1. Purpose

To ensure uniform procedure for operation of licence as per Conformity Assessment Scheme for Milk and Milk Products for all dairy unit/ organizations certified under this scheme.

2. Scope

This document provides guidance for operation of licence as per Conformity Assessment Scheme for Milk and Milk Products and shall be read in conjunction with the Scheme-IX of BIS (Conformity Assessment) Regulations (Sixth Amendment), 2021.

3. General Principles for Operation of Licence

The Bureau grants a licence based on successful assessment of the following through visit to the manufacturing premises:

i) Requirements of Product Certification as per relevant Indian Standard(s);

ii) Assessment of Food Safety Management System implemented by the organization as per IS/ISO 22000; and

iii) Process requirements as given in Annex-II of Scheme document.

4. Operation of Licence- The licence is granted for a period of three years. A surveillance audit shall be conducted once every year except in the third year, where re-certification audit shall be carried out.

5. Extension and reduction of scope

5.1 Inclusion of Product(s) in the scope of licence: At any time, the manufacturer may request for inclusion or reduction of products or variety or a group of varieties in the scope of licence. Inclusion of a product or product varieties will be considered after the manufacturer provides evidence that the product(s) conforms to the relevant Indian Standard by any one or combination of the following methods:

Demonstration of Product Conformity	Inclusion of product/ variety(ies)
Independent Test report from Third party laboratory submitted with inclusion request *(as defined in the scheme)*	Inclusion on the basis of complete and conforming Test Report
Independent test report from third-party laboratory not submitted with inclusion request	1) Complete factory testing 2) Sample may be drawn for independent testing 3) Combination of 1) and 2) Inclusion based on factory Test Report/ Receiving of Independent test report as applicable

The manufacturer shall also submit details of any consequent changes in management system, process requirements, availability of additional manufacturing machinery and testing facilities, in the prescribed proforma (Annex-1).

If there are no changes in inspection and testing plan or infrastructure including manufacturing machinery and test equipment and extension in scope of licence is in the same group of sampling guidelines, the test report(s) is not required for extension in scope of licence.

5.2 Change of Scope of Management System: The licensee may request to include new systems/processes/activities and/or delete systems/processes/activities in the existing licence. The same may be verified through an audit preferably combined with surveillance audit ensuring that the new system/process is under the same documented system. Any such addition/reduction shall be in line with the requirements of the standard used for certification.

5.3 Fee for Inclusion/ Extension of scope: An amount of Rs. 5000/- shall be chargeable per addition in scope of licence for new product or variety or group of varieties, where grouping guidelines are available, or process, or system and the audit fee charges as specified in the scheme shall be applicable.

6. Surveillance

6.1 Surveillance audit: A surveillance audit shall be carried out annually as detailed in the Scheme document. No audit fee will be charged from the licensee for surveillance audit. Surveillance audit may include drawl of sample from factory or from dispatch point for testing.

6.2 Market surveillance: The MSCORs shall make efforts for market surveillance of each product under the scope of the licence. Wherever possible (in cases where the samples can be stored at ambient temperature or if cold chain can be maintained) samples shall be drawn from the market for testing in independent laboratories permitted under this scheme. For other products, samples may be drawn from dispatch point or feedback may be obtained from organized buyers. Product wise sampling guidelines from product manuals may be referred for sample size.

7. Re-certification:

An application for re-certification shall be made by the licensee five months before expiration of licence. Re-certification of licence is done after successful evaluation of process requirements and Food Safety Management Systems through a re-certification audit as detailed in the Scheme document .

8. Actions on account of following instances during the operation of licence:

Sr. No.	Instances	Actions to be taken
1	Use of Standard Mark on the non-conforming product or the manufacturer is using Standard Mark in a manner not permitted or may be misleading.	Issuance of 21 days cancellation notice
2	Not implementing the provisions of a revised standard or amendment to Indian Standard within time limit upon revision of an Indian Standard or issue of amendment to an Indian Standard.	Issuance of 21 days cancellation notice
3	Non-compliance of any instruction issued by the Bureau from time to time.	Issuance of 21 days cancellation notice
4	Failure of sample: Test report indicating non-conformity of the product to the relevant Indian Standard.	Failure intimation letter to be sent - within 15 days Submission of root cause analysis corrective action- 30 days within receipt of intimation letter. Verification of Corrective actions may be done through documentary evidence or through visit, as the case may be. Issuance of 21 days cancellation notice if sample drawn for verification of corrective actions is found failing or if CA are not received within 45 days from issue of failure intimation letter or corrective actions are incomplete/ inadequate.
5	Non-availability of testing personnel even as Standard Mark is being used.	Auditor to raise a non-conformity at the site which is to be followed by a Letter from MSCO(R) within 7 days seeking clarification. If it is observed that the products are dispatched to market without testing, 21 days cancellation notice may be served.

6	Major deviation observed in the implementation of inspection and testing plan.	Auditor to raise a non-conformity at the site which is to be followed by a Letter from MSCO(R) within 15 days seeking clarification. Submission of root cause analysis corrective action- 30 days within receipt of intimation letter. However, if licensee is unable to complete corrective actions within this time, cancellation notice shall be issued.
7	Major deviation observed in the compliance to management system requirements as per relevant Indian Standard.	Auditor to raise a non-conformity at the site which is to be followed by a Letter from MSCO(R) within 15 days seeking clarification. Submission of root cause analysis corrective action- 30 days within receipt of intimation letter. However, if licensee is unable to complete corrective actions within this time, cancellation notice shall be issued.
8	Major deviation observed in the compliance to specified process requirements.	Auditor to raise a non-conformity at the site which is to be followed by a Letter from MSCO(R) within 15 days seeking clarification. Submission of root cause analysis corrective action- 30 days within receipt of intimation letter. However, if licensee is unable to complete corrective actions within this time, cancellation notice shall be issued.
9	The manufacturer has relocated premises without prior intimation.	The licensee is required to impose self-stoppage of marking in case of shifting of premises. If licensee has resumed marking without permission from the Bureau, 21 days cancellation notice shall be issued.

10	The manufacturer has discontinued operation for more than six months without intimation.	Clarification may be obtained from the licensee. The licensee is required to impose self-stoppage of marking.
11	The manufacturer has not taken Corrective actions within 3 months (for situations other than Sl. No. 4, 6, 7 and 8).	The licensee may request additional time for completion of corrective actions with sufficient justification. DDGR may permit additional time upto 90 days for taking corrective actions. However, if licensee is unable to complete corrective actions within this time, cancellation notice shall be issued.
12	The manufacturer has indulged in false declaration in relation to the licence or falsification of records or unfair trade practices.	Issuance of 21 days cancellation notice.

9. Cancellation

The Bureau may cancel or refuse re-certification of a licence, after giving notice of 21 days, if-

a) the licence has been issued in error.
b) The holder of licence has violated any of the conditions of licence.

ANNEX- 1
DECLARATION REGARDING MANUFACTURING MACHINERY

No entry to be crossed

1. Application/Licence Number:

2. Name/Address:

Sr.No.	Machinery	Make/identification No.	Production Capacity per day, if applicable	Number	Remarks

Note: Attach extra sheet, if required.

I hereby declare that the machinery details of which given above are available with us I also declare that I will send prior intimation to Bureau of Indian Standards whenever any machinery is not available due to any reason. Signature of Firm's Representative Name Designati on Date *If any part of the manufacturing activity is outsourced, details of machinery used for outsourced activity shall be indicated in a separate form along with complete address of the outsourced premises.	I have verified the availability of the above mentioned machinery during my inspection. Sign of Bureau of Indian Standards certification officer _____ Name: Designation: Date of verification :

DECLARATION REGARDING TEST EQUIPMENT

No entry to be crossed

1. Application/Licence Number:

2. Name/Address:

S. No.	Test Equipment/Chemicals & Identification Number (where applicable)	Least Count & Range (where applicable)	Valid Calibration (where required) Yes/No	Test used in with clause reference	Remarks (Indicate No. of Eqpt.)

Note: Attach extra sheet, if required

I hereby declare that the testing equipment details of which given above are available with us I also declare that I will send prior intimation to Bureau of Indian Standards whenever any testing equipment is not available due to any reason. Signature of firm's representative Name Designation Date	I have verified the availability of the above mentioned testing equipment during my inspection. Sig. of Bureau of Indian Standards certification officer Name: Designation: Date of verification :