn in accordance with the procedure given in Codex guidelines Ref: CAC/GL 16 and Commission Decision 98/179/EC. If there is a departure from recommended sampling procedures, records accompanying the sample should fully describe procedures actually followed.
- 8) The laboratory sample shall be in duplicate. One sample shall be for analysis to carry out two sets of the complete analytical procedure. Another as control/reference sample for carrying out two sets of the complete analytical procedure in two different laboratories, in case of dispute. In case the sample is to be tested for different parameters in different laboratories, additional sample shall be drawn at the same time in triplicate or in quadruplet, etc. as decided by the EIA.
- 9) The quantity of each of the laboratory sample shall be sufficient to enable the testing laboratories to carry out the analytical procedures necessary to complete the screening and the confirmatory analysis. The minimum quantity of each sample shall be drawn as given in Annex 1. However, EIA concerned may confirm with the testing laboratory about the quantity of laboratory sample required to carry out the tests for the specified set of parameters.
- 10) The Samples shall be collected in suitable containers to maintain sample integrity and traceability, ensuring to prevent substitution, cross-contamination, spoilage, damage and leakage. The containers shall be clean and inert containers such as HDPE of food grade packaging material or PET / glass bottles. Care shall be taken during the sampling and sample handling to prevent contamination of sample by any foreign substance from sampling tools, sampler or the environment.
- 11) The sample containers shall be officially sealed appropriately to prevent tampering, labelled and packed in secured and controlled conditions like refrigeration to prevent deterioration, ensuring integrity. EIA shall pay specific attention to transport boxes, temperature and delivery times to the designated testing laboratory, keeping in mind the suitable storage and transport conditions for the analyte / matrix combination to ensure analyte stability and sample integrity.
- 12) The label on sample shall contain sample code, name of the sample, date of sampling, sample quantity and details of the sampling officer (name, designation, and signature).
- 13) The records of the samples drawn indicating name of the matrix, identity of source, quantity, place/stage of sampling, etc. shall be maintained for the purpose of follow-up actions, in the event of detection of residues or contaminants.
- 14) The officer shall prepare sampling report as per the format given at Annex 5 for the office record. The sampling report shall contain all appropriate information required for analyst and for the officials for follow-up action, if necessary. The sampling report is to be signed by the sampling officer and the owner / representative of the establishment may be invited to sign the report. The record of the sample drawn shall also be maintained by the food business operator.
- 15) A Sample slip shall be prepared by the sampling officer as per the format given at Annex 6 for the testing laboratory, which will be handed over to the testing laboratory together with the sample. The Sample slip shall contain the sampling details and the specific set of parameters indicating the name(s) of the substance(s) / analyte(s) to be tested as given in the Regulatory Programme (Annex 3). A copy of the Sample slip shall be maintained in the office records.
- 16) The sampling official shall ensure that the laboratory samples reach to the designated testing laboratory without any undue delay, on collection and in any case period between the collection of

sample and receipt of sample at the laboratory shall not exceed 48 hours with adequate refrigeration facility to prevent putrefaction, deterioration, etc. Failure to reach the sample in the scheduled time or receiving in damaged condition or in the condition not possible to be analysed by the laboratory, will necessitate rescheduling and resampling. The EIA shall intimate the laboratory by e-mail and/or over phone about the sample being sent to the laboratory and request to acknowledge the receipt of the same immediately.

10. Testing in Designated Official Laboratories

- 1) The designated laboratories for analysis of residues and contaminants as per the residue control programme shall have valid scope of EIC approval. The names of the designated laboratories for the purpose are listed in Annex 4.
- 2) The laboratory shall acknowledge the receipt of sample as soon as it is received at the laboratory.
- 3) In case the samples are not received in proper condition and in scheduled time, the laboratory shall inform the EIA official without delay whether resampling is necessary.
- 4) One laboratory sample shall be secured in controlled condition as reference sample. It can be discarded after 30 days in case of compliant test results. In case of non-compliant test results, the sample may be required to be analysed on request from EIA officer. Such sample shall be destroyed only after consent from EIA.
- 5) Other laboratory sample shall be combined and mixed well. Each sample shall be divided into at least two equivalent sub-samples each allowing the complete analytical procedure.
- 6) The laboratories shall test samples by the validated methods as per EU requirements, for the set / group of residues and contaminants those specified in the Sampling slip (as specified in the Annex 3 of the RMP). The interpretation of results and the method shall be demonstrably "Fit for Purpose" in accordance with ISO/IEC 17025:2005 and relevant EU requirements, before it is put to use.
- 7) The laboratories shall carry out the tests in its EIC approved laboratory premises. In case of exigencies, only with prior permission from EIA concerned, the testing can be subcontracted to another EIC approved designated laboratory having valid scope for testing the parameter. In such case, the laboratory shall clearly identify the results of the sub-contracted tests and identity of the sub-contracted laboratory on its test report issued.
- 8) The analytical results derived from laboratory samples must be supported by acceptable quality control data in compliance to EU requirements. The lot shall be taken as compliant if the result does not exceed the acceptable limits.
- 9) The laboratory shall issue the test report, in duplicate, as per Annex 7, immediately after analysis, in any case not later than 10 days from the receipt of the sample. The non-compliant test results shall be reported immediately to the EIA without delay. In such situation, a scanned copy of the test report shall be sent to the EIA immediately by e-mail / fax followed by the test report by post.
- 10) The designated laboratories shall submit monthly statement of samples tested under the residue control programme, to EIA as per Annex 11, by the 1st week of the following month. EIA shall ensure that the test reports and statements are submitted by the designated laboratories in time and compiled for onward submission to EIC.

11. Alert Intimation and Follow-up Actions

- 1) In case of non-compliant results, EIA shall issue Alert Intimation to the establishment concerned as per Annex 8, within a day of receipt of the non-compliant test results from the laboratory by e-mail / fax. A copy of the Alert Intimation may be sent to EIC and a copy to Computer Division, EIC, for placing on website for information to all stakeholders. The establishment shall be intimated to identify the exact source of the contamination and immediately furnish all the information about the identified animal and farm of origin or departure including registration/approval numbers and also the full details of the examination / inspection / testing, its results/reports and the status of the non-compliant product from which sample has been drawn. The product at all stages of the processing / food chain from the non-compliant identified source shall be cordoned immediately for further follow-up and corrective actions.
- 2) EIA shall also inform the establishment concerned to

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- a) Refrain from further exports to EU countries unless permitted by EIA concerned.
 - b) Refrain from procuring the raw material from the identified source, i.e. farmer, producer, farm, animal, etc. till corrective actions followed by verifications have been completed.
 - c) Refrain from procuring the raw material from the region or vicinity in the range of 30 km radius of the identified source farm / animal / producer, if there is possibility of contamination of the substance in question, from the other farm / animal / producer because of animal diseases, inadequate bio-safety measure, etc.
 - d) Refrain from procuring the raw material from the other source farm / animal / producer having similar practices or similar environment, which may also be the possible source of the contamination of the substance in question.
 - e) Cordon the batch of the primary produce, the sample of which exceeds the limit of residues and shall be disposed of suitably with supporting records, under intimation to EIAs.
 - f) Cordon the raw material / produce in stock from the identified source and take appropriate disposal measures. The supporting records of decision and disposal shall be maintained.
 - g) Cordon the products produced from the lot/batch that the sample(s) drawn from it is/are non-compliant and refrain from exporting, till appropriate disposal measures are taken.
 - h) Cordon the products processed from the identified source, when test results of the sample(s) drawn is/are non-compliant and refrain from exporting, till appropriate disposal measures are taken.
 - i) Not to export any of the products to EU that is processed from the identified source or non-compliant batch / lot.
 - j) For verification of the contamination in the identified sources by testing, a separate sample shall be taken from each batch / lot with uniform characteristic of primary production and details shall be furnished to the EIA concerned along with actions taken report.
 - k) Continue to procure the raw material from the other sources with due diligence only after appropriate follow-up actions to eliminate the possibility of the contamination of the substance in question, under intimation to EIA concerned.
 - l) Increase the frequency of testing samples under self-monitoring residue plan, for the substance / analyte for which the alert intimation is issued, until compliance is ensured / observed, in any case not less than for a period of next six months in case of permitted substances (Group B substances) and for a period of twelve months in case of prohibited / unauthorized substances (Group A substances). A sample shall be drawn by the establishment from the identified source(s) on fortnightly basis under intimation to the EIA concerned. The sample shall be tested for the contaminant in question in the designated EIC approved laboratory and the test results shall be sent to the EIA concerned directly by the laboratory.
 - m) Arrange training and awareness programmes to the producers and other concerned personnel, on preventive measures and avoid recurrence of the residues of the substances / contaminants in question.
 - n) It shall cooperate and give free access to the EIA officials and other concerned to investigate and take follow-up actions as per the guidelines given in this Residue Monitoring Plan and other necessary actions deemed fit.
- 3) The EIA shall also inform about the incidence to the other approved establishment and other stakeholders to take preventive measures for possible potential contamination.
 - 4) EIA may re-test the non-compliant sample(s) on request from the unit for re-confirmation on the expenses of the unit. In such case, the reference/control sample shall be tested in two different EIA laboratories/EIC approved laboratories designated for testing samples under the RMP. The result shall be treated as no-compliant, even if one of the two samples is found to be non-compliant on re-testing. In case both the samples are compliant to the requirements, the EIA concerned shall withdraw Alert Intimation, which shall take effect from that date.
 - 5) Within two days, an officer of EIA, who is responsible for implementation of the programme, shall immediately carry out investigation to find out the root cause of the contamination. EIA may take

assistance of an expert in the field from other organization / national research institution to carry out root cause analysis, if required.

- 6) The officer(s) shall identify the source of contamination, which may be from feed, feed ingredients, water, soil, environment, containers, improper agriculture practices or improper animal husbandry practices, etc.
- 7) The investigating officer(s) shall also verify administration/usage of veterinary drugs, animal disease in the vicinity, animal husbandry practices followed, withdrawal period followed in case of medication of permitted drugs/substances, bio-security measures, possibility of cross-contaminations from any other source, etc. and the relevant records.
- 8) The investigating officer(s) shall draw sample(s) from the suspected primary product / intermediate product and test for the contaminant in question, on the expenses of establishments, to verify and confirm the source of contamination. A separate sample shall be drawn from a lot / batch of primary produce / intermediate product from a single source with uniform characteristics and conditions applied during production, handling, storage, transportation, etc. No composite sample shall be taken from the different sources.
- 9) The investigating officer shall inform the establishment concerned to take corrective actions and preventive measures for possible potential contamination and avoid recurrence.
- 10) Based on the outcome of the investigation, EIA shall suspend or withdraw the registration / approval of the primary producer / farm / source and inform to all concerned stake holders and other approved processing establishments, so that they refrain from sourcing raw material from this source(s)
- 11) The EIA may suspend the processing and certification of the product to export to EU, till it satisfies with the corrective actions and preventive measures taken by the establishment.
- 12) After taking appropriate preventive measures by the establishment concerned, it shall offer five batches/lots of primary produce from same / similar source for testing a sample from each for the substance in question.
- 13) The EIA shall draw five suspected / targeted samples from the primary production of the identified/suspected sources and test all the samples for the substance / contaminant in question on the expenses of establishments, to verify results of the corrective actions and preventive measures taken. No composite sample shall be taken from the different sources. EIA may initiate process for withdrawal of approval of the establishment in case of non-compliant test results for any of the samples. In case of all compliant results, EIA may revoke suspension of approval / production.
- 14) The export of product processed from the raw material obtained from the identified source shall be resumed only after the complete follow-up actions and preventive measures taken by the establishment to the satisfaction of the EIA concerned and after due permission from the EIA concerned.
- 15) In the event of repeated non-compliant test results for same substance or different substances, EIA shall carry out sampling and testing on monthly basis from the identified source, for the substance in question, for the next six months in case of permitted substances (Group B substances) and for a period of twelve months in case of prohibited / unauthorized substances (Group A substances), on the expenses of establishment.
- 16) The EIA shall suspend / withdraw the approval of the establishment to process the product for export to EU or any other importing country, as applicable, if the follow-up actions, corrective actions and preventive measures taken by the establishments are not adequate and not sufficient to ensure to prevent the contamination of the substance in the food chain and the system implemented by the establishment does not ensure food safety.
- 17) The EIA may revoke alert intimation after satisfactory results of the samples drawn during the follow up investigation and monitoring visit for testing specific contaminant from identified source and on finding corrective actions/ preventive actions are satisfactory.
- 18) The EIA shall send a comprehensive report to EIC on the investigation carried out and follow-up actions taken on above.

12. Statements and Reports

- 1) The EIA concerned shall send a monthly cumulative statement (status as on at the end of the month, on or before seventh working day of the following month) of actual samples drawn and tested against

planned samples, results, number of non-compliant results, if any, and status of follow-up action in case of non-compliant test results, to the EIC as per the format at Annex 10.

- 2) The EIA concerned shall maintain consolidated report and send a quarterly cumulative statement (status as on at the end of the quarter, on or before seventh working day of the following quarter) to EIC as per the format given at Annex 11.
- 3) The EIA concerned shall send a monthly status report on follow-up actions taken for each of the non-compliant test results as per the format given at Annex 12, along with the monthly cumulative statement.

13. Responsibilities of approved processing establishment

- 1) The establishment shall not import or process imported raw material / primary produce for export EU or any other importing country that have imposed restrictions. For export to other countries where restriction has been not imposed either by importing country or Government of India, imported raw material / primary produce shall not be processed without prior approval / permission from EIA concerned. Unauthorised / unapproved practices by the approved establishment shall lead to immediate suspension / withdrawal of approval.
- 2) The establishment shall ensure that primary producer / farm and their suppliers have valid registration / approval from the EIA concerned or registration with the relevant authority recognised by EIC, as specified in the instructions issued by EIC from time to time.
- 3) The establishment shall have implemented Food Safety Management System based on HACCP principles to eliminate / prevent possible potential hazards from feed, hatcheries, farms, farm water, etc. as well as during processing and ensure compliance to food safety requirements of importing country. The establishment shall ensure that food grade containers are used at all stages of primary production, storage, handling, transportation, etc. Tin containers, rusty containers, etc., which would be the source of contaminants of different unacceptable substance in the food shall not be used for these purposes in the entire food chain and shall have implemented good veterinary practices (GVP), good manufacturing practices (GMP) and good hygiene practices (GHP), as applicable.
- 4) The establishment shall assess/audit the primary producer / farm / primary produce supplier including establishments like hatcheries, feed mill, etc. from which the food safety of the primary produce is determined. The establishment shall ensure that the producers are trained and competent to produce and supply the raw materials as per the requirements.
- 5) The establishment shall register / approve and assign a reference identification code to each of the primary producers / farm. It shall maintain the records as given in the format at Annex 9 for each of the food business operator (FBO), involved in food chain during primary production and handling of the primary produce (i.e. primary producer, farm, feed mill, hatcheries, supplier, etc., as applicable). It shall maintain a list of all the primary producers / farms as well as the suppliers to primary production like feed mills, hatcheries, etc., as a result of which the produce shall be used as raw material for processing of the products for export.
- 6) The establishment shall ensure that the primary producer / farm / primary produce supplier aware of the requirements for the primary produce food safety for export to EU and produce, store, handle the same as per the guidelines / procedure established by the establishment to comply with the EU requirements.
- 7) The establishment shall exercise control over the primary producers / farms / suppliers and the suppliers of the primary producers of raw materials by adhering with the dosage level and withdrawal period for administrating permitted pharmacologically active substances to comply with EU requirements. There shall not be storage and treatment of unauthorized and/or illegal treatment of substances during the primary production, storage, transportation, etc.
- 8) The establishment shall implemented self-residue monitoring plan (SRMP) to comply with the EU requirements (Council Directive 96/23/EC) for the residues of pharmacologically active substances, residues of pesticides, other environmental contaminants like heavy metals, etc. The sample drawn under the SRMP shall be homogenized and the representative of the lot or batch with uniform characteristics based on the source / production and traceable to the individual primary producer / farmer / farm. No composite sample shall be taken from the different sources

- 9) The establishment shall exercise control over the primary producers / farms / suppliers and the suppliers of the primary producers of raw materials through periodic food safety audits to comply with the EU requirements for the residues of pharmacologically active substances, residues of pesticides, other environmental contaminants like heavy metals, etc.
 - 10) The establishment shall maintain a record of traceability for each of the sample drawn either under its self-residue monitoring plan or the samples drawn by EIA officials under the official control programme like Residue Monitoring Plan, routine monitoring or surveillance programmes, complaint handling procedure, follow-up actions due to non-compliant results, etc. All the relevant records of implementation of food safety / residue and contaminants controls shall be made available for inspection and audits at any time by the officials of EIA concerned, officials of EIC and delegates from importing country, as and when required, or for any other purpose to comply with the rules and instructions issued by EIC from time to time.
 - 11) The establishment shall cooperate with the EIA official(s) / representative(s) and give free access to carry out sampling and monitoring for official control, whenever required. The sampling shall be unforeseen, unexpected, in variable intervals, not at fixed time or on a particular day of the week, and with an element of surprise.
 - 12) The establishment shall have established procedure for appropriate corrective actions and disposal of non-compliant product, in the event of non-compliant result(s). Appropriate follow-up actions shall be taken by the establishment, in case of non-compliant results of the samples drawn for testing under its self-residue monitoring plan or the samples drawn by EIA officials under the Official control programme like Residue Monitoring Plan, routine monitoring or surveillance programmes, complaint handling procedure, etc. The establishment shall find out root cause of the contamination, take appropriate corrective actions and preventive measures to eliminate the possible potential contamination.
 - 13) The establishment shall take appropriate actions to eliminate cause of contamination and prevent recurrence in the event of non-compliant results of samples tested at importing country and consignment rejected or Alert notification issued by the importing country.
- 14. Responsibilities of Export Inspection Agency (EIA)**
- 1) The EIA concerned shall ensure the implementation of RMP in its jurisdiction at regional level and coordinate with the related activities, as given in in this guideline.
 - 2) The EIA concerned shall ensure that the plan is completed by the month of March, as per its monthly scheduled plan for the year. For any technical reason, if the numbers of samples, to be collected and tested by EIA in a month are not carried out, it shall be undertaken in very first week of the next month. The same shall not be applicable for the month of March.
 - 3) The EIA concerned shall carry out sampling and testing as per the RMP and adhere to the requirements.
 - 4) The EIA concerned shall ensure that establishment is not carrying out any unapproved / unauthorised practices which may lead to the contamination
 - 5) The EIA concerned shall ensure that the establishment is procuring the raw material from the sources approved / registered by EIA. EIC may also recognise, statutory / regulatory body for the purpose of registration of food business operators in primary production.
 - 6) The EIA concerned shall suspend / withdraw approval of the processing establishment if the raw material is being procured from the primary producer / farm / source that does not have valid registration / approval.
 - 7) The EIA concerned shall ensure that the establishment has identified the sources and records are maintained appropriately;
 - 8) The EIA concerned shall ensure that the approved establishment is adhering to self-residue monitoring plan and taking appropriate preventive measures to eliminate possible potential hazards by contamination.
 - 9) The EIA concerned shall ensure that the samples are delivered to the designated laboratory in scheduled time (48 hrs.) and the test results are obtained from the laboratories within ten days from the receipt of the samples, for further immediate actions and compliance to the scheduled plan;

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- 10) The EIA concerned shall verify and ensure that the tests are carried out as per the Sampling Slip that was sent by the EIA and are in line with the parameters to be tested as per the RMP.
- 11) The EIA concerned shall take appropriate follow-up actions, as stated in this guideline, in case of the non-compliant results and furnish status reports till actions are completed to its satisfaction. EIA may take assistance of expert from other organization / national research institution to carry out root cause analysis, if required.
- 12) The EIA concerned shall review the test reports unit-wise and it's region-wise on monthly basis and shall furnish the consolidated reports to EIC as stated in this guidelines.
- 13) The EIA concerned shall maintain and timely furnish additional information, if any, on the RMP implementation, as and when necessary. All RMP related information may be sent by e-mail with data prepared in Excel format, as attachments followed by duly signed postal copy to EIC.
- 14) The EIA shall withdraw the approval of the establishment for export to EU, if the requirements are not complied.
- 15) The EIA shall not inspect and certify the product under the consignment wise inspection (CWI) system for export to EU countries.

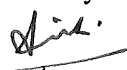
15. Surveillance System

- 1) The RMP data received from all the EIAs will be compiled at EIC for furnishing the consolidated RMP test results to European Commission (EC).
- 2) The RMP may be reviewed by EIC, if need be, to consider changes and change in requirements.
- 3) EIC shall co-ordinate with EC to fulfil their requirements on residue control programmes for export of the product to EU.
- 4) EIC may coordinate for arrangement of awareness programmes for EIA officials, Testing laboratories, officials of other institutions involved in implementation of the residue control programme and the approved processing establishments.
- 5) EIC shall carry out audit of the EIAs and designated testing laboratories, once in a year, to verify the compliance to the requirements.
- 6) EIC being the competent authority for implementation of the RMP, may initiate stringent actions against the EIA concerned and approved processing establishment(s) on non-compliance to the requirements of this guideline and EU requirements.
- 7) The RMP shall be reviewed by EIC on yearly basis and revised accordingly for implementation in the subsequent financial year.

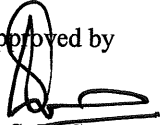
Prepared by


Sabeerali.A.M
Assistant Director, EIC

Verified by


Dr Amit Sharma
Joint Director, EIC

Approved by


Dr. S. K. Saxena
Director, EIC



Sampling Plan

1. Criteria:

- 1.1 The number of samples drawn shall be equal to 1 per 15000 tonnes of the annual milk production for processing in approved establishment for export to EU.
- 1.2 As per the EU plan template, the group wise breakdown of sampling and testing is as given below:
- Groups A6, B1, B2a and B2e : 70 % of the total number of samples, (Each sample shall be tested for at least four different compounds from at least three groups)
 - Group B3a, B3b, B3c and B3d : 15% of the total number of samples.
 - Balance 15 % of the total number of samples shall be tested for the presence of substances for their possible use in the sector in India and previous year's result data

2. Planning:

- 2.1 There are two milk processing establishments approved for export to EU. The total production volume of the farms from where the raw materials are procured for the year 2016-17 was 984584 MT.
- 2.2 With the consideration of 10% growth in the year 2017-18 the expected total production volume of these farms is 1083042 MT.
- 2.3 **Although, 72 samples to be drawn for the year based on the above production volume of the farms, as per commission decision of 27th October 1997 (97/747/EC) a minimum of 300 samples shall be drawn for the year.**

The group wise breakdown shall be as given below:

Set Number	Parameters to be tested in raw milk under the group	Number of samples
Set-1	A6+B1+B2a	42
Set-2	A6+B1+B2a	42
Set-3	A6+B1+B2a	42
Set-4	A6+B1+B2a	42
Set-5	A6+B1+B2e	42
Set-6	B3a+B3b+B3c+B3d	45
Set-7	A6+B1+B3c+B3d	45
Total	--	300

Note: samples must be drawn from different batches/Lots/Sources for each group under each set. However it would be considered as one sample at the respective set.

- 2.4 Substances of the Groups shall be tested for their possible use in the sector in India and previous year's result data.
- 2.5 Testing of Group A substances is aimed at detecting the illegal administration of prohibited substances, while testing of Group B substances is aimed at controlling abusive administration of approved substances, contamination of pesticides and environmental substances to comply with MRLs/MLs.
- 2.6 The samples shall be allotted to the EIAs in the proportion of number of approved establishments for export to EU.

3. Sample size:

The sample size shall depend on the analytical method used. Minimum quantity required for each laboratory sample of raw milk shall be 500 ml.

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Annex 2

Parameters under the RMP

Group	Substances	Compound or marker residue	Level of action (i.e. Concentration above which a result is deemed non-compliant) [µg/kg] i.e. MRPL / MRL/ML
A6	Chloramphenicol	Chloramphenicol	0.3*
	Furazolidone metabolite	Amino-oxazolidinone (AOZ)	1*
	Nitrofurazone metabolite	Semicarbazide (SEM)	1*
	Nitrofurantoin metabolite	Aminohydantoin (AHD).	1*
	Furaladone metabolite	3-amino-5-morpholinomethyl-2-oxazolidinone (AMOZ)	1*
	Nitroimidazoles	Metronidazole	1*
	Nitroimidazoles	Ronidazole	1*
B1	Antibacterial Substances	Dihydrostreptomycin including Streptomycin	200
		Doxycycline	10*
		Enrofloxacin (sum of enrofloxacin and ciprofloxacin)	100
		Erythromycin A	40
		Gentamicin (sum of gentamicin C1, gentamicin C1a, gentamicin C2 and gentamicin C2a)	100
		Kanamycin A	150
		Neomycin B	1500
		Spectinomycin	200
		Sulphonamides (Sulfadimidine, Sulfadiazine, Sulfadimethoxine, Sulfadoxine, Sulfamethazine, Sulfanilamide, Sulfamirazine, Sulfamethoxypyridazine, Sulfamethiazole, Sulfathiazol)	100 (combined limit)
		Sum of Chlorotetracycline and 4-epi- Chlorotetracycline	100
		Sum of Oxytetracycline and 4-epi- Oxytetracycline	100
		Sum of Tetracycline and 4-epi-Tetracycline	100
		Spiramycin (sum of spiramycin and neospiramycin)	200
		Thiamphenicol	50
		Tilmicosin	50
		Total residual antibiotics, as Beta Lactum	100
		Trimethoprim	50
		Tylosin A	50
B2a	Anthelmintics	Albendazole (sum of albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole)	100
		Fenbendazole (Sum of extractable residues which may be oxidised to oxfendazole sulphone)	10
		Ivermectin (22, 23-Dihydro-ivermectin B1a)	10*
		Morantel (sum of residues which may be hydrolysed to N-methyl-1,3-propanediamine and expressed as morantel equivalents)	50
B2e	Non-steroidal anti-inflammatory drugs (NSAID)	Phenyl Butazone	5*
B3a	Organochlorine Compounds including PCBs	Aldrin and dieldrin as dieldrin	6
		Chlordane (sum of cis- and trans-chlordane)	2
		Endosulfan (sum of alpha- and beta-isomers and endosulfan-sulphate expresses as endosulfan)	50
		Lindane (HCH-gamma)	1
		Heptachlor (sum of heptachlor and heptachlor epoxide expressed as heptachlor)	4
		Methoxychlor	10

Contd..2

EIC'S RESIDUE MONITORING PLAN (RMP)
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Annex 2

-- 2 --

Group	Substances	Compound or marker residue	Level of action (i.e. Concentration above which a result is deemed non-compliant) [$\mu\text{g/kg}$] i.e. MRPL / MRL/ML
B3b	Organophosphorus Compounds	Diazinon	10
		Fenthion (fenthion and its oxigen analogue, their sulfoxides and sulfone expressed as parent)	10
		Malathion (sum of malathion and malaoxon expressed as malathion)	20
		Parathion-methyl (sum of Parathion-methyl and paraoxon-methyl expressed as Parathion-methyl)	20
		Phosalone	10
B3c	Chemical elements	Lead	20
		Lead (in Milk Fat)	100
B3d	Mycotoxins	Aflatoxin M1	0.05

- * The detection below the prescribed limit by validated internationally accepted method as per EU requirements shall be treated as non-compliance of the sampled lot and corrective actions shall be followed as per the procedure.

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Annex 3

Regulatory Programme for Control of Residues

National PRODUCTION DATA in TONNES (2016-17), approx.	1654,00,000 MT	
EU EXPORT DATA in TONNES (2016-17) (Instant Mixes)	1.8 MT	
PRODUCTION DATA in TONNES for calculation of SAMPLE NUMBERS.(referring to previous year's production for export considering 10% growth)	1083042 MT	
Number of samples according to a per EU requirements	Min	Plan
	300	300
Matrix to be Analyzed	Raw Milk	
Testing Laboratory (ies)	Annex-4	

Group of substances to be monitored			Compound or marker residue	Method (e.g.)	Level of action (i.e. Concentration above which a result is deemed non-compliant) [µg/kg] i.e. MRPL / MRL/ML	Number of samples	
Set no.	Group	Substances				Min	Plan
Set-1	A6	Chloramphenicol	Chloramphenicol	LC-MS-MS	0.3*	42	42
	B1	Antibacterial Substances	Dihydrostreptomycin including Streptomycin	LC-MS-MS	200		
			Doxycycline	LC-MS-MS	10*		
			Enrofloxacin (sum of enrofloxacin and ciprofloxacin)	LC-MS-MS	100		
			Erythromycin A	LC-MS-MS	40		
	B2a	Anthelmintics	Albendazole (sum of albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole)	LC-MS-MS	100		
Set-2	A6	Furazolidone metabolite	Amino-oxazolidinone (AOZ)	LC-MS-MS	1*	42	42
		Nitrofurazone metabolite	Semicarbazide (SEM)	LC-MS-MS	1*		
	B1	Antibacterial Substances	Gentamicin (sum of gentamicin C1, gentamicin C1a, gentamicin C2 and gentamicin C2a)	LC-MS-MS	100		
			Kanamycin A	LC-MS-MS	150		
			Neomycin B	LC-MS-MS	1500		
			Spectinomycin	LC-MS-MS	200		
	B2a	Anthelmintics	Fenbendazole (Sum of extractable residues which may be oxidised to oxfendazole sulphone)	LC-MS-MS	10		
Set-3	A6	Nitrofurantoin metabolite	Aminohydantoin (AHD).	LC-MS-MS	1*	42	42
		Furaltadone metabolite	3-amino-5-morpholinomethyl-2-oxazolidinone (AMOZ)	LC-MS-MS	1*		
	B1	Antibacterial Substances	Sulphonamides (Sulfadimidine, Sulfadiazine, Sulfadimethoxine, Sulfadoxine, Sulfamethazine, Sulfanilamide, Sulfamirazine, Sulfamethoxypyridazine, Sulfamethiazole, Sulfathiazol)	LC-MS-MS	100 (combined limit)		
			Sum of Chlorotetracycline and 4-epi-Chlorotetracycline	LC-MS-MS	100		
			Sum of Oxytetracycline and 4-epi-Oxytetracycline	LC-MS-MS	100		
			Sum of Tetracycline and 4-epi-Tetracycline	LC-MS-MS	100		
	B2a	Anthelmintics	Ivermectin (22, 23-Dihydro-ivermectin B1a)	LC-MS-MS	10*		

Contd..2

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Annex 3

-- 2 --

Group of substances to be monitored			Compound or marker residue	Method (e.g.)	Level of action (i.e. Concentration above which a result is deemed non-compliant) [$\mu\text{g/kg}$] i.e. MRPL/ MRL/ML	Number of samples	
Set no.	Group	Substances				Min	Plan
Set-4	A6	Nitroimidazoles	Metronidazole	LC-MS-MS	1*	42	42
	B1	Antibacterial Substances	Spiramycin (sum of spiramycin and neospiramycin)	LC-MS-MS	200		
			Thiamphenicol	LC-MS-MS	50		
			Tilmicosin	LC-MS-MS	50		
	B2a	Anthelmintics	Morantel (sum of residues which may be hydrolysed to N-methyl-1,3-propanediamine and expressed as morantel equivalents)	LC-MS-MS	50		
Set-5	A6	Nitroimidazoles	Ronidazole	LC-MS-MS	1*	42	42
	B1	Antibacterial Substances	Total residual antibiotics, as Beta Lactum	Delvokit-SP/LC-MS-MS	100		
			Trimethoprim	LC-MS-MS	50		
			Tylosin A	LC-MS-MS	50		
	B2e	Non-steroidal anti-inflammatory drugs (NSAID)	Phenyl Butazone	GC-MS/ LC-MS-MS	5*		
Set-6	B3a	Organochlorine Compounds including PCBs	Aldrin and dieldrin as dieldrin	GC-MSMS	6	45	45
			Chlordane (sum of cis- and trans-chlordane)	GC-MSMS	2		
			Endosulfan (sum of alpha- and beta-isomers and endosulfan-sulphate expressed as endosulfan)	GC-MSMS	50		
			Lindane (HCH-gamma)	GC-MSMS	1		
			Heptachlor (sum of heptachlor and heptachlor epoxide expressed as heptachlor)	GC-MSMS	4		
			Methoxychlor	GC-MSMS	10		
	B3b	Organophosphorus Compounds	Diazinon	GC-MSMS	10		
			Fenthion (fenthion and its oxygen analogue, their sulfoxides and sulfone expressed as parent)	GC-MSMS	10		
			Malathion (sum of malathion and malaoxon expressed as malathion)	GC-MSMS	20		
			Parathion-methyl (sum of Parathion-methyl and paraoxon-methyl expressed as Parathion-methyl)	GC-MSMS	20		
			Phosalone	GC-MSMS	10		
	B3c	Chemical elements	Lead	ICP MS	20		
			Lead (in Milk Fat)	ICP MS	100		
	B3d	Mycotoxins	Aflatoxin M1	LC-MS-MS	0.05		

Contd..3

EIC'S RESIDUE MONITORING PLAN (RMP)
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Annex 3

-- 3 --

Group of substances to be monitored			Compound or marker residue	Method (e.g.)	Level of action (i.e. Concentration above which a result is deemed non- compliant) [$\mu\text{g/kg}$] i.e. MRPL/ MRL/ML	Number of samples	
Set no.	Group	Substances				Min	Plan
Set-7	A6	Chloramphenicol	Chloramphenicol	LC-MS-MS	0.3*	45	45
		Furazolidone metabolite	Amino-oxazolidinone (AOZ)	LC-MS-MS	1*		
		Nitrofurazone metabolite	Semicarbazide (SEM)	LC-MS-MS	1*		
	B1	Antibacterial Substances	Total residual antibiotics, as Beta Lactum	Delvokit- SP/LC-MS- MS	100		
	B3c	Chemical Elements	Lead	ICP MS	20		
			Lead (in Milk Fat)	ICP MS	100		
	B3d	Mycotoxins	Aflatoxin M1	LC-MS-MS	0.05		

- * The detection below the prescribed limit by validated internationally accepted method as per EU requirements shall be treated as non-compliance of the sampled lot and corrective actions shall be followed as per the procedure.

Designated approved laboratories for testing of residues and contaminants

The following laboratories are designated for testing of the RMP samples from the establishments approved for export to EU:

- 1) Pilot Test House, Export Inspection Agency-Mumbai, E-3, MIDC Area, Marol, Andheri (East) Mumbai – 400 093
(Tel. 022-28363396, Fax. 022-2836 9868; E-mail: pth-lab@eicindia.gov.in)
- 2) Geo-Chem Laboratories (P) Limited, Pragati, Adjacent to Crompton Greaves, Kanjur Marg (E), Mumbai – 400 042
(Tel. 022-61915100; Fax. 022-61915101; E-mail: laboratory@geochemgroup.com)
- 3) Delhi Test House, A-62/3, G.T. Karnal Road, Industrial Area, Opp. Hans Cinema, Azadpur, Delhi – 110033
(Tel. 011-47075555; Fax.011-47075550; E-mail: info@delhitesthouse.com)

Note:

- *In case, none of the designated laboratory has the valid scope of approval for testing a particular substance, sometimes newly considered/introduced substance(s) under the RMP, EIA shall request the lab to test the parameter by validated method in compliance to the EU requirements. However, EIA shall request the lab to get approved from EIC at the earliest and keep the Director (I&QC), EIC, informed.*
- *EIAs shall draw the samples as per the monthly plan preferably in the first fortnight of the every month and complete the yearly sampling plan by the first fortnight of the month of March.*
- *EIAs shall adhere to the instructions.*

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Annex 5

EXPORT INSPECTION AGENCY-_____

(Address of the Agency)

SAMPLING REPORT

(To be prepared by the official drawing sample along with a copy each for the EIA concerned and EIA Approved / registered Establishment. The original copy of the sampling report shall remain at the EIA concerned)

S. No.	Particulars	Details / Information (to be filled)
1.	Sample Code (to be traceable) <i>(The sample code may be assigned with unique number in the order; RMP/(two alphabets for product such as MP/EP/PM/HN)/ (Year as 20__ - __) / (EIA ID i.e. 01 to 05) / (Sub-office ID) / (unique number of sample in three digits))</i>	
2.	Date of sampling	
3.	Name of Sample / Matrix (raw material / product for testing)	
4.	Details of sample packing and sealing (method of sealing)	
5.	Group / Set of parameters / substances to be tested by the laboratory, as per the RMP for the year	
6.	Sample quantity	
7.	Number of samples taken from the same source for testing a group of substances	
8.	Sampling procedure / details adopted in brief	
9.	EIA Approval No. / EIA Registration No.	
10.	Name and address of the EIC / EIA approved / registered processing establishment	
11.	Name & address of the place from where sampling is done (like Farm, Centre, Supplier, Storage, feed mill, etc.) and EIC/EIA Registration / Approval No. <i>(If not registered/approved by EIA, please state.)</i>	
12.	Name of State and District of the location from where sampling is done	
13.	Identification of Animal or Product (Traceability of sampling location)	
14.	Animal Species / Variety (from where sample is taken)	
15.	Lot / Batch Number of the produce / raw material from where sample is taken	
16.	Quantity of the lot/batch	
17.	Date of production	
18.	Name(s) of pharmacologically substance(s) administered for treatment, if any and concentration used during the last one month (when sampling is from farm)	
19.	Any other information:	

CERTIFICATE

This is to certify that I have personally drawn the sample as detailed above as per the Residue Monitoring Plan. The establishment has maintained the required records for traceability.

Date: _____ Signature of Owner/Representative
Place: _____ (Name and designation of authorized person)

Signature of EIA official (Sampling Official)
Name and Designation

DECLARATION (Strike-out whichever is not applicable)

1. I/We, hereby, declare that the produce received from the place as detailed above or produced from the material from which sample is drawn, only will be used for processing for export to EU and that no other similar produce / raw material from un-authorised source will be mixed with it.
2. I/we hereby declare that I/we will ensure that the produce/raw material produced and procured for further processing for export to EU will be complying with EU requirements for residues and contaminants and the non-compliant produce/raw material will not be used for processing for export.
3. I/We also declare that in case any of the above samples found to contain any residues of pharmacologically active substances or pesticides or any other contaminant(s) in excess of the prescribed levels, it would not be processed or mixed with production for export to EU.

Date: _____ Signature of the Authorised Officer of Approved Processing Establishment
Place: _____ (Name and designation of the authorized person)
(Exporter / processor seal)

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Annex 6

EXPORT INSPECTION AGENCY- _____
(Address of the Agency)

SAMPLE SLIP

(To be prepared by the sampling official to be sent to the designated laboratory for analysis. A copy of the same shall maintained at the EIA concerned)

S. No.	Particulars	Details to be filled
1.	Sample Code	
2.	Date of sampling	
3.	Name of Sample / Matrix (raw material / product for testing)	
4.	Details of sample packing and sealing (method of sealing)	
5.	Sample quantity	
6.	Number of samples taken from the same source for testing a group of substances	
7.	Parameters / Substances to be tested by the laboratory, as per the RMP for the year _____ (year). Please specify.	
8.	Standards specifications against which the results are to be declared by the laboratory	

Date: _____

Place: _____

Signature of EIA official (Sampling Official)
Name and Designation

To,
(Name & Address of the laboratory)

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Annex 7

(The testing laboratory shall submit the test report to EIA in this format on its Letter Head)

TEST REPORT

Test Report No. _____

Date: _____

S. No.	Particulars	Details to be filled
1.	Sample Code	
2.	Date of sampling	
3.	Date of sample receiving	
4.	Details of sample packing and sealing (method of sealing)	
5.	Name of Sample / Matrix (raw material / product for testing)	
6.	Animal Species / Variety (from where sample is taken)	
7.	Sample quantity and number of samples for testing a group/set of substances	
8.	Sampled by (name, designation and organization of the sampling officer)	
9.	Name and Address of the EIA	
10.	Date of starting of analysis	
11.	Date of completion of analysis	
12.	Group/Set of parameters/substances analysed by the laboratory, as per the RMP for the year	

TEST RESULTS

Sl. No.	Parameter tested for	*Unit of measurement	**Results with corrected recovery along with level of recovery	Limit of determination / quantification: LOQ / CC α / CC β , as applicable (e.g. LOQ in case of pesticides, CC β , for Screening test, CC α for drugs & contaminants etc.)	LOD, as applicable	Level of action (i.e. Concentration above which a result is deemed non-compliant) [μ g/kg] e.g. MRL / MRPL / ML ***	Analytical Method (e.g. ELISA, Delvoset, Four Plate, TLC, HPLC, LC-MS-MS, etc.)	Specification, standard/test method against which product tested like AOAC, BIS, in-house, etc.	Validation protocol (e.g. specify like 2002/657/EC, IUPAC, CODEX etc.	Remarks (Conformity with the Level of action)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
1.										
2.										
3.										
4.										

CERTIFICATE

- 1) This is to certify that the sample stated above was tested for parameter(s) / substance(s) as per the request and the results are mentioned in Column (4) of the table given above.
- 2) This is to certify that the laboratory has valid EIC approval as on date.
- 3) This is to certify that the sample is not tested in other laboratory for any of the parameter / substance stated in this test report.
- 4) This is to certify that the sample is compliant/non-compliant as per the MRL/MRPL/ML (If the sample is non-compliant, please specify.)
(Strike-out whichever is not applicable)

Signature of Analyst
Name and designation

Signature of Authorized Person
Name and designation

(Seal of the Laboratory)

Note:

- a) The laboratory shall ensure that analysis is carried out as per EU requirements and the test results are communicated to EIA immediately after completion of the analysis. The tests shall be completed within the stipulated time frame.
- b) * Specify the unit of measurement as μ g/kg or ng/kg to avoid any confusion and use the same unit of measurement in all parameters.
- c) ** Results reported must be inclusive of recovery correction/correction factor for the batch assay. Result may be expressed as $x \pm U$ in case of reporting substances; wherein x is result and U is expanded uncertainty, as per method validation
- d) *** Minimum Required Performance Limits (MRPLs) for prohibited veterinary drugs, Maximum Residue Limits (MRLs) for veterinary medicines, Maximum Residue Levels (MRLs) for pesticides and Maximum Limits (MLs) for contaminants like heavy metals, etc.

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Annex 8

ALERT INTIMATION

(To be issued by the EIA concerned on its letter head)

Detection of _____ (residues of pharmacologically active substances/pesticide residues/heavy metals)
above the acceptable level

No. _____

Date: _____

S. No.	Particulars	Details / Information
1.	Name of Sample / Matrix (raw material / product for testing)	
2.	Name(s) of pharmacologically active substance(s) / pesticide residues / heavy metals / other contaminants detected and level of detection (result)	
3.	Acceptable level of residues / contaminants	
4.	Date of Test Report	
5.	Sample Code	
6.	Date of sampling	
7.	Sampled by (name, designation and organization of the sampling officer)	
8.	Number of samples taken from the same source for testing a group of substances	
9.	EIA Approval No. / EIA Registration No.	
10.	Name and address of the EIC / EIA approved / registered processing establishment	
11.	Name & address of the place from where sampling is done (like Farm, Centre, Supplier, Storage, feed mill, etc.) and EIC/EIA Registration / Approval No. (If not registered/approved by EIA, please state.)	
12.	Name of State and District of the location from where sampling is done	
13.	Identification of Animal or Product (Traceability of sampling location)	
14.	Animal Species / Variety (from where sample is taken)	
15.	Lot / Batch Number of the produce / raw material from where sample is taken	
16.	Date of production	
17.	Quantity of the lot/batch	
18.	Recommendations by EIA concerned, if any	The establishment is requested to initiate immediate actions as per the Appendix-1.

Date: _____
Place: _____

Signature of Agency In charge (EIA concerned)
Name and Designation

Copy to:

1. The Director (I&QC), Export Inspection Council, New Delhi
2. The Computer Division, EIC for updating on EIC website

Appendix-1

- 1) Identify the exact source of the contamination
- 2) Immediately furnish all the information about the identified animal and farm of origin or departure including registration/approval numbers
- 3) The full details of the examination / inspection / testing, its results/reports.
- 4) The status of the non-compliant product from which sample has been drawn.
- 5) Further, the establishment shall;
 - a) refrain from further exports to EU countries unless permitted by EIA concerned.
 - b) refrain from procuring the raw material from the identified source, i.e. farmer, producer, farm, animal, etc. till corrective actions followed by verifications have been completed.
 - c) refrain from procuring the raw material from the region or vicinity in the range of 30 km radius of the identified source farm / animal / producer, if there is possibility of contamination of the substance in question, from the other farm / animal / producer because of animal diseases, inadequate bio-safety measure, etc.
 - d) refrain from procuring the raw material from the other source farm / animal / producer having similar practices or similar environment, which may also be the possible source of the contamination of the substance in question.
 - e) cordon the batch of the primary produce, the sample of which exceeds the limit of residues and shall be disposed of suitably with supporting records, under intimation to EIAs.
 - f) cordon the raw material / produce in stock from the identified source and take appropriate disposal measures. The supporting records of decision and disposal shall be maintained.
 - g) cordon the products produced from the lot/batch that the sample(s) drawn from it is/are non-compliant and refrain from exporting, till appropriate disposal measures are taken.
 - h) cordon the products processed from the identified source, when test results of the sample(s) drawn is/are non-compliant and refrain from exporting, till appropriate disposal measures are taken.
 - i) not export any of the products to EU that is processed from the identified source or non-compliant batch / lot.
 - j) verify the contamination in the identified source(s) by testing. A separate sample shall be taken from each batch / lot with uniform characteristic of primary production and details shall be furnished to the EIA concerned along with actions taken report.
 - k) continue to procure the raw material from the other sources with due diligence only after appropriate follow-up actions to eliminate the possibility of the contamination of the substance in question, under intimation to EIA concerned.
 - l) increase the frequency of testing samples under self-monitoring residue plan, for the substance / analyte for which the alert intimation is issued, until compliance is ensured / observed, in any case not less than for a period of next six months in case of permitted substances (Group B substances) and for a period of twelve months in case of prohibited / unauthorized substances (Group A substances). A sample shall be drawn by the establishment from the identified source(s) on fortnightly basis under intimation to the EIA concerned. The sample shall be tested for the substance/contaminant in question in the designated EIC approved laboratory and the test results shall be sent to the EIA concerned directly by the laboratory.
 - m) arrange training and awareness programmes to the producers and other concerned personnel, on preventive measures and avoid recurrence of the residues of substances / contaminants in question.
 - n) cooperate and give free access to the EIA officials and other concerned to investigate and take follow-up actions as per the guidelines given in the Residue Monitoring Plan and other necessary actions deemed fit.

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Annex 9

(Name, Address and EIA approval number of the Approved Processing Establishment)

RECORD OF PRODUCER / SUPPLIER

(to be maintained by the Approved Processing Establishment)

Sl.	Particulars	Details / Information (to be filled)
1.	Name, postal address and contact details of the Food Business Operator (FBO) (e.g. who is producing, supplying, storing, handling the produce / material for production of food products for export to EU)	
2.	Name of State and District of the location	
3.	Name, postal Address and Contact Details of the Owner	
4.	Name the product of the establishment [feed, chicks or raw material (honey, milk, eggs, broilers, etc.)]	
5.	Type of activity (e.g. Farm, Supplier, Storage, etc.)	
6.	EIC/EIA Registration / Approval No. and validity	
7.	Approval status of the producer/supplier/handler by the processing establishment (date of assessment, approval and capacity)	
8.	Production / handling capacity per annum	
9.	Details of source of material (chicks, bees, feed ingredients, compound feed, etc., as applicable), traceability and controls exercised for food safety (to prevent contamination in food chain)	
10.	Animal Species for production of food of animal origin / Variety (e.g. flora)	
11.	Period of production in a year (season)	
12.	Name of medication permitted, dosage and withdrawal period	
13.	Brief details of type of process production/handling, storage, provision for traceability (marking/identifications), containers / packing, transportation, etc.	
14.	Details of system for quality checks and testing facility, if any.	
15.	Details of contract for supply/handle the material with EIA Approved / EIA Registered Food Business Operator (FBO), if any. Specify the EIA Approval No. / EIA Registration No.	
16.	Name, address and EIA Approval No of the EIA approved processing establishment for export to EU to whom the raw material / product will be supplied (Targeted destination)	
17.	Any other information:	

DECLARATION (Strike-out whichever is not applicable)

1. We, hereby, declare that the material produced / handled will be as per the requirements of EIC/EIA and the importing country for export.
2. We, hereby, declare that the material produced / handled will not be mixed any other similar produce / raw material from un-authorised source.
3. We, hereby, declare that the material produced / handled will meet the importing country's requirements for residues of pharmacologically active substances or pesticides, pesticide residues and other contaminants.
4. We, hereby, declare that the non-compliant produce/raw material because of any residue of pharmacologically active substances or pesticides or any other contaminant(s) in excess of the prescribed levels, will be disposed off appropriately and will not be supplied to the EIA approved processing establishment directly or indirectly.
5. We, hereby, declare that the records of production / handling, storage, transportation, traceability at all level, administration of permitted medicines (if any), quality checks/audits and testing, follow-up actions (in case of non-compliant results); as appropriate, shall be maintained.

Date: _____

Signature of Owner/Representative of the
producer/supplier/food handler
(Name, designation and address)
(Approval No. of the FBO)

Signature of authorised person of EIA approved
processing establishment
(Name, designation and address of the signatory)
(Approval No. of the Unit)

Place: _____

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Annex 10

Monthly Status of RMP implementation
(To be submitted by EIA to EIC on monthly basis)

Matrix:

RMP up to the month / year (cumulative up to and including the month):

Number of approved units in the region for export to EU / Non-EU:

Name of the EIA:

Set / Group of Substances	Number of Samples			Name of Laboratory	Number of Non-compliant Results (Above Level of Action)	Non-compliant Results (name of substance and test results)	Actions taken in case of non-compliant results (Enclose separate sheet for each non-compliant result)
	Planned	Sampled	Tested				
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

If the number of samples drawn is less than planned, please give the reason thereof

N.B. The EIA-concerned shall annex the status of follow-up actions taken for each of the non-compliant result.

Signature of Agency In charge
Name and Designation
Organization

Date:

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Annex 11

Statement of RMP implementation

(To be submitted by the designated laboratory to the EIA concerned on monthly basis)

(Compiled statement to be submitted by EIA to EIC on quarterly basis)

Matrix:

RMP up to the month / year (cumulative up to and including the month):

Name of the EIA:

Set / Group of Substances	Compound or Marker Residue	Number of Samples / Tests			Method (e.g.)	Level of Action (Above which a Result is deemed Non-Compliant) i.e. MRPL / MRL	Limit of Quantification [$\mu\text{g/Kg}$]	Name of Laboratory	Number of Non-Compliant Results (Above Level of Action)	Actions taken in case of non-compliant results (Enclose separate sheet for each non-compliant result)
		Planned	Sampled	Tested						
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)

If the number of samples drawn is less than planned, please give the reason thereof

N.B. The EIA-concerned shall annex the status of follow-up actions taken for each of the non-compliant result.

Signature of Agency In charge
Name and Designation
Organization

Date:

EIC'S RESIDUE MONITORING PLAN (RMP)
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Annex- 12

Report on Non-Compliant Results

(To be submitted by EIA to EIC immediately and the status on monthly basis for each non-compliant result)

Matrix:

RMP up to the month / year (cumulative up to and including the month):

Name of the EIA:

Sl. No.	Sample Code	Test Report No. & Date	Date of sampling	Sample source	Sample name	Compound or Marker Residue detected	Results	Method of Analysis & equipment used	Level of Action (Above which a Result is deemed Non-Compliant) i.e. MRPL / MRL
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)

N.B. The EIA-concerned shall annex the status of follow-up actions taken for each of the non-compliant result.

Signature of Agency In charge
Name and Designation
Organization

Date: