Information and guidance on the testing of milk for antibiotic residues

April 2009

Intended audience:	Interested parties along the milk production chain – farmers, milk purchasers and processors, and the enforcement authorities.
Regional coverage:	UK.
Legal status:	Guidance to accompany EC Regulation.
Purpose:	This Guidance advises on the implementation of Regulation (EC) No 853/2004 as regards the testing of milk for antibiotic residues. In particular, the requirements at Annex III, Section IX, Chapter I.III.4 that food business operators must initiate procedures to ensure that raw milk is not placed on the market if it contains antibiotic residues in excess of regulated limits

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REGULATIONS REFERRED TO IN THIS GUIDANCE

Regulation (EC) No 853/2004, laying down specific hygiene rules for food of animal origin.

Regulation (EC) No 1774/2002 laying down health rules concerning Animal By-Products not intended for human consumption **.**

The Veterinary Medicines Regulations 2008 (SI 2297)

Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.

INTENDED AUDIENCE

This Guidance is intended for the information of all interested parties along the milk production chain – milk producers, milk purchasers and processors (including SMEs) and the enforcement authorities.

PURPOSE AND LEGAL STATUS

Guidance on regulation

This Guidance provides informal, non-binding advice on the legal requirements of Regulation (EC) 853/2004 and should be read in conjunction with the legislation itself. The Guidance relates specifically to the requirements for the testing of milk for antibiotic residues - in particular those at Annex III, Section IX, Chapter I.III.2, 4 and 5 of the Regulation. The text of the Guidance will be subject to review if further advice is issued by the European Commission on the implementation of these provisions.

This Guidance should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power. Every effort has been made to ensure that these guidance notes are as helpful as possible. However, it is ultimately the responsibility of individual businesses to ensure their compliance with the law. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/environmental health department of the local authority (or in Northern Ireland, the Department of Agriculture and Rural Development (DARD))

INFORMATION AND GUIDANCE ON THE REQUIREMENTS OF HYGIENE LEGISLATION FOR THE TESTING OF MILK FOR ANTIBIOTIC RESIDUES

Summary

1. The approach to the control of antibiotic residues in milk is multifaceted. The primary control is on farm and begins with the correct prescription and administration of the antibiotics and the careful adherence to withdrawal periods. In short, milk producers must ensure that milk from animals under treatment or in the withdrawal period does not enter the food chain. The primary controls are complemented by the testing of milk for antibiotics, undertaken by food businesses at various points in the supply chain, including on farm. It is up to individual food business operators (including milk producers) to determine their own sampling and testing regime, taking account of other testing undertaken in the distribution chain, including any testing carried out on their behalf.

2. Regulation (EC) No 853/2004, (Annex III, Section IX, Chapter I.III.2, 4 and 5) requires that:

> i) food business operators must initiate procedures to ensure that raw milk is not placed on the market if it contains antibiotic residues in excess of regulated limits (Maximum Residue Limit – MRL);
>
> ii) food business operators must inform the competent authority where this requirement is not met, and take corrective measures; and
>
> iii) a representative number of random samples of raw milk be tested to monitor the effectiveness of the initiated procedures.

Thus, there is no requirement to test **all** raw milk collected from milk production holdings but food business operators should ensure that appropriate testing is in place to meet the requirement of (i) above. Such testing may be undertaken by food businesses at various points in the supply chain, including on farm.

3. The sampling and testing mentioned at 2(iii) above may be carried out by, or on behalf of, producers, collectors or processors of milk. It may also be undertaken for, or on behalf of, groups of producers or in the context of a national or regional control scheme. It is not envisaged that this requirement applies to the milk of animals that have not undergone antibiotic treatment, unless such milk is mixed with milk from animals that have been treated with antibiotics. It is emphasised that the MRLs relate to raw milk, not to processed milk or to dairy products.

4. There are a number of rapid screening tests currently available on the market that can be used to determine the presence of antibiotics in milk. They fall into one of two types:

i) immune-receptor tests whose spectrum of detection is normally limited to β-lactam antibiotics and give a result within 5-10 minutes; and

ii) microbial inhibitor tests which detect a wider range of antimicrobial substances, including β-lactams, and give a result within 3 hours or less.

Choosing the most appropriate screening test to use will depend on the specific circumstances, and the test kit should ideally operate at or near to the MRL for the antibiotics that have been used. Advice should be sought from the test kit manufacturer, if necessary.

5. Figures 1 and 2 illustrate the marketing and disposal and information flow requirements following the testing of milk for antibiotic residues. Figure 3 illustrates how a food business operator should determine the outcome of antibiotic testing.

PART A: GENERAL GUIDANCE

Testing of Milk at the Production Holding

See Figure 1

6. Milk producers sometimes test the milk of individual animals which have been treated with antibiotics, and/or they may also test milk from the farm bulk tank. Antibiotics may be administered to animals 'on-label' (which means the dose administration and withdrawal period instructions appearing on the label are followed), or 'off-label' (i.e. as directed by a veterinarian).

Antibiotics used On-Label

7. There is no requirement to test the milk of treated animals at the end of the 'on-label' withdrawal period, although some producers may choose to do so for precautionary or commercial reasons. In cases where antibiotics used 'on-label' have been correctly administered and the withdrawal period followed but milk fails an antibiotic test, milk from the affected animal must continue to be withheld from the food chain for a further period. Producers should not place milk on the market or process it for sale for human consumption until a test from subsequent milking has achieved a pass result.

8. Producers are encouraged to report the details of cases where antibiotic test failures have occurred after the withdrawal period for correctly administered on-label antibiotic use. These cases should be reported to the Veterinary Medicines Directorate (VMD) under the Suspected Adverse Reaction Surveillance Scheme (SARSS) using form MLA 2. This is a voluntary but important scheme for the monitoring of suspected adverse reactions to veterinary medicines. All reports are followed up and could, for example, lead to a review of the MRL or the withdrawal period. More information may be found at:
http://www.vmd.gov.uk/Publications/SARSS/SARSS.htm

Antibiotics used Off-Label

9. Where antibiotics are used 'off-label' there is a minimum withdrawal period of 7 days, at the end of which the milk of individual animals should be tested. In cases where the milk fails the test, milk from the affected animal must continue to be withheld from the food chain for a further period. Producers should not place milk on the market or process it for sale for human consumption until a test from subsequent milking has achieved a pass result. It should be noted that the 7 day withdrawal period is only a statutory minimum and the prescribing veterinary surgeon can specify a longer period if it is considered necessary.

Disposal of Failed Milk

10. Milk which has failed an antibiotic test at the production holding of origin does not fall within the scope of animal by-products legislation and therefore may be disposed of at the farm, for example in the slurry tank or by spreading on the land. It must not be placed on the market or processed for human consumption. Producers who process their own milk and do not buy in any other milk can also dispose of any milk by these methods. However, producer-processors who buy in raw milk from elsewhere must dispose of any such milk which fails an antibiotic test (together with any milk with which it may have been mixed) in line with the disposal rules set out in Paragraph 17 below. Their HACCP-based procedures should make clear which disposal routes are to be followed.

Record Keeping

11. In addition to keeping records of all medicines purchased and medicines administered to dairy animals, milk producers should keep records of the results of all antibiotic testing they undertake and make them available for inspection by the competent authority on request. This will allow producers to demonstrate the controls they have in place to comply with the legislative requirements. The Veterinary Medicines Regulations 2008 require milk producers to keep records of antibiotics administered to their animals for 5 years. It is good practice to communicate the name(s) of the antibiotic(s) used to milk purchasers if requested to do so. More information can be found at:
http://www.vmd.gov.uk/General/VMR/vmgn/VMGNote16.pdf

On Farm Test Failures which do not need to be notified

12. Antibiotic test failures from samples taken on farm do not need to be notified to the competent authority in respect of –

- milk from an individual animal which has been tested to determine its suitability for inclusion in the bulk tank;
- milk from the bulk tank which has not left the production holding.

In both cases, this is because such testing is integral to the routine control of antibiotics and does not involve the milk being placed on the market or its use for human consumption.

Testing of Road Tanker Loads or Storage Silos of Milk by Milk Purchasers and/or Processors (other than producers who only process their own milk)
See Figure 2

13. There is no requirement for milk purchasers/processors to test milk for antibiotics, but many choose to do so for commercial or precautionary reasons. Some milk purchasers/processors test milk samples taken from a road tanker arriving at the processing establishment, prior to acceptance, while others may take delivery of the milk and then test it, e.g. in silo.

14. Some milk purchasers/processors may test at both road tanker and silo stages – however, in this case, it is possible that the tanker test could show a test failure for antibiotics, while the result in respect of the silo into which the tanker load has been offloaded shows a pass result. In these circumstances, milk purchasers/processors holding any milk in the knowledge that it has failed either a road tanker or silo antibiotic test may not place that milk on the market or use it for human consumption. This applies also to any milk with which it may have been mixed, and any processed products derived from such milk.

15. In all circumstances, milk purchasers/processors should ensure that their HACCP-based procedures and purchase specifications make clear what actions should follow when milk fails an antibiotic test.

16. It is not lawful to place unfit milk on the market for human consumption. As regards milk which fails a primary screening test[1], such milk may not be sold or transferred on. Any steps to verify the result of the primary screening test must therefore be taken with these constraints in mind.

Disposal of Failed Milk

17. Where milk has failed a rapid screening test for antibiotics, and no further steps are to be taken to identify and quantify the antibiotic present, the only option is to dispose of the milk as Category 2 animal by-product in accordance with animal by-products legislation. Arrangements for disposal should be made in co-operation with the owner whose milk was responsible for the failure. Further information about animal by-products legislation requirements may be found on the Defra, Scottish Executive and Department of Agriculture and Rural Development (DARD) websites:

http://www.defra.gov.uk/animalh/by-prods/default.htm

http://www.scotland.gov.uk/Topics/Agriculture/animal-welfare/policies/PolicyInfo/AnimalByProducts/Introduction

[1] The initial test on the first sample taken from the batch of milk being screened.

http:// www.dardni.gov.uk/index/animal-health/animal-by-products.htm

Notifying the Competent Authority of Test Failures

18. Regulation (EC) No 853/2004 specifies that food business operators are responsible for notifying antibiotic test failures to the competent authority. The Annex sets out the relevant competent authorities in the various devolved administrations. It is envisaged that the European Commission will clarify in due course as to the food business operator responsible for reporting test failures where the testing has been undertaken for, or on behalf of, the owner of the milk and also the frequency of reporting test failures.

19 In the meantime purchasers/processors should arrange to notify antibiotic test result failures on milk samples taken from road tankers or silos to the relevant competent authority as soon as reasonably practicable. However, where the testing has been carried out on behalf of the owner, unless there are contractual arrangements to the contrary, the owner should be responsible for reporting the failure to the competent authority. Notification should generally be made by the food business operator's office which is responsible for follow up action and arranging disposal of the milk – this may be at the testing site, but more usually an Operational Office or the Head Office. The competent authority is responsible for monitoring the corrective follow-up action taken by the food business operator in such cases, including the disposal of animal by-products in accordance with the legislation.

20. In addition the purchaser/processor or owner as appropriate, should promptly identify the milk production holding which is the source of any antibiotic test failure and inform the producer of the failure. This is in keeping with the requirement that producers must take steps to correct the situation. On a monthly basis, the purchaser/processor (or owner) of the milk should also notify the relevant competent authority responsible for checking that the appropriate corrective actions have been taken at the production holding. Purchasers/processors should ensure that no further milk is accepted from the relevant producer(s) until it can be shown that the problem has been rectified.

PART B:

GUIDANCE ON THE ACTIONS TO BE TAKEN FOLLOWING AN ANTIBIOTIC SCREENING TEST FAILURE

This guidance applies in relation to the testing of milk in road tankers or in storage silos (i.e. away from the farm of production). However, the verification procedures in respect of antibiotic test failures are also relevant to on farm producer-processors. The procedures are also illustrated at Figure 3.

21. In the event that a sample fails the primary screening test, food business operators may:

a). Verify the result of the primary screening test using positive and negative control samples.

or

b) Identify and quantify the antibiotic(s) by appropriate chemical testing. If the residue is above the relevant MRL(s) the milk should be disposed of as a Category 2 animal by-product according to Regulation (EC) No 1774/2002. If the residue is at or below the relevant MRL(s) the milk may be considered as meeting the requirements of Regulation (EC) No 853/2004, and may therefore be used for human consumption.

or

c) Accept the result of the primary screening test and dispose of the milk as a Category 2 animal by-product according to Regulation (EC) No 1774/2002.

The verification test described at 'a)' must use the same test method, on a fresh sample from the same bulk source. The verification should include appropriate negative and positive control samples (where practical and available, or as instructed by the test kit manufacturer) and these should be shown to give the expected result.

22. If the result of the verification confirms the antibiotic test failure there remain two options:

a) Identify and quantify the antibiotic(s) by appropriate chemical testing. If the residue is above the relevant MRL(s) the milk should be disposed of as a Category 2 animal by-product according to Regulation (EC) No 1774/2002. If the residue is at or below the relevant MRL(s) the milk may be considered as meeting the requirements of Regulation (EC) No 853/2004, and may therefore be used for human consumption.

or

b) Dispose of the milk as a Category 2 animal by-product according to Regulation (EC) No 1774/2002,

Verification: Interpretation of results

23. The results of the verification should be interpreted as follows:

- If the negative control sample shows a test 'pass' result, and the positive control shows a test 'fail' result, and the second test sample also fails the test, then it must be concluded that the consignment contains one or more antibiotics.

- If the negative control sample shows a test 'pass' result, and the positive control shows a test 'fail' result, and the second test sample passes the test, then it must be concluded that the primary test result was unreliable and that the consignment contains no detectable antibiotics.

- If the negative control sample shows a test 'fail' result and/or the positive control shows a test 'pass' result, then it must be concluded that the reagents or the test conditions are unreliable. A new test using reagents and materials from a different production batch should be used. The retest should again incorporate appropriate positive and negative controls for which the obtained data should be assessed as above.

- Where negative and positive controls are not available and the verification test shows a pass result, then it must be concluded that either the primary screening test result or the verification test result was unreliable. In these circumstances, it is recommended that further investigation be carried out, such as the use of a new reagent batch or the testing of farm traceability samples[2], before a decision is taken on the suitability of the tested milk for human consumption.

Sample storage

24. The time between the primary and verification tests should be less than 24 hours. During this period all milk samples should be kept at or below 6°C.

Staff training

25. Staff carrying out the screening and verification tests should be competent to perform the methods correctly.

[2] In some cases a test failure may indicate the presence of substances other than antibiotics.

Laboratory procedures

26. Testing sites should be able to demonstrate that laboratory quality control procedures are in operation. It is recommended that they participate in an appropriate external proficiency testing scheme(s), have comprehensive documented procedures and maintain appropriate records. Ideally they should be accredited to a recognised laboratory accreditation scheme.

ANNEX

Competent Authority to be notified of antibiotic test failures
(See also paragraphs 18-20)

England & Wales

i) Results from farm bulk tank samples which have been tested by milk purchasers/processors should be reported to:

Animal Health Dairy Hygiene (formerly the Dairy Hygiene Inspectorate)
414 Quantock House,
Paul Street
Taunton
Somerset TA1 3NX
Tel: 01823 337922
Fax: 01823 348418
Email: DHI.Taunton@animalhealth.gsi.gov.uk

ii) Results from road tanker/silo samples should be reported to:

The Local Food Authority – either the Trading Standards Department or the Environmental Health Department, dependent on local practice.

Scotland

All samples –

The Local Food Authority

i) Results from farm bulk tank samples should be reported to the authority local to farm.

ii) Results from road tanker/silo samples should be reported to the authority local to the food business operator responsible for follow up action and disposal of the milk.

Northern Ireland

All samples –

The Department of Agriculture and Rural Development (DARD)
Quality Assurance Branch (QAB)
Room 1019
Dundonald House

Belfast
BT4 3SB
Tel: 02890 525001
Fax: 02890 524671
Email: qab.admin@dardni.gov.uk

Cross Border movement of milk.

When milk is moved between devolved administrations the same basic principles should be applied - the responsibility will rest with the owner of the milk at the time the failure is detected (who will be responsible for arranging disposal of the milk).

As an example, milk collected from a farm in Scotland but processed/tested as part of a tanker load owned by a company in England should be reported as follows-

i) to the local authority (in England) which is local to the food business operator's office responsible for follow up action and arranging disposal of the milk;
and
ii) where the farm which is the source of the failure is identified, to the local authority for that farm (in Scotland).

FIGURE 1 **Testing of Milk at Production Holdings by the Producer**

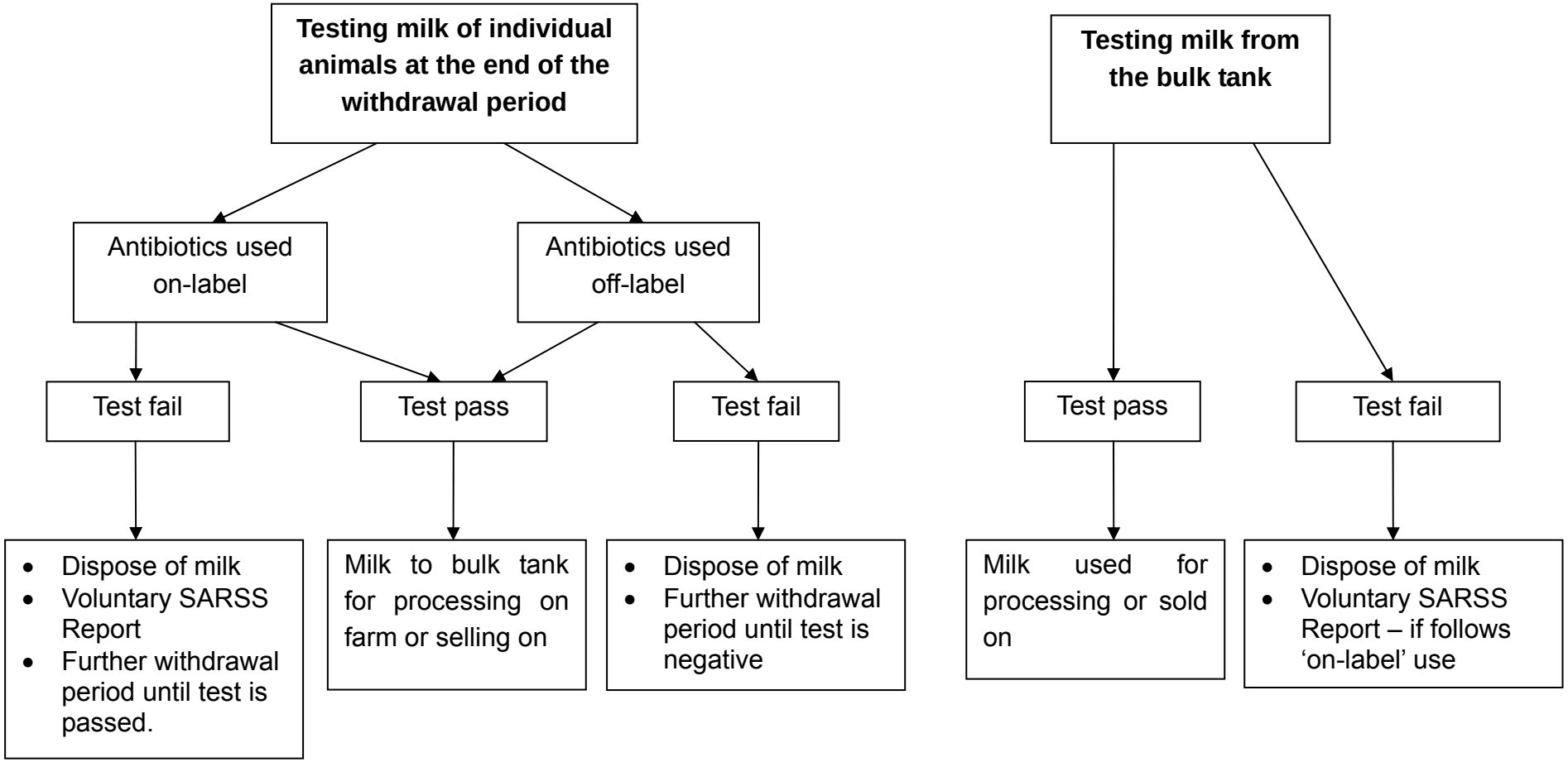


FIGURE 2 **Testing of Milk by Milk Purchasers and Processors**

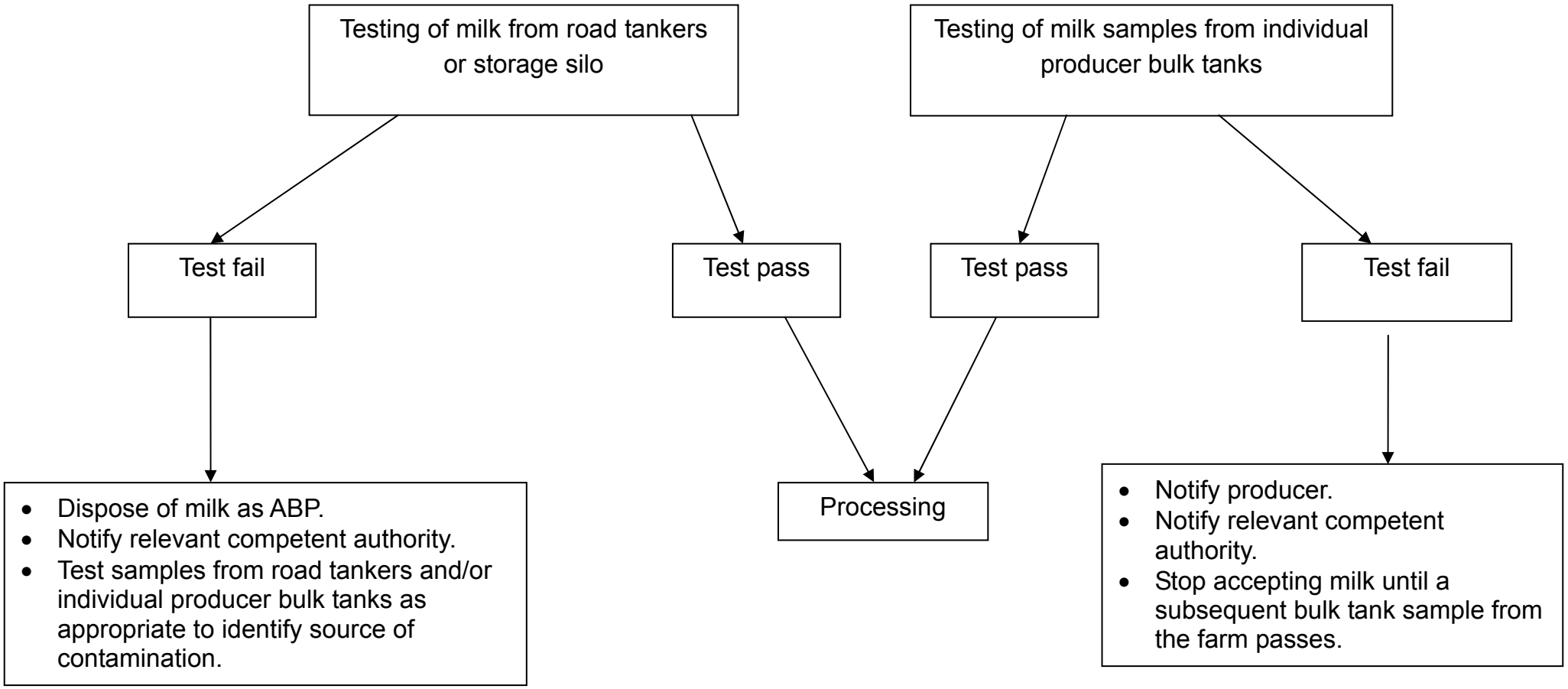
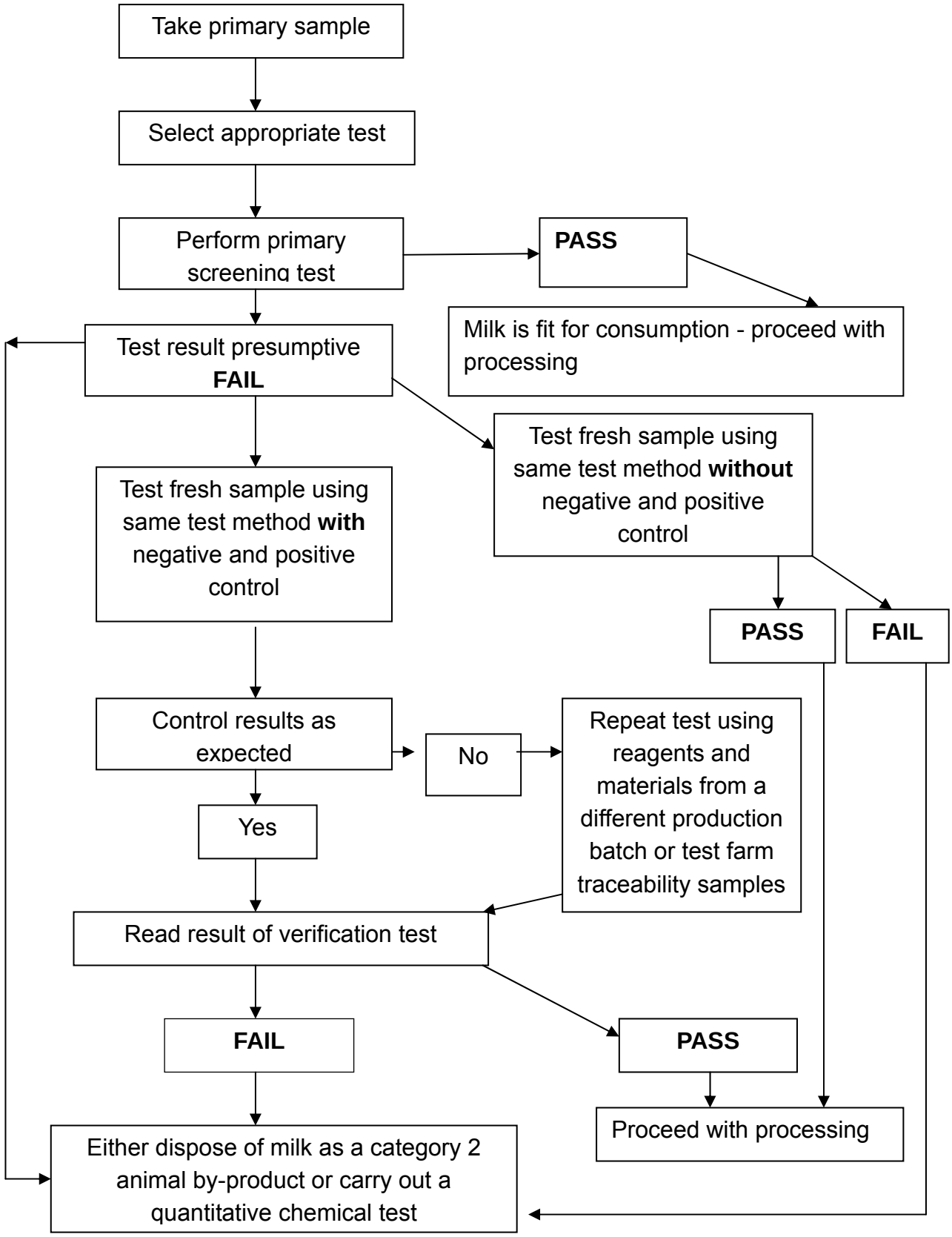


FIGURE 3 **Decision tree to illustrate the testing of road tanker/storage silo milk**



1. GLOSSARY OF TERMS

Antibiotics used on-label	Antibiotics administered in accordance with manufacturers instructions.
Antibiotics used off-label	Antibiotics administered outside the terms of their marketing authorisation according to instructions by a veterinarian.
MRL	Maximum Residue Limit as laid down in EU legislation. MRLs are published as Council Regulation 2377/90 EC. This can be found on : http://ec.europa.eu/enterprise/pharmaceuticals/mrl/mrl_key.htm NB This is a large and complex document and the details of MRLs are in the annexes. Advice may also be sought on the VMD website: http://www.vmd.gov.uk/General/VMR/vmr.htm
Negative control	A sample of similar type milk from healthy animals that is known to be free of inhibitory substances.
Positive control	A sample containing a known concentration of an antibiotic. The choice of antibiotic should be appropriate to the type of rapid test being used. The concentration of this antibiotic should be at or above the MRL.
Primary screening test	The initial test on the first sample taken from the batch of milk being screened.
Rapid test	A commercial screening test that is designed to be performed for quality control or assurance purposes, normally not quantitative.
SMEs	Small and medium sized enterprises.
Verification test	A repeat of the primary screening test using positive and negative control samples (where practical and available or as instructed by the test kit manufacturer).

2. CONTACT DETAILS

Any questions about this guidance should be addressed to:

Dairy Hygiene Branch
Food Standards Agency
Aviation House
125 Kingsway
London
WC2B 6NH

Telephone: 020 7276 8987 or 8986 (Fax: 8910).

E-mail: dairy.hygiene@foodstandards.gsi.gov.uk