SEPTEMBER 2008

DEFRA GUIDANCE

APPROVAL OF COMPOSTING AND BIOGAS PLANTS TO TREAT CATEGORY 3 ANIMAL BY-PRODUCTS AND/OR CATERING WASTE UNDER REGULATION 208/2006

APPROVAL OF TECHNICAL PLANTS FOR THE PRODUCTION OF MANURE PRODUCTS UNDER REGULATION 208/2006

REPLACEMENT OF ENTEROBACTERIACEAE WITH E. COLI OR ENTEROCOCCACEAE IN ROUTINE SAMPLING IN ALL COMPOSTING AND BIOGAS PLANTS

1. Background

1(a). Regulation (EC) 1774/2002

1. Composting and biogas plants treating category 3 animal by-products and catering waste have previously been approved under Regulation 1774/2002. They must meet certain time/temperature treatment standards set out in Annex VI of the Regulation. The EU standard for the treatment of animal by-products in 1774/2002 is 70°C for 1 hour at a maximum particle size of 12mm in one plane. Plants treating only catering waste could be allowed to operate at certain other standards set by national legislation, but these were similarly based on time/temperature/particle size treatment standards.

2. Technical plants for the production of manure products have also previously been approved under Regulation 1774/2002. The EU treatment standard for manure is also 70°C/1 hour/12mm particle size. However the UK chooses only to require this standard for products intended to be traded internationally.

1(b). Regulation (EC) 208/2006

3. Regulation 208/2006 allows for the approval of alternative composting and biogas standards for the treatment of animal by-products. Rather than setting out the process requirements (time/temperature/particle size) for treatment of raw material it permits the operator to specify their own treatment parameters, provided that the operator can demonstrate through microbiological testing of the finished product that the system has produced sufficient pathogen reduction (and of course provided the system still complies with all other aspects of 1774/2002). The operator must be able to demonstrate 5 log reduction of certain marker bacteria. The Regulation also requires that a 3 log reduction of infectivity in thermoresistant viruses is demonstrated 'whenever they are identified as a relevant hazard'. As material from composting and biogas plants is likely to end up on land to which animals may have access (following a suitable grazing ban in the case of

farmed animals) Defra's current position is that viruses will be assumed to be a relevant hazard and the 3 log reduction of infectivity of thermoresistant viruses must be demonstrated.

4. Similarly the processing of manure in technical plants is now not restricted under 208/2006 to the single EU treatment standard in 1774/2002, but may also benefit from the same demonstration of 5 log reduction of certain marker bacteria, and 3 log reduction of infectivity in thermoresistant viruses.

2. New Marker Pathogens For Sampling Under 208/2006

5. Under the existing 1774/2002 rules, the marker organisms which must be used for sampling in composting and biogas plants are clearly specified (Salmonella and *Enterobacteriaceae*). The tests for these markers are well-established, and previously the protocol has been for samples to be sent to Defra-approved private laboratories who would test for the presence of these markers (official tests taken by Animal Health would be sent to the VLA). The VLA would be responsible for approving the private laboratories. The VLA would also be responsible for the QA audit of the testing itself.

6. However, Regulation 208/2006 allows for the introduction of 2 new elements:

(i) new marker organisms not previously tested for by the VLA and not necessarily with well-established tests available (e.g. *Enterococcaceae*).

(ii) Regulation 208/2006 also permits the operator to nominate other markers that they may wish to use, provided this marker can be used to demonstrate to the satisfaction of the approving officer an equivalent risk reduction to the markers named in the Regulation.

7. This is a highly flexible approach and the existing testing regime cannot support it. We believe that beyond a few key players there will not be a lot of uptake for testing under 208/2006, and laboratories are unlikely to be prepared to support expensive development work on a large number of new and unfamiliar tests, which may then hardly ever be used. We need to look at new, more flexible and more targeted ways to approach testing.

3. Regulation (EC) 882/2004

8. Under Regulation (EC) 882/2004 on official controls for the verification of compliance with feed and food law, and animal health and welfare rules, laboratory tests where they are carried out as part of an official control should be carried out in accordance with the provisions of the Regulation. Regulation 882/2004 sets out the various standards (e.g. ISO (International Organisation for Standardisation) standards) that must be met by laboratories wishing to be approved or designated under this legislation. The new composting and biogas rules under 208/2006 are an opportunity to introduce a more flexible

approach in accordance with the provisions of the Official Food and Feed Controls.

4. Proposed Protocol For An Approval Under Regulation 208/2006

(i) The operators themselves should identify the laboratory which they wish to use for their testing. This laboratory must be accredited under ISO 17025 (specifying the general requirements for the competence to carry out tests and/or calibrations, including sampling) to perform testing on each marker chosen for use (or, failing that, the laboratory or the operator will have to pay for the laboratory to gain such an accreditation).

(ii) The laboratory will need to send the approving body proof of their accreditation. This will be Animal Health in England, Scottish Government in Scotland, and Welsh Assembly Government in Wales. Providing this information will enable the laboratory to be added to a list of laboratories designated under Regulation 882/2004 to carry out this work on behalf of the Competent Authority.

(iii) The approving officers will continue to take their own tests as usual, although they will now need to test for the new marker organisms rather than those tested for previously under Regulation (EC) 1774/2002. These organisms may vary depending on whether the test is for site validation or for ongoing background sampling (see Annex I). These samples will also have to be sent to an ISO 17025 accredited laboratory. This need not be (but in practice with the 208/2006 markers, probably will be) the same laboratory. The frequency of testing will be set by the inspecting officer according to considerations such as size/throughput of plant. This will be in line with the sampling rates previously used under 1774/2002.

(iv) In the UK the laboratory would have to be accredited by the United Kingdom Accreditation Service (UKAS). Laboratories within the EU could also be used, but these would similarly need to be accredited by their own national accreditation bodies.

(v) It is part of the 17025 ISO that laboratories carry out quality analysis (QA) testing. We suggest that under the proposed scheme laboratories arrange their own QA. Defra will not be carrying out audit tests as we do under the existing 1774/2002 rules.

(vi) Regulation 208/2006 also requires the operator to supply a risk assessment of their proposed system to demonstrate its capacity to achieve the requirements of the Regulation. We propose that it will be for the operator to produce the risk assessment (as part of a Hazard Analysis and Critical Control Points (HACCP) plan), which will be required in order for their plant to be approved. This will need to take account of any potential hazards that may occur in the system and how these will be controlled and/or eliminated. This should include an assessment of the hazards present in the input material.

(vii) Validation of the plant will be carried out by Animal Health. The HACCP plan must be agreed with the approving officer. The method of validation to be used must also be agreed with the approving officer. One possible method of validation has been used for many years in Germany (the German Ordnance) and this is attached at Annex II as an example of a validation method. The Regulation is not prescriptive about how the validation is achieved and alternative methods may be used subject to agreement with the approving officer.

5. Replacement Of *Enterobacteriaceae* With *Escherichia Coli* Or *Enterococcaceae* In Routine Sampling In All Composting And Biogas Plants

9. As well as introducing alternative standards for composting based on pathogen reduction, Regulation 208/2006 also makes changes to the ongoing sampling regime previously set out in Regulation 1774/2002. These changes apply to **all approved composting and biogas plants handling animal by-products**, not just to those approved under Regulation 208/2006.

10. Under Regulation 1774/2002 the ongoing sampling regime for composting and biogas plants handling animal by-products was Salmonella and *Enterobacteriaceae*. The requirement to test for Salmonella remains the same under Regulation 208/2006. However the test for *Enterobacteriaceae* has now been changed to a choice between either *Escherichia coli* or *Enterococcaceae* (but see para 15 below).

11. Composting and biogas plants handling only catering waste will not be affected by this change, as they are required on a routine basis only to test for Salmonella, and this has not changed.

6. Transitional Measures

12. Under Regulation 882/2004, all laboratories carrying out official tests must be accredited to ISO 17025.

13. However, Regulation 2076/2005 lays down transitional measures for this requirement of Regulation 882/2004. It permits laboratories who were carrying out official tests prior to 1 January 2006 to continue using these tests until 31 December 2009.

14. From **1 January 2010** all laboratories carrying out official tests must be accredited to the ISO 17025 standard for those tests. This includes all tests required either by Regulation 208/2006 or by Regulation 1774/2002.

15. We have also permitted laboratories that previously were testing for *Enterobacteriaceae* under Regulation 1774/2002 a transitional period which enabled them to continue testing for this organism while official guidance on the implementation of Regulation 208/2006 was drawn up. These laboratories should now be moving to testing for *Escherichia coli* or

Enterococcaceae in accordance with Regulation 208/2006. In line with all laboratories operating under Regulation 882/2004, we would expect these laboratories to be testing for *Escherichia coli* or *Enterococcaceae* to the ISO 17025 standard by 1 January 2010.

16. Operators whose laboratories are still testing for *Enterobacteriaceae* may wish to check with their laboratory whether they intend to move to testing for the new markers by 1 January 2010, otherwise an alternative laboratory which is adopting the new markers may need to be identified.

7. Links To Legislation

Regulation (EC) 1774/2002 laying down health rules concerning animal by-products not intended for human consumption

Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

Regulation (EC) 2076/2005 laying down transitional arrangements for the implementation of Regulation 882/2004

The Animal By-Products Regulations 2005

The Animal By-Products (Scotland) Regulations 2003

The Animal By-Products (Wales) Regulations 2003

Animal By-Products (Northern Ireland) Regulations 2003 (SR 2003/495)

Annex I

Listed markers for validation and on-going sampling under Regulation 208/2006

Markers used in validation (log reduction to be demonstrated)	**Markers used in ongoing testing**
Enterococcus faecalis: 5 log 10	*Escherichia coli* or *Enterococcaceae*: n=5, c=1, m=1000, M=5000 in 1 g
Salmonella Senftenberg (775W, H25 negative): 5 log 10	*Salmonella*: absence in 25 g: n=5; c=0; m=0; M=0
Parvovirus: 3 log 10 (where identified as a relevant hazard)	

The Regulation also permits the use during validation of alternative markers if they are: (a) endogenous to the material and present in sufficient quantity, or (b) a well characterised test organism or virus introduced in a suitable test body. The test must demonstrate reduction of the marker organisms equivalent to the markers in the table.