

TO EACH MILK PURCHASER OR USERS OF OWN MILK SUPPLIES

Trader Notice: DH/TN/01/2018 (Revised May 2018)

Date: Effective from 16th May, 2018

EU Hygiene Regulations in relation to TBC and SCC for Raw Milk.

The purpose of this notice is to provide guidance in implementing the requirements of the EU Hygiene Regulations with regard to the testing of raw milk for Plate Counts and Somatic Cell Counts to ensure compliance with the criteria laid down in the Regulation.

Note: References in this circular to raw milk also includes colostrum, where appropriate.

1. Legislative requirements in relation to TBC and SCC

The following criteria apply for raw milk in accordance with the provisions of Annex III, Section IX, Chapter I, III of Regulation (EC) No. 853 of 2004 and the provisions of Chapter II, Annex IV of Regulation (EC) No. 854 of 2004.

- i. A representative number of samples of raw milk from milk production holdings taken by random sampling must be checked for compliance with the legislation.
- ii. The checks may be carried out by, or on behalf of:
 - a. The food business operator producing the milk
 - b. The food business operator collecting or processing the milk
 - c. A group of food business operators.
- iii. Food business operators producing or, as appropriate, collecting raw milk, must initiate procedures to ensure that raw milk meets the following criteria:

Raw Cows' Milk

Plate count at 30°C (per ml)	≤ 100 000 (*)
Somatic cell count (per ml)	≤ 400 000 (**)

(*) Rolling geometric average over a two-month period, with at least two samples per month.

(**) Rolling geometric average over a three-month period, with at least one sample per month, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.

Raw milk from other species

Plate count at 30° C (per ml)	≤ 1 500 000 (*)
-------------------------------	-----------------

(*) Rolling geometric average over a two-month period, with at least two samples per month.

- iv. However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion:

Plate count at 30°C (per ml)	≤ 500 000 (*)
------------------------------	---------------

(*) Rolling geometric average over a two-month period, with at least two samples per month.

- v. When raw milk fails to comply the food business operator must initiate the following actions:
 - a. Inform (formally) the Competent Authority at Dairy Controls and Certification Division i.e. the local Inspector.
 - b. Immediately take measures to correct the situation.

- vi. As required by Regulation 854/2004, if the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and/or somatic cell count, collection/delivery of raw milk from the production holding is to be suspended.
- vii. Milk produced on a holding from which collection or delivery has been suspended may not be collected or delivered to, an approved milk purchaser.
- viii. The above suspension is to remain in place until the food business operator has proved that the raw milk again complies with the criteria. See Paragraph 5 below setting out procedures for resumption of deliveries following suspension.
- ix. Milk Purchasers should note that the criteria for raw milk in accordance with these provisions are rejection standards and milk producers should aim for considerably lower levels of TBC and SCC to consistently meet the requirements.

2. Sampling Procedure

- i. Samples should be taken by the **milk purchaser only** from milk collected or delivered from individual production holdings.
- ii. The samples shall be randomly taken and tested without forewarning as to the test parameter.
- iii. Sampling must be representative of the milk collected or delivered from individual production holdings. It is not permitted for the milk purchaser to knowingly take a sample from milk which is not representative of the milk collected or delivered at any stage in determining compliance with the legislation.
- iv. Where collection has been suspended, a special sampling procedure must be put in place to prove that the raw milk again complies with the criteria in order for collection or delivery to resume and corrective action has taken place. See also paragraph 5 below.

3. Testing Frequency and Methodology

- i. Total Bacteria Count (Plate count)
In the case of TBC, the Regulation provides that compliance with the standard is to be determined on the basis of a rolling geometric average of the results obtained over a two month period, with at least two samples each month.
- ii. Somatic Cell Count
In the case of SCC, the Regulation provides that compliance with the standard is to be determined on the basis of a rolling geometric average of the results over a three-month period, with at least one sample each month.
- iii. The requirements for both TBC and SCC are to be determined over consecutive months.

4. Breach of Standards

TBC

While a minimum of two tests must be carried out per month, it is permissible to carry out a greater number each month, provided all the individual results are taken into account in calculating the geometric average. Where, after the geometric average of the results of two consecutive months are calculated, and a supplier's milk is found to be > 100,000 per ml for cows' milk, the milk purchaser should engage with the producer immediately to initiate corrective action. A further three month recovery period is provided in the legislation for corrective action. Where at the end of the three month recovery period, the geometric average of the results for the last two months still exceeds 100,000 per ml., deliveries of milk from that holding must be suspended. Collection/delivery of milk from a suspended holding is not permitted. Consequently, it is imperative that corrective action commences as soon as possible after the milk at first exceeds 100,000 per ml or, where possible, at an earlier stage, when trend analysis indicates a potential problem. Delivery of milk can only resume when it is proved that the milk is again compliant.

SCC

While a minimum of one test must be carried out per month, it is permissible to carry out a greater number each month, provided all the individual results are taken into account in calculating the geometric average.

Where, after the geometric average of the results of three consecutive months are calculated, and a supplier's milk is found to be > 400,000 per ml for cows' milk the milk purchaser should engage with the producer immediately to initiate corrective action. A further three month recovery period is provided in the legislation for corrective action. Where at the end of the three month recovery period, the geometric average of the results for the last three months still exceeds 400,000 per ml, deliveries of milk from that holding must be suspended. Collection/delivery of milk from a suspended holding is not permitted. Consequently, it is imperative that corrective action commences as soon as possible after the milk at first exceeds 400,000 per ml or, where possible, at an earlier stage, when trend analysis indicates a potential problem. Delivery of milk can only resume when it is proved that the milk is again compliant i.e. corrective action, which can be verified if necessary, has taken place. Corrective action in the case of SCC is a series of interventions leading to long term improvement in udder health in the herd. It is not permissible to tender milk from unhealthy animals for collection or delivery at any stage. See Paragraph 9 Records to be maintained.

5. Procedures for resumption of deliveries following suspension

- i. Milk produced on a holding from which collection or delivery has been suspended may not be collected or delivered to, an approved milk purchaser, in the absence of corrective action at farm level.
- ii. Milk purchasers should establish documented procedures in establishing compliance with the criteria where a producer is under suspension. Suspension is to remain in place until the food business operator has proved that corrective action has taken place and the raw milk again complies with the criteria.
- iii. In the absence of corrective action, the use of multiple test results to achieve compliance is not permitted.
- iv. On resumption of deliveries there should be an increased level of monitoring of such producers to confirm corrective action remained in place.

6. End of Lactation Break in Production

Where supply ceases from a production holding for a period of at least one calendar month at or about the end of the herd's lactation, then when supply recommences the calculation of the geometric average for the purposes of determining compliances with the TBC and SCC standards laid down in the Regulations should start afresh; there should be no regard to the results of testing carried out before the break in production.

7. Transfer of supplies, new suppliers, dual suppliers etc.

Where a producer transfers his supply to another milk purchaser, that milk purchaser must obtain the results of all Plate Count and SCC tests carried out by the previous purchaser over the last six months in order to determine the status of that producer's milk insofar as compliance with the Regulations is concerned.

In the case of dual suppliers, testing frequency by each FBO processing their milk should meet the requirements in Paragraph 3. All test results for TBC and SCC should be taken into account to calculate the Geometric Mean in order to ensure that non-compliant milk is not collected/delivered.

8. Records

Milk purchasers are obliged to maintain accurate records on an ongoing basis as follows:

- i. Records including dates relating to sampling and testing.
- ii. Individual laboratory results for all TBC and SCC tests including primary records.
- iii. Records of the calculated geometric averages.
- iv. Records of all notifications to the local Inspector where raw milk at first fails to comply with the requirements set out in paragraph 1.
- v. Where relevant, documented procedures to deal with situations where a producer's milk is found to be in breach of the prescribed standard and the corrective actions taken within the 3 month period.
- vi. Documented procedures to prove the raw milk again complies with the criteria where collection of milk is re-admitted following suspension and corrective action taken place.

These records, including primary laboratory records, must be maintained for inspection by the Department or by the EU Commission for a period of at least 3 years as required under Regulation 10 of Statutory Instrument 432 of 2009, the European Communities (Food and Feed Hygiene) Regulations 2009.

9. Laboratory

The testing requirements for TBC and SCC shall be as set out in Regulation (EC) No. 2074/2005 as amended by Regulation (EC) No. 1664/2006.

Testing laboratories shall cooperate with the National Reference Laboratory in its role in checking the consistency and uniformity of results obtained at and between Milk Purchaser laboratories and implement whatever action DAFM deems necessary from time to time.

All testing laboratories under the control of approved milk purchasers will also be subject to official controls. For those milk purchasers who avail of outside laboratories, the primary record is the record as recorded at that outside laboratory. Any record requested by DAFM should be made available by the milk purchaser.

10. Failure to Operate the Testing and Recording System

Milk purchasers who fail to operate the system laid down in whole or in part are in breach of the Regulations and risk withdrawal of their approval to operate as a Food Business Operator as well as prosecution under these Regulations.

Milk and Meat Hygiene/ABP Division
Department of Agriculture, Food and the Marine

16 May 2018

DH/TN/01/2018 (Revised May 2018)