

DRAFT FOR PUBLIC CONSULTATION: INFORMATION AND GUIDANCE ON THE TESTING OF MILK FOR ANTIBIOTIC RESIDUES IN THE UK

Summary Report of Responses to the Consultation

The public consultation on the draft 'Information and Guidance on the Testing of Milk for Antibiotic Residues in the UK' was issued on 5th October 2007 and closed on 28th December 2007. The consultation sought the views on the draft guidance for testing of milk for antibiotic residues. The draft guidance had been drawn up in consultation with an independent expert group on antibiotics in milk which also advised the Food Standards Agency' (FSA) on scientific and practical aspects surrounding the control of antibiotic residues in milk. The independent group included representatives from the dairy industry, the Veterinary Medicines Directorate and LACORS and information about its work can be found at <http://www.food.gov.uk/foodindustry/farmingfood/vetmeds/testingmilk/> . The draft Guidance is intended to provide advice on compliance with the legislation and ensure uniform best practice in the UK.

The proposed guidance set out an explanation of the marketing, disposal and information flow requirements following the antibiotic testing of milk. It provided this information in respect of testing carried out by (a) milk producers and (b) milk purchasers and/or processors.

The FSA is grateful to those stakeholders who responded and the table below sets out a summary of the responses received. Its considered responses to stakeholders' comments are given in the last column of the table.

The Guidance has been revised in the light of comments received and will be published on the FSA website.

List Of Stakeholders Who Responded

1. Dairy UK
2. Eden District Council
3. The European Commission – Health & Consumer Protection Directorate E – Safety of The Food Chain
4. European Dairy Association
5. LACORS
6. RUMA (Responsible Use of Medicines in Agriculture Alliance)
7. Salford City Council (which are additional comments to that made on behalf of the Greater Manchester Food liaison group)
8. West Yorkshire Principal Food Officer Group, Lancashire Food Officer Group And Greater Manchester Food Liaison Group
9. Falkirk Council
10. Department of Agriculture and Rural Development, NI, (Quality Assurance Branch)
11. IDEXX Laboratories (USA)
12. Charm Sciences Inc. (USA)

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Respondent	Summary of Comment	FSA Comment
UK Organisations		
1. Dairy UK	<p>1. Welcome the limited flexibility this guidance allows in that rapid antibiotic test results which are positive can now be verified by repeating the test with appropriate controls but do not consider the guidance goes far enough.</p> <p>2. Rapid tests operate to sensitivities for the commonly found residues of below the MRL. Consequently some milk failing the rapid tests will have residues below the MRL and are therefore within legal limits. It is not practical to require quantitative chemical testing to determine whether or not the residues are below the MRL.</p> <p>3. In other Member States it is permitted for rapid tests to be followed by a microbial inhibitor test, and the latter result is taken as final. For commonly used antibiotics the latter tests operate closer to (though still within) the MRL.</p> <p>4. Consider that adoption of procedures in line with other Member States would avoid unnecessary destruction of milk, with consequent economic and environmental consequences, (taking into account the safety factors built into the MRLs).</p> <p>5. Milk which has failed a rapid test may, for the reasons explained above, have residues below the MRL therefore consider that such milk should be allowed to be presented for possible sale to another party, along with a description of the testing already carried out and the test results, to allow the new party to test the milk using a microbial inhibitory test. In the UK milk buying cooperatives are the first owner of some milk, but may not have the facilities for carrying out any further testing which could be required.</p> <p>6. As the hygiene regulations are harmonised across the European Union, cannot see how there can be justification for imposing a testing regime on the UK which is not required in other Member States. This could also affect trade in milk between other Member States and the UK.</p> <p>7. Suggest the reporting of antibiotic failures is carried out in ways which reduce the administrative task for both industry and enforcement authorities. For many companies this would best be achieved by the reporting of antibiotic failures, and other failures such as somatic cell counts being carried out monthly to the local authority (presumably Trading Standards).</p>	<p>1. Noted.</p> <p>2- 6. The FSA notes the wish of Dairy UK to be permitted to operate a testing regime in line with those allegedly being operated in other Member States. The FSA has raised this apparent discrepancy with the European Commission.</p> <p>7. Noted.</p>

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<p>2. Eden District Council</p>	<p>Still not clear as to what is expected in terms of antibiotic testing by food business operators who process milk. Are fbos, particularly small scale ice cream manufacturers who get milk from various farms expected to test the milk used for antibiotic levels on a daily basis? The draft guidance seems to suggest that there is no requirement for milk processors to test milk. What is required of fbos in relation to antibiotic testing (ie. test the milk used on a daily basis, or just a sample now and then)?</p>	<p>As part of their due diligence, FBOs should be confident that their product satisfies the legal requirements. Although the legislation does not specify who should test milk for residues, it does require it to be tested at some stage of the food chain. See also the response to comments from LACORS.</p>
<p>3. The European Commission – Health & Consumer Protection Directorate E – Safety of The Food Chain</p>	<p>Have started consultations with different concerned parties (dairy industry, kit manufacturers and laboratories in charge of official controls). Consultations aimed at collecting information on the matter and at considering the need for further EU guidance on this issue directed at food business operators and competent authorities. The Legal Services of the Commission has strongly recommended that Health & Consumer Protection Directorate E not to give further opinions as this question is <i>sub judice</i>. Therefore regret the reply may not be more substantial.</p>	<p>The Commission is aware of the importance to the UK of resolving these issues and the FSA looks forward to taking part in discussions at European level at the earliest opportunity.</p>
<p>4. European Dairy Association</p>	<p>Concerned this guidance could disrupt trade in raw milk between companies in other Member States and the UK. General practice in other Member States when a positive result is obtained using a rapid (results in less than 10 minutes) test on a tanker load of milk is for the result to be confirmed by the recognised microbial inhibitory screening test. The latter result is the considered the final result.</p> <p>A paper dated June 2007 on Strategies for Minimising Antibiotic Residues In Raw Milk (which has previously been sent to the European Commission) was also submitted.</p>	<p>The FSA notes the wish of industry to operate a testing regime in the UK in line with those allegedly being operated in other Member States. The FSA has raised this apparent discrepancy with the European Commission.</p>
<p>5. LACORS</p>	<p>1. <i>Sampling</i>: The clarification that the main control should be 'at source' (ie. on farm) is welcomed. Not envisaged that representative sampling would be required for milk from untreated animals. Local authorities may not be clear on this so it is worth stating explicitly.</p> <p>2. Additional guidance needed on the frequency of representative sampling. Understand that this cannot be fully defined as it is ultimately for producers to decide, some guidance for local authorities would be welcome so that they are able to effectively advise producers that contact them for</p>	<p>1. Noted.</p> <p>2- 3. The FSA agrees that guidance would be best provided by an Industry Guide to Good Hygiene Practice for the dairy sector and encourages industry to expedite its development. The FSA is participating in discussions on a draft Guide and will explore with the working group how</p>

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	<p>advice. It may be that the FSA opts to include such advice in an Industry Guide, for example.</p> <p>3. Although there is no requirement for milk purchasers to test milk samples, it would be useful to provide some indication of 'good practice' in this area. Understand that this cannot to be fully defined as it will dependent on producer and circumstance, but Environmental Health Departments may be called upon to provide advice in this area, particularly where the disposal of unsatisfactory milk will form part of the HACCP. Again, this may form part of an Industry Guide.</p> <p>4. <i>Roles:</i> Keen for the guidance to highlight any obligations LAs have, to check food business operator compliance (eg. at visits, by sampling). In particular, how should paragraph 5 (b) of Article 4 of Reg EC 854/2004 be interpreted? If more visits or sampling are required then the resource issues for local authorities would need to be considered.</p> <p>5. It would be useful for any guidance to be accompanied by a 'matrix of responsibilities', outlining where enforcement responsibility lies (eg. Animal Health, Environmental Health, Trading Standards). This will be particularly important for two-tier authorities where District Councils will have a responsibility for HACCP audits, and County Councils for issues relating to chemical residues and Animal By-Products. LACORS would be happy to assist in the drafting of any such document.</p> <p>6. Please note that the 'Competent Authority to be notified of antibiotic test failures' (page 11) for tanker/silo samples may be the Environmental Health Department rather than Trading Standards (eg. for some unitary authorities).</p> <p>7. <i>Animal By-Products:</i> Unclear how local authorities will oversee the disposal of Animal By-Products when, according to the guidance, they will only be notified at the end of each month (presumably after the event). LACORS would not want to see the introduction of onerous new requirements to monitor the disposal of ABPs but would not want it assumed that local authorities had responsibility for something they would have little control over.</p> <p>8. <i>Flow Diagrams:</i> The options for verification/retesting of tanker/silo milk indicated in Figure 4 do not seem reflected in Figure 2. Figure 3 does not include the action required to dispose of milk in the event</p>	<p>best to include guidance on the testing of milk for antibiotics.</p> <p>4. This aspect is addressed in general guidance set out in the Code of Practice and Practice Guidance –[in particular Code of Practice Section 6.]</p> <p>5. Welcome this suggestion. FSA has contacted LACORS to put forward a first draft document on a matrix of responsibilities.</p> <p>6. Noted.</p> <p>7. There is no requirement for Enforcement Officers to oversee the disposal of animal by-products. However EHOs should, as part of their normal inspection and enforcement role, ensure that FBOs are aware of the requirements of the ABP Regulations (see Defra guidance at http://www.defra.gov.uk/animalh/by-prods/pdf/milk.pdf)and ensure appropriate arrangements in place for compliance. Disposal sites are approved and inspected (risk based inspections) by Animal</p>
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	<p>of an unsatisfactory test result.</p>	<p>Health.</p> <p>8. Figure 4 – Noted. Failures are rarely found in the Statutory Surveillance Programme. If one occurs and it is a serious breach then a risk assessment is carried out and the producer would be informed of the result and contacted to see if there is a problem. It would be too late in any case to deal with the failing batch as analysis may occur many months after receiving the sample.</p>
<p>6. RUMA (Responsible Use of Medicines in Agriculture Alliance)</p>	<p>1. Any measures to control antibiotics residues in milk should be proportionate to the problem. The issue of residues in milk in excess of the current regulated maximum residue limits is a problem of contamination and not one of public health.</p> <p>2. Logical that the organisation initiating the laboratory testing should ensure that positive antibiotic test results are notified to the relevant competent authority and the primary producer of the milk.</p> <p>3. The primary producer needs to know of the test failure as soon as it is available so that remedial action can be undertaken to prevent further contamination occurring. Unless information is available speedily the possible reason for the failure will probably not be found. The longer notification is left, the more likely it is that the source of the problem will remain undetected.</p> <p>4. If the failure is to be investigated it is again important that such persons/organisations who will undertake any investigation are also rapidly informed.</p> <p>5. When testing, only the maximum residue level (MRL) as laid down in the EU legislation should be used. Some milk purchasers will undertake tests which will give positive results for some antibiotics at well below the MRL. This is an unfair penalty for a primary milk producer as the milk can still legally be sold. It also means that there is no standardisation of testing.</p> <p>6. Primary producers should be made aware of the approximate frequency at which their milk is tested, and how quickly they will be informed following a failure.</p> <p>7. Milk producers and veterinary surgeons might be unaware that when antibiotics are used "off label" that the milk of individual treated animals</p>	<p>1 – 2. Noted.</p> <p>3. Agree.</p> <p>4. Noted.</p> <p>5. This is not technically possible.</p> <p>6. This is a matter for the milk industry and those who carry out the testing.</p> <p>7. Noted.</p>

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	<p>must be tested after the minimum withdrawal period of seven days.</p> <p>8. Not certain to whom this document is aimed. However the primary producers have, if anything, too much information being provided for them and this document does take some reading before any relevant items are found. The flow diagrams are useful and for the most part they are more easy to follow.</p> <p>9. If this document is to be circulated to primary producers it is suggested that there should be references to where other information can be obtained on why antibiotic failures occur and how to prevent them. Recently a useful practical guide on avoiding antibiotic residues has been provided to milk producers in the form of a poster by one of RUMA's member organisations, the National Office of Animal Health. This initiative has been supported by RUMA as well as by other RUMA organisations involved in milk production including Dairy UK and the British Cattle Veterinary Association, a Division of the British Veterinary Association.</p> <p>10. Following recent re-organisations it is not clear to most including many primary producers and others, as into which organisation the Dairy Hygiene Inspectorate have been absorbed.</p>	<p>8. Noted.</p> <p>9. The FSA has supported the initiative to produce the NOAH guide on avoiding antibiotic residues and was involved in discussions on the poster.</p> <p>10. Noted. In April 2007 DHI became part of Animal Health, an executive Agency of Defra and is now called Animal Health Dairy Hygiene. This will be reflected in the text.</p>
<p>7. Salford City Council (which are additional comments to that made on behalf of the Greater Manchester Food liaison group)</p>	<p>1. Guidance considered from an industrial dairies perspective.</p> <p>2. Figure 3 outlines the statutory surveillance program and the subsequent action to be taken depending on the MRL, but the guidance does not determine the parameters for the MRL. Regulations (EC) No 853/2004 refers to Annexes I and III of Regulations (EEC) 2377/90 which says the list is to be established. Suggest the guidance should contain the MRL as this information is difficult to obtain.</p> <p>3. In the evidence base section of the consultation, it states that the rationale for the guidance was as a lack of detail on sampling and testing which has lead to inconsistencies. It is felt that the guidance does not address this issue as there is no indication of the expected frequency of testing and therefore we do not feel that this will address consistency, as it may be interpreted differently throughout different local authorities/ food liaison groups.</p> <p>4. The estimated time for an enforcement officer and a food business operator to read and understand the guidance is greatly underestimated and therefore subsequently the costs are likely to be greatly underestimated.</p>	<p>1. Noted.</p> <p>2. 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</p> <p>3. Please see response to LACORS points 2-3.</p> <p>4. The estimated time will be increased.</p>

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<p>8. West Yorkshire Principal Food Officer Group, Lancashire Food Officer Group And Greater Manchester Food Liaison Group</p>	<ol style="list-style-type: none"> 1. Guidance considered from the perspective of local authority enforcement at on-farm producer/processors which is the area of our expertise. 2. Generally the guidance is too complex and has apparent contradictions which require very detailed reading to resolve. Not in agreement with the opinion on page 19 that just one hour is required by enforcement officers and the dairy industry to read and understand the guidance. Suggest that a simple summary document in plain English should be produced for primary producers/on-farm dairies (i.e. Single sheet, A4). 3. Request that a section and corresponding flow chart should be included which specifically deals with on-farm producer/processors. 4. Need for guidance on the type of testing and the testing frequency similar to that produced by the Food Authority of Ireland. This is particularly relevant to a small on-farm processor who buys milk from neighbouring farms and does not have the resources of major buyers/wholesalers, but who is still required to carry out testing. 5. Particularly concerned by paragraphs 7, 8 and 9 which are very confusing. Clearer guidance is needed on what testing is REQUIRED of producers and that which is optional. The nuances of the words MUST and MAY are not appreciated by small farmers. It is naive to expect most small farmers to do anything other than what is absolutely necessary, particularly where significant costs may be incurred. 6. Examples of scenarios submitted which were considered in reviewing the text. 7. Clearer guidance is also needed in setting out circumstances when a producer MUST notify the competent authority. 8. Concerned that in Annex 1 on page 11 the competent authority is identified as i) AHDH and ii) Local authority Trading Standards Dept. Our understanding is that Reg EC 853/2004 is enforced by Food Authorities (Environmental Health Depts.) and it is they who should be notified. 	<ol style="list-style-type: none"> 1. Noted. 2. The estimated time will be increased. The FSA will consider a simplified version of the guidance aimed at primary producer s and on-farm processors. 3. See Figure 2 (right hand side). 4. Please see response to LACORS points 2-3. 5. Noted – will review text. 7. Have reviewed this and consider the draft Guidance is clear on this point. 8. Please see response to LACORS point 6.
<p>Devolved Regions:</p>		

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<p>9. Falkirk Council</p>	<p>The Draft Guidance Annex A: 1. Would consider the frequency recommended in guidance that notification of antibiotic failures should be on a monthly basis, to be satisfactory in normal circumstances; 2. Suggest that the person responsible for the first test be responsible for notifying any failure. In which case, on balance, the owner of the milk should take responsibility for the reporting. The Draft Impact Assessment Annex B 3. i). In terms of cost we do not have any additional comments to make. ii) In terms of benefits agree that Option 2 would serve to clarify the responsibilities of all agencies involved and also to provide a means of reducing wastes. There are no additional comments at this time from Falkirk Council.</p>	<p>Noted.</p>
<p>10. Department of Agriculture and Rural Development, NI, (Quality Assurance Branch)</p>	<p>1. Part 1 General guidance, Page 3, Paragraph 8 (penultimate sentence): suggest that this sentence commence with: <i>In addition to keeping records of all medicines purchased and medicines administered to dairy animals, milk producers should keep records of all the antibiotic testing they undertake</i> 2. Page 4, Paragraph 11: Do not support the statement that “there is no requirement for milk processors to test milk” and would not agree that it would be acceptable for a processor to test silo milk only while ignoring all milk received at tanker level. 3. Regulation (EC) 853/2004 Annex III Section IX Chapter 1,III,4 requires FBOs to “initiate procedures to ensure that RAW MILK is not placed on the market containing antibiotic residues in excess of authorised levels. The “placing on the market transaction” in the majority of cases is at point of receipt of tanker loads of milk at factory intake bays. 4. Regulation (EC) 852/2004 Annex II Chapter IX requires an FBO not to accept raw materials if they are known to be or MIGHT REASONABLY EXPECTED TO BE contaminated with foreign substances. Bulking up milk in silo tanks, although a normal procedure, should not be considered as a sorting or a preparatory procedure and the final product which, although testing negative for antibiotics, could potentially contain a tanker load or a number of tanker loads of Category 2 ABP should not be perceived as fit for human consumption. Experience has shown that the likelihood of any tanker load of raw milk containing antibiotics is not insignificant.</p>	<p>1. Noted and text reviewed. 2. The Regulations do not specify where the sampling should be done. 3. Regulation (EC) 178/2002 defines ‘placing on the market’ as meaning the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer [...] and the sale, distribution, and other forms of transfer themselves. There is not one place/point specified. Commission Decision 2006/694 concurred with this definition. 4- 5. The Regulations do not specify where the sampling should be done. 6. Noted</p>

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	<p>5. Would not be content with a factory HACCP plan that totally ignored antibiotic checks on raw milk at the point of acceptance from road tankers. and would expect at least a reasonable percentage of incoming tanker loads to be tested each day.</p> <p>6. Page 5, Paragraph 15: suggest that reporting tanker and silo check failures on a monthly basis is insufficient to enable the Competent Authority (CA) to verify the actual disposal of some of the ABP milk. We would also expect the owner of the milk to identify and report the offending producer(s) involved to enable investigation at farm level to be carried out urgently.</p> <p>7. In NI the party that carried out the first (and possibly the confirmatory) screen test – [this is usually the receiving factory and not the owner of the milk but the receiver and the owner of the milk can be one and the same] reports immediately to DARDQAB by phone, fax or e mail. QAB can then follow up with the owner re the offending producer and disposal details. Milk owners also report to DARD on all disposals this can be monthly or more frequently.</p> <p>8. Suggest that the party carrying out the screen test reports initially to the CA immediately following a failure result and that the owner of the milk reports on how the milk was disposed of. This should be more frequent than monthly.</p> <p>9. Following an FVO Mission to ROI during September last it appears that they were not prepared to accept a test verifying the initial screen test and that they insisted that if the initial screen was positive then the milk was immediately to be designated Cat 2 ABP.</p>	<p>7. Noted</p> <p>8. Noted</p> <p>9. Noted. We await the report of the FVO Mission.</p>
<p>Comments from Interested Parties outside the EU:</p>		
<p>11. IDEXX Laboratories (USA)</p>	<p>The following is for consideration:</p> <p>1. A published table of reference of MRLs for the most frequently used antibiotics. This reference table would be helpful to test users and kit manufacturers.</p> <p>2. Regarding the use of rapid screening test methods, encouraging the publication of standards achieved by the test kit manufacturer by an accredited or recognised organisation to ensure the consistent quality of residue test kits used.</p> <p>3. Pg16 / Figure4: Testing of Tanker/Silo Milk</p>	<p>1. Please see response to Salford City Council point 2.</p> <p>2. Noted.</p> <p>3. No other comments received from industry during the</p>

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	<p>'Repeat test using reagents and materials from a different production batch of test farm traceability samples' [<i>sic</i>] – This is interpreted to mean that the user/tester will be required to use a screening test kit manufactured from an alternative lot of material if so, that may pose a difficulty for the user as they will be required to always maintain 2 batches or lots of the kits on hand in order to complete the retest within 24 hours. Test kits may expire prior to be used up and maintaining 2 current lots of products may not always be available to the user.</p>	<p>consultation concerning the practicalities of this.</p>
<p>12. Charm Sciences Inc. (USA)</p>	<p>In the interests of equivalence the policies put forward in UK guidance should be consistent with US document/protocols as well as participating EC countries documentation. There are some areas that need to be clarified or amended to maintain consistency-</p> <p>1. Equivalence Statement: Initial screening test positives (primary screening test positive) should be confirmed by the same test in duplicate and using positive and negative controls. The positive and negative controls determine that the test is working properly, and if the controls are in the expected range and either of the duplicate retests is positive, the sample is confirmed as a presumptive positive (verified positive). If the controls are out of range, it indicates the test is not working and a different test must be used to determine the status of the milk. Comment-</p> <ul style="list-style-type: none"> ○ Item 17 of the guidance appears to allow the destruction of milk without control verification that the initial test is working properly. In the event the initial test is not working properly and no controls are performed to verify the test and equipment are working correctly, economic damage is caused to the owner of the milk. We as a test kit manufacturer want to prevent accidental destruction and economic loss from tanker loads of milk being improperly disposed. We therefore supply controls as part of the kit and write confirmation protocols into the test kit instructions. Some test kit manufacturers do not manufacture or supply controls, but still support control use in determining the status of the trueness of the initial screening result prior to milk destruction. Using controls is good manufacturing practice. ○ Item 19 bullet point 4, is not good manufacturing practice and should be deleted. Without controls, there is no proof that a 	<p>Noted. Equivalence in this area is a matter for the EU Commission.</p> <p>1. The FSA agree that the use of positive and negative controls is good practice, where recommended by the kit manufacturer.</p> <p>The Guidance reflects the advice of the Antibiotics Expert Group who will be invited to comment .</p>

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	<p>second negative test is more reliable than the initial first positive result.</p> <ul style="list-style-type: none"> ○ The other 3 bullet points of Item 19 are agreed, however the first should be revised to be a duplicate sample and if either duplicate result gives a positive result. The second bullet should be revised to be that both duplicate results are negative. ○ Item 17.2 should be revised to be a duplicate re-test. <p>2. Equivalence Statement: Once a test is determined presumptive positive, the result and sample ID is reported to the regulatory authority and the sample is not offered for resale until the status of the sample had been determined by the regulatory authority. Comment-</p> <ul style="list-style-type: none"> ○ Item 14 of the proposed guidance appears to be consistent with this statement, but how is it enforceable without an immediate reporting requirement in Item 15?. <p>3: Equivalence Statement: The regulatory authority may decide to confirm the presumptive positive with the same test, in duplicate with controls, or they may decide to use another test that has been shown to detect the same drugs (below safety thresholds) as the initial screening test. Comments-</p> <ul style="list-style-type: none"> ○ The proposed monthly reporting schedule of Item 15 of the guidance prevents regulatory involvement in confirmation of presumptive positives. If positives are reported immediately, then the regulatory authority could supervise subsequent testing and ultimate determination of sale status before the milk goes bad. This is more consistent with US programs and the confirmation tests conducted in Belgium. ○ Item 18 is written such that a company doing screening and verification, could also perform subsequent MRL status testing (confirmation testing), but without any regulatory oversight. If the lack of regulatory oversight is intentionally in the guidance, then at a minimum, confirmation testing at MRL levels should be performed by a laboratory with demonstrated proficiency/competency in the method and without a financial interest in the outcome of the result. 	<p>2. Noted.</p> <p>3. Noted.</p>
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	<p>4. Equivalence Statement: Only tests that have been evaluated under a specific evaluation program and shown to meet performance specifications may be used to comply with the program. Comment-</p> <ul style="list-style-type: none"> o EU has no equivalent evaluation system. UK has the Milk Quality Forum tests done by Donald Muir at Hannah Research Institute. <p>5. Equivalence Statement: All tankers of milk must be screened for the most common antibiotics, beta-lactam, prior to unloading. Producer samples are checked at least 4 times every 6 months. Comment- This is not consistent with Item 11 of the proposed guidance, where there is not any requirement or frequency suggested.</p>	<p>4. Noted.</p> <p>5. The Regulations do not specify where the sampling should be done nor the frequency of testing.</p>

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