INDIA

MILK PRODUCT

RESIDUE MONITORING PLAN (RMP) FOR EXPORT TO EU

YEAR 2011-12

Export Inspection Council
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EIC'S RESIDUE MONITORING PLAN (RMP)
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As per the notification on export of milk and milk products published in the Gazette of India, Part - II, Section 3, Sub-section (ii) issued on 16-12-2000, following guidelines have been designed to monitor and minimize/ prevent the likelihood of contamination of the residues of veterinary drugs, pesticides, aflatoxin and heavy metals that may be present in milk & milk products and to provide an indication to the extent the participants comply with the regulations and policies in force:

1.	Objective	1.1	To establish a system and lay down control measures for monitoring, identification and evaluation of potential hazardous residues of Veterinary drugs, pesticides, heavy metals, aflatoxin, etc in raw milk, that have health hazards / are reasonably likely to occur and are concerns of European Union.
		1.2	To establish a system for corrective action in the event of detection of prohibited residues and residues detected at levels higher than those established through the RMP.
		1.3	To effectively minimize or prevent introduction / contamination of Veterinary drugs, pesticide, heavy metals, residues, aflatoxin, etc. in milk products exported from India to the European Union in excess of the permitted levels as detailed under Annex -2
		1.4	To enhance trust and confidence in the safety of the Milk and Milk Products; exchange information to the interested parties about the likely risks associated with Milk and Milk Products.
2.	Scope	2.1	This residue monitoring plan shall be applicable for the Milk processing plants that are approved for export to EU vide Notification published in the Gazette of India, Part - II, Section 3, Sub-section (ii) issued on 16-12-2000, (as given in Annexure-1)
3	Sampling and testing frequency	3.1	To achieve the objectives given at 1 above, residue monitoring shall be carried out by the Export Inspection Agencies of Export Inspection council (EIC). 60 samples ([1]) of raw milk shall be drawn , out of which; - 42 samples ([2]) shall be tested for presence of identified veterinary drugs - 9 samples ([3]) shall be tested for the presence of identified pesticides, lead and Aflatoxin M1. - 9 samples ([4]) shall be tested for presence of A6, B1 and B2a.
4	Testing	4.1	Each Raw Milk sample as per clause 3.1 shall be tested for parameters given in Annex-2
		4.2	The testing shall be as per the method given in the latest edition of AOAC / Codex / or as per the internationally recognized and acceptable methods or as per the EU requirements. The methods employed for analysis shall be validated as per the standard equivalent to Commission Decision 2002/657/EC or requirements in other specific EU legislation, for performance of analytical methods. The interpretation of results and the method shall be demonstrably "Fit for Purpose" in accordance with ISO/IEC:17025 before it is put to use
		4.3	The labs receiving samples under RMP shall carry out the tests in its own premises and can subcontract only in case of exigencies to another EIC approved laboratory having valid scope for testing the parameter.
5	Sampling Procedure	5.1	Primary sample in duplicate along with the sample slip as per format given at Annex-3 shall be drawn from the raw milk containers (cans / bulk coolers / tankers) by the official designated and will be traceable to the individual milk producer / farmer / farm.
		5.2	Primary samples shall be drawn from the traceable container in which raw milk is received / stored / transported so as to make a true representative sample as per the procedure given below: a) Primary samples shall be drawn after thoroughly homogenizing the milk in the container, by plunging/agitating. b) Details and identification number (wherever available) of source(s) of Raw milk shall be recorded in such a way that it is possible to trace back the source of the raw milk to the milk producer / farmer / farm through milk collection centre/ chilling centre / the route / approved establishment.
		5.3	No preservative is to be added to the raw milk samples. Temperature of the samples is to be maintained at 4 to 8°C by refrigeration or using ice / ice packs / dry ice and transported under strict controlled conditions ensuring sample's integrity to the EIA lab / EIC approved laboratory having valid scope of approval as stated in Annex-4, as planned by EIA concerned for testing as per clause 4 above.

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5	Sampling Procedure	5.4	Primary samples should reach to the concerned approved lab without any undue delay, on collection and in any case period between the collection of sample and receipt of sample at lab should not exceed 2 days with adequate refrigeration facility. Labs will only analyse samples received at refrigeration temperature (4.0 to 8.0degrees Celsius) and if in good condition.
		5.5	Failure to submit a sample as scheduled will necessitate rescheduling of the collection on receiving information from the receiving lab
6.	Procedure for Issuance of Test Report	6.1	The lab shall send the test report to EIA, as per the format given at Annex-5 within two working days (excluding the period of testing), preferably within 20 days from the date of sampling. In case the lab is using the facilities of another EIC approved lab (that shall also be approved for the same RMP), the test report issued by the lab shall clearly identify the results on their test report of the sub-contracted tests. The sub-contracting of any test shall be carried out only on exigency and only with prior approval of EIA / EIC.
7.	Corrective Action in case of non-compliance	7.1	In case, the residues levels are found to be exceeding the prescribed limits, the respective EIA shall advise the exporters to: - Refrain from exporting dairy products produced from raw milk batches in the processing units where milk samples drawn under RMP are found non-complying. - Identify the exact source of the contaminated milk and do not accept the raw milk from the identified source as well from the 30 km radius of the identified source till corrective actions have been completed. - The milk products of the batches identified as non-compliant based on the results of raw milk sample testing, should not be exported to the EU. - Conduct regular training for suppliers to prevent / minimise residue / contamination in the raw milk - To provide the documentary evidence / information about the status / disposal of the non-compliant product. - Draw additional samples (under own check system) from the identified area of source of contamination for the non-compliant parameter(s) for a period of three months at the interval of fortnight.
		7.2	A quarterly statement of test reports (except non-compliant that shall be immediate), as per the format given at Annex-6 generated by the EIAs shall be sent to EIC. In case of non-compliant result it should be reported immediately, for further corrective actions.
8.	Monitoring and Reviewing	8.1	EIC will compile the test data received from all the EIAs relating to monitoring data and review it every three months. If need be, the review may be taken up earlier than three months.
		8.2	Based on the previous year experience of EIAs and the testing data, RMP will be reviewed once in a year and the same will be modified if required.

(1) *Total throughput of the approved milk products processing establishments for export to EU in the year 2009-10 was 822463MT. With the consideration of 10% growth the expected throughput is 904710 MT. As per the criteria defined in the Commission Decision of 27th October 1997 fixing the levels and frequencies of sampling for monitoring of certain substances and residues thereof in certain animal products (Text with EEA) (97/747/EC), one sample is to be tested for every 15000 Tonnes of milk. Under the Scenario III to implement RMP for milk wherein only four units have been approved for export to EU countries total 60 samples shall be drawn under RMP for milk products for the year, based on the total throughput of the above mentioned number of approved milk products processing establishment for export to EU in the year 2009-10.*

(2) *70% of the total samples shall be examined for Veterinary Drugs. Each sample shall be tested for at least four different compounds from at least three groups A6, B1, B2 (a) and B2 (e)*

(3) *15% of total samples shall be tested for the presence of residues designated in group B3*

(4) *15 % of total samples shall be tested for the presence of substances for their possible use in the sector in India and previous year's result data.*

Prepared by

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Approved by

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Director, EIC

New Delhi
Date: 22.03.2011

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Annex-2

Regulatory Programme for Control of Residues

National PRODUCTION DATA in TONNES (2009-10), approx.	108500000	
EU EXPORT DATA in TONNES (2009-10)	Nil	
PRODUCTION DATA in TONNES for calculation of SAMPLE NUMBERS.(referring to previous year's production for export considering 10% growth)	904710	
Number of samples according to a per eu requirements	Min	Plan
	60	60
Matrix to be Analyzed	Raw Milk	
Testing Laboratory (ies)	Annex-4 of RMP	

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	Number of samples		
Set no.	Group	Substances				Min	Min	Plan
Set-1	A6	Nitrofurantoin metabolite	Aminohydantoin (AHD).	LC-MS-MS	1*	42	14	14
		Furaltadone metabolite	3-amino-5-morpholinomethyl-2-oxazolidinone (AMOZ)	LC-MS-MS	1*			
		Furazolidone metabolite	Amino-oxazolidinone (AOZ)	LC-MS-MS	1*			
		Nitrofurazone metabolite	Semicarbazide (SEM)	LC-MS-MS	1*			
	B1	Antibacterial Substances	Sulphonamides (Sulfadimidine, Sulfadiazine, Sulfadimethoxine, Sulfadoxine, Sulfamethazine, Sulfanilamide, Sulfamirazine, Sulfamethoxypyridazine, Sulfamethiazole, Sulfathiazol)	HPLC-UV	100 (combined limit)			
			Tetracyclines (Sum of parent drug and its 4- epimer) - (Chlortetracycline, Doxycycline, Oxytetracycline, Tetracycline)	HPLC-UV	100 (combined limit)			
			Total residual antibiotics, as Beta Lactum (Penicillin-G, Ampicillin, Amoxicillin, Cefacetrile, Cefalexin, Cefalonium, Cefaperazon, Cefapirin, Ceftiofur, Cloxacillin, Dicloxacillin, Oxacillin, Nafcillin)	Delvokit-SP	100			
			Trimethoprim	HPLC-UV	50			
	B2e	Non-steroidal anti-inflammatory drugs (NSAID)	Phenyl Butazone	GC-MS	10*			

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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	Number of samples		
Set no.	Group	Substances				Min	Min	Plan
Set-2	A6	Chloramphenicol	Chloramphenicol	LC-MS-MS	0.3*		14	14
		Nitroimidazoles	Metronidazole	LC-MS-MS	1*			
	B1	Antibacterial Substances	Dihydrostreptomycin including Streptomycin	HPLC-UV	200			
			Gentamicin (sum of gentamicinC1, gentamicin C1a,gentamicin C2 and gentamicin C2a)	HPLC-UV	100			
			Kanamycin A	HPLC-UV	150			
			Neomycin B	HPLC-UV	1500			
			Spectinomycin	HPLC-UV	200			
	B2a	Antihelmintics	Ivermectin (22, 23-Dihydro-avermectin B1a)	HPLC-UV	10*			
			Morantel (sum of residues which may be hydrolysed to N-methyl-1,3-propanediamine and expressed as morantel equivalents)	HPLC-UV	50			
Set-3	A6	Nitroimidazoles	Ronidazole	LC-MS-MS	1*		14	14
	B1	Antibacterial Substances	Doxycycline	HPLC-UV	10*			
			Enrofloxacin (sum of enrofloxacin and ciprofloxacin)	HPLC-UV	100			
			Erythromycin A	HPLC-UV	40			
			Spiramycin (sum of spiramycin and neospiramycin)	HPLC-UV	200			
			Thiamphenicol	HPLC-UV	50			
			Tilmicosin	HPLC-UV	50			
			Trimethoprim	HPLC-UV	50			
			Tylosin A	HPLC-UV	50			
	B2a	Antihelmintics	Albendazole (sum of albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole)	HPLC-UV	100			
			Fenbendazole (Sum of extractableresidues which maybe oxidised tooxfendazole sulphone)	HPLC-UV	10			

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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	Number of samples		
Set no.	Group	Substances				Min	Min	Plan
Set-4	B3a	Organochlorine Compounds including PCBs	Aldrin and dieldrin as dieldrin	GC	6 (Combined limit)	9	9	9
			Chlordane (sum of cis- and trans-chlrodane)	GC	2			
			Endosulfan (sum of alpha- and beta-isomers and endosulfan-sulphate expresses as endosulfan)	GC	50			
			HCH-gamma (Lindane)	GC	1			
			Heptachlor (sum of heptachlor and heptachlor epoxide expressed as heptachlor)	GC	4			
			Methoxychlor	GC	10			
	B3b	Organophosphorus Compounds	Diazinon	GC	10			
			Dichlorovos	GC	10			
			Ethion	GC	10			
			Fenthion (fenthion and its oxigen analogue, their sulfoxides and sulfone expressed as parent)	GC	10			
			Malathion (sum of malathion and malaoxon expressed as malathion)	GC	20			
			Parathion-methyl (sum of Parathion-methyl and paraoxon-methyl expressed as Parathion-methyl)	GC	20			
			Phosalone	GC	10			
	B3c	Chemical elements	Lead	AAS	20			
			Lead (in Milk Fat)	AAS	100			
	B3d	Mycotoxins	Aflatoxin M1	LC-MS-MS	0.05			
Set-5	A6	Chloramphenicol	Chloramphenicol	LC-MS-MS	0.3*	9	9	9
		Nitrofurantoin metabolite	Aminohydantoin (AHD).	LC-MS-MS	1*			
		Furaltadone metabolite	3-amino-5-morpholinomethyl-2-oxazolidinone (AMOZ)	LC-MS-MS	1*			
		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 (Penicillin-G, Ampicillin, Amoxicillin, Cefacetrile, Cefalexin, Cefalonium, Cefaperazon, Cefapirin, Ceftiofur, Cloxacillin, Dicloxacillin, Oxacillin, Nafcillin)	Delvokit-SP	100			
	B3c	Chemical Elements	Lead	AAS	20			
			Lead (in Milk Fat)	AAS	100			
	B3d	Mycotoxins	Aflatoxin M1	ELISA / LC-MS-MS	0.05			

- ** indicates lower limit of analytical determination*

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- *Testing of Group A substances is aimed at detecting the illegal administration of prohibited substances and abusive administration of approved substances while testing of Group B substances is aimed at controlling the compliance with MRLs for residues and veterinary medicinal products.*

The samples shall be tested in the laboratories stated in Annex-4 based on the validity and scope of their approval under the EIC laboratory approval scheme, in compliance to the Commission Decision 2002/657/EC or other specific EC requirements for export to EU countries.

In case of any ambiguity regarding the MRLs and test methods etc, the current EC regulations, directives and guidelines in force shall be taken as reference. Wherever, detection limit is not mentioned, it shall be less that the MRL stated above.

LCL:-Lowest calibrated Level,
LOQ/LOD: - Limit of Quantitation/ Limit of Determination
The above terms should be applied to the complete analytical method.

Definitions:

LCL: - Lowest calibrated level. The lowest concentration (or mass) of analyte with which the determination system is successfully calibrated, throughout the analysis batch, See also "reporting limit"

LOD: - Limit of determination (see LOQ below).

LOQ: - Limit of quantitation (quantification) (also known as limit of determination, LOD), the minimum concentration or mass of the analyte that can be quantified with acceptable accuracy and precision and should apply to the complete analytical method. Variously defined, but must be a value greater than the limit of detection. With most methods and determination systems, the LOQ has no fixed value. LOQ is preferable to LOD because it avoids possible confusion with "limit of detection". However, in legislation MRLs that are set at the limit of quantification/ determination are referred to as "LOD MRLs", not "LOQ MRLs".

Reporting limit or reporting level: The lowest level at which residues will be reported as absolute numbers. It may represent the practical LOQ, or it may be above that level to limit costs. It must not be lower than the corresponding LCL. For residue monitoring purposes where samples for surveys are analysed over a 12-month period, the same reporting limit should be achievable throughout the whole year.

Limit of detection: The minimum concentration or mass of the analyte that can be detected with acceptable certainty, though not quantifiable with acceptable precision. Various definitions are used but, for convenience, it is often the quantity of analyte that generates a response 3 times greater than the noise level of the detection system. Definitions based on standard deviation of blank values can be difficult to apply in chromatographic analysis. With most methods and determination systems, the limit of detection has no fixed value. The term is usually restricted to the response of the detection system/ analytical equipment but, in principle, it should be applied to the complete analytical method.

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Annex-3

Laboratory Sample submission form : To be sent to lab along with sample

1. Name of EIA :
2. Date of Sampling & time :
3. Nature of Sample : Raw/ Heat treated
4. Sample Bottle Container Code :
5. Parameters to be tested
6. Product description along with batch number
   a. Area/ Source/ route/chilling centre(s)
   b. Type of milk sample (Product description)
   c. Tanker no.
   d. Temperature of sample at the time of collection

Signature of EIA official

Note: No preservative/ formaldehyde should be added in the sample and the sample needs to be transported at refrigeration temperature (4.0 to 8.0 degree Celsius/ in ice/ ice packs/dry ice so as to maintain cold chain till sample reaches lab).

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Annex 4

List of Laboratories used for testing of residues and contaminants

I. EIA Laboratories having valid scope of approval for testing of residues and contaminants:

1. Pilot Test House
   Export Inspection Agency-Mumbai, E-3, MIDC Area, Marol, Andheri (East), Mumbai-400 093

2. Export Inspection Agency-Kochi, 27/1767 A, Shipyard Quarters Road, Panampilly Nagar (South), Kochi - 682 036

3. Export Inspection Agency-Kolkata, World Trade Centre, 14/1B Ezra Street, Calcutta - 700 001.

4. Export Inspection Agency-Chennai, 6th Floor CMDA Tower II, # 1, Gandhi Irwin Road, Egmore, Chennai–600 008

II. EIC approved laboratories: The laboratories approved under the EIC laboratory approval scheme, having valid scope of approval for testing of residues and contaminants,,.

Note: The EIA laboratories or the EIC approved laboratories having competence to test the residues and contaminants and who has validated the testing methods as per EC requirements shall be used for testing of the residues and contaminants.

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Annex-5

Format of Test Report
(To be issued on the Letterhead of the EIC approved laboratory under Milk Products RMP)

Report No._____
Date:

- Date & time of Sampling :
- Sampled by ** :
- Condition of sample at the time of receipt : Temp. : -____°C, Satisfactory/Un-Satisfactory
- Nature of Sample :
- Sample Code & related details
  (as listed in the Laboratory sample submission form) :
- Date & time of Sample received in Lab for analysis :
- Date of testing :
- Date of issue of test report :

Sl. No.	Parameter tested for	*Unit of measurement	**Results with corrected recovery along with level of recovery	Limit of determination / quantification: LOQ / CCα / CCβ, as applicable (e.g. LOQ in case of pesticdes, CCβ,for Screening test, CCα for drugs & contaminants, etc)	LOD, as applicable	Level of action (i.e. Concentration above which a result is deemed non-compliant) [µg/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)

*** Specify the unit of measurement as µg/Kg or mg/Kg to avoid any confusion and use the same unit of measurement in all parameters.**

** Results reported must be inclusive of recovery correction/correction factor for the batch assay. Result may be expressed as x ± U in case of reporting substances; wherein x is result and U is expanded uncertainty, as per method validation

*** *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.*

CERTIFICATE

1) This is to certify that the sample stated above was tested for substance(s) as per the request and the results are mentioned in Column 4 of the table given above.
2) The EIC approval of this laboratory is valid as on date.
3) The sample collected from _____ meets the **MRL/ MRPL / ML** - YES/NO
4) If no, give reasons

Name of Analyst &
Signature

Authorized Signatory &
Seal of the Laboratory

N.B. The laboratory shall ensure that the test certificates are issued immediately after completion of the analysis. The tests shall be completed within ten days of receipt of the samples.

New Delhi
Date: 22.03.2011

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Annex- 6

Format of Quarterly Statement (Raw milk RMP)
to be submitted by EIA giving details of Test Reports of Approved Milk Processing Plants

Number of approved units in the region:

Number of units from where samples have been drawn:

Month & Year:
A. Format for Quarterly status of target

Sr. No.	Type of sample (Raw/ Final)	Parameters Tested for	MRLs	Number of samples drawn	Number of samples for which testing have been completed	Name of Lab to which sample submitted	Number of samples conforming	Number of samples not conforming	Remarks (details of areas of non-conforming samples)

B. Format for Communication of Non-Compliant/ Failed Samples (To be reported to EIC immediately)

S. No.	Sample Code /Sample No.	Date of receipt	Date of completion of test	Name of the exporter with Approval no.	Type of product	Test Certificate No.	Parameter Failed	Reported Results	MRL	Method of Analysis & equipment used s	Results communicated to EIA

Signature of concerned EIA In-charge

New Delhi
Date: 22.03.2011