ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

ACMSF RESPONSE TO THE WASTE AND RESOURCES ACTION PROGRAMME REPORT ON: QUALITY, SAFETY AND USE OF DIGESTATE IN UK AGRICULTURE

At the September 2011 meeting the Committee considered the Waste and Resources Action Programme (WRAP) report on the quality, safety and use of digestate in UK agriculture (paper ACM/1035)[1]. Although the Committee made some comments on this report[2], members noted that because of the amount of information presented they would like to consider the report in detail.

A subgroup of Committee members were asked to discuss the risk assessment in more detail and their comments (see Annex1) were considered by the Committee at their 19 January 2012 meeting[3] and subsequently approved via correspondence.

Secretariat
May 2012

[1] http://www.food.gov.uk/multimedia/pdfs/committee/acm1035wrap.pdf
[2] http://acmsf.food.gov.uk/acmsfmeets/acmsf2011/acmsf220911/acmsfmin110911
[3] http://acmsf.food.gov.uk/acmsfmeets/acmsf2012/acmsf190112/acmsf-min-19Jan12

Annex 1

WASTE AND RESOURCES ACTION PROGRAMME (WRAP): QUALITY, SAFETY AND USE OF DIGESTATE IN UK AGRICULTURE

Comments have been framed to reflect the specific questions posed by the FSA via ACM 1035[4]

Summary

The report assesses a range of relevant food safety risks, focusing on the issues of greatest importance, considering a wider range of pathogens than the previous report (ACM 976)[5]. The general approach taken appears to be robust. Depending on the availability of data for different pathogens the approach varies from full quantitative risk assessment to evidence based discussion which is, on balance justified. In some cases, however only partial literature appears to have been recorded under the evidence based discussion sections. Additionally the stated levels of accuracy assigned to the risk assessments are difficult to justify given the uncertainty and assumptions within the calculations.

The overall conclusion that the risks associated with the use of PAS110 compliant composts in agriculture are low is reasonable based on the evidence presented. The quantitative assessments of risk point to additional cases of infection associated with anaerobic digestate (AD) use being considerably less than one per year in most instances.

In relation to data gaps and further work, the emerging risk from non-O157 VTEC should be considered. Although this would affect the potential risk attributed to VTEC it would be unlikely to impact on the overall conclusions. The significance of unpasteurised feedstock on possible risk should be considered. Additionally, if pasteurisation is applied after the AD process there should be consideration of the potential for pathogen growth to high levels within the digester reducing its efficacy. Full compliance with optimum procedures, input selection, anaerobic digestion and pasteurisation appear to be assumed. Real-life experience indicates that complete compliance in all cases is most unlikely and the issue of procedure bypass could be given further consideration/quantification.

The conclusions derived on the impacts of composting and AD on *C. botulinum* are not unreasonable. It is acknowledged that the available data is limited. However in some cases the data presented is conflicting and statements are not backed up by evidence. A number of suggestions for clarifying statements, addressing data gaps and simplifying this section have been made.

---

[4] http://www.food.gov.uk/multimedia/pdfs/committee/acm1035wrap.pdf
[5] http://www.food.gov.uk/multimedia/pdfs/committee/acm976wrap.pdf

The biofertiliser matrix appears logical for the hazards covered and the proposed risk management recommendations are likely to reduce residual food safety risks provided satisfactory compliance with these proposed recommendations can be maintained. However, given the role that has been highlighted for pasteurisation in the assessment, the use of unpasteurised digestate on Category 3 fresh produce should be reconsidered.

Qi. Members are asked to provide peer-review comments on microbiological food safety aspects of the draft report on the quality, safety and use of digestate in UK agriculture.

1. The overall report benefits from the provision of clear executive summaries of each section, with the use of bullet-points.

2. The microbiological risk-assessment benefits from consideration of a wider range of pathogens than previously. The basis of selection of pathogens to consider further in the report appears to have been driven by input from Stakeholder Steering Groups (SSG). This SSG approach has merit for a number of aspects of the development of this work. However, it would also have been helpful to have some increased clarity around the rationale used to select and prioritise the agents considered. The approach varied for different pathogens depending on the availability of data to populate quantitative risk assessments. This is a pragmatic approach based on what is available in the literature, and on balance is justified by the need to consider a wider range of pathogens.

3. From a broader editorial perspective, it would be helpful to move the sections in the microbiological-risk assessment which simply highlight benefits of the processing technology to a separate section of the overall report. As currently structured it detracts to some extent from the overall impression of objectivity that is engendered upon reading this section.

Qii. Do Members consider the approach used in this risk assessment to be appropriate and sufficiently rigorous to fully assess the microbiological safety risks associated with application of PAS 110 compliant digestates to food producing land?

4. Overall, the report assesses a range of relevant food safety risks, focusing on the issues of greatest importance. The general approach taken appears to be robust.

5. The approach does not follow the conventional structure of a formal risk assessment/risk management document. Statement of purpose, hazard identification, hazard characterisation, exposure assessment and risk characterisation all appear within different chapters of the document, but not always in a logical sequence and without consistent grouping of information and comment.

6. The range of potential pathogens considered has been widened considerably and now covers the main areas of concern. Selected pathogens (e.g. *Campylobacter, Listeria, Salmonella* spp, C. *botulinum*, scrapie and *E. coli* 0157) are considered in great detail. Other pathogens, notably fungi and parasites are subject to "evidence based discussion" (see pages 335-344) rather than standard risk assessment. It is stated that this differential approach reflects available information. The information recorded under "evidence based discussion" represents only a part of the relevant published literature for the pathogens under consideration and some pathogens are therefore dealt with in outline only.

7. The stated levels of accuracy assigned to the various risk assessments (often to two decimal places) are difficult to justify given the uncertainty and assumptions within the calculations. It would be helpful to include confidence intervals so that the degree of uncertainty associated with the results was made transparent. Similarly, the design of investigations reported in Chapter 1 (anaerobic digestate quality for Welsh agriculture) does not appear to incorporate a power calculation; hence the selection of the number of sites and repeat investigations appear arbitrary and opportunistic in design.

8. The risk guidance model does give good information on predicted 6 log kill of bacterial vegetative pathogens during batch pasteurisation (applied to all feedstock before AD) , and the 5 log kill of key viruses.

9. Effects of Digestion/decay in soils
The effects of digestion give added confidence that vegetative bacterial pathogens are well discussed as are pathogen decay rates in soils.

Qiii. In relation to microbiological food safety, do Members agree with the overall conclusion that the risks associated with the use of PAS 110 compliant composts in agriculture are low?

10. The overall conclusion is reasonable on the basis of the evidence presented and considered in the document and with respect to the scope of the assessment. However, the lack of effectiveness in terms of TSEs may be an issue that requires additional consideration.

11. Definition of "low risk" is difficult as this is a subjective assessment however, the quantitative assessment of risk point to additional cases of infection associated with digestate use being considerably less than one per year in most instances.

12. The scope refers to PAS 110 compliant digestate. It is noted that batch pasteurisation is a key control. The assessment places that process on the feedstock before AD begins and assumes that 'short circuiting' (i.e. the appearance of non-pasteurised feedstock within the pasteurised feedstock going into the AD process) is minimised. The latter is obviously a key part of the risk reduction strategy. Full compliance with optimum procedures, input

selection, anaerobic digestion and pasteurisation appear to be assumed. Real-life experience indicates that complete compliance in all cases is most unlikely and prevention of bypass could be given further consideration.

13. It is noted that the preliminary microbial reduction strategy is pasteurisation, however PAS 110 does note that certain material can be used unpasteurised (noted as on-farm feedstocks). It would be of interest to understand the scale and significance of such unpasteurised feedstocks on possible risk, and why they are excluded from the need to pasteurise. Additionally it does not appear clear where the pasteurisation step is applied, in the risk guidance (section 1.3.1) it is applied before digestion, in PAS 110 there appears to be no clear indication of when pasteurisation is applied, although in the C.*botulinum* review there is some indication (section 3.4.2.4) that it can be applied before or after digestion. If indeed pasteurisation could be applied after the AD process, there should be some consideration of the potential for pathogen growth to high levels within the digester and whether or not the heat process applied could cope with these. The risk guidance would tend to suggest that bacterial pathogens decline within the AD process, but some comments indicating the pathogen reduction of using AD before pasteurisation (if indeed this can be done within PAS 110 compliance) would be useful.

Qiv. Do Members consider that the review of impacts of composting and anaerobic digestion processes on Clostridium botulinum sufficiently addresses the Committees comments in response to WRAP's previous compost risk assessment?

14. Chapter VI (pages 222 to 286) considers the effects of composting and anaerobic digestion on C. *botulinum* in considerable detail. In terms of publication, it would be better to quote only the final objective(s) (page 223): as agreed with WRAP after the initial data review. "Full understanding" is, in any case over-ambitious. It is suggested that information is presented with a special focus on the last 2 bullet points, perhaps moving the supporting information to appendices. On balance the widening of consideration to other clostridia is probably beneficial, at least with respect to animal health issues.

15. The overall approach seems to be sound but it does produce a very complex model, and highlights a fairly long list of data gaps (in section 5.2). This may be simplified by concentrating only on the effect of anaerobic digestion (in essence, ignoring everything on both sides of the equation) - though this might be simple in theory it might be very difficult in practice. Section 5.1 makes no reference to direct human health risks (as opposed to risks to grazing animals). In spite of all the detail in the report it is difficult to disagree with the final bullet point in the conclusions "Any additional (or reduced) risk from the use of compost or digestates is currently unknown".

16. As highlighted to the Committee in the presentation to ACMSF the extent to which this matter can be fully resolved is somewhat limited by the currently available data and the lack of data to populate a quantitative risk assessment.

However, the conclusions reached on the basis of the literature-review conducted are not unreasonable in the light of the available data.

17. There is limited and conflicting information in the review with respect to the effect of the AD process on C.*botulinum* (3.4.5.1). Whilst the review states that no evidence has been found of significant measurable growth, neither is any evidence presented to indicate that growth does not occur. The authors note that anaerobic digestion may not be a complete process such that not all materials are subject to full decomposition. In addition, published investigations of the efficiency of the anaerobic digestion process on C. *botulinum* have variable results. However, associated measures such as heat drying, lime treatment and pasteurisation are expected to have significant effect in reducing levels of pre-formed toxin and vegetative bacteria.

18. The review makes many statements but in many cases gives few data to back them up. It would appear logical that feedstock could be contaminated with C. *botulinum*. It is also logical that a pre-digester pasteurisation should give a kill of vegetative C.*botulinum*, and probably denature toxin.

19. The impact of the AD process on C.*botulinum* spores is less certain, and it would be difficult to confidently conclude that the organism would not grow. C. *botulinum* spores will persist through the pasteurisation process, although the calculated additional risk inherent in such growth is much lower than that already present due to the widespread presence of C. *botulinum* in the agricultural environment.

20. Comments made in the review about naturally occurring clostridia present in soils (section 5.1) fail to grasp the need to understand the possible increase in risk, associated with potential future increased use of digestate in agriculture.

21. The findings suggest:

- Soil spore numbers (C.*botulinum*) will be impacted (increased) if contaminated organic materials are added (p.231).

- Growth of C.*botulinum* in soils: conflicting evidence given. Conclusion: some growth is likely but not likely to survive for significant periods (p.232).

- Spores may survive in soils, although germination may only occur under favourable conditions (p.232).

- Spore survival rates would logically appear to depend on initial concentrations, although reports would suggest a gradual decrease in numbers over time (p.232). Some consideration should have been given to any ability of the spores to move in and out of the viable non-culturable state (VNC) i.e. to become temporarily unculturable on standard media used. It is relevant to know if such spores are 'dead' or simply non- culturable.

- A German study indicated botulinum toxin could be detected in digestate amended soils (p.232) but there is no mention of controls within this work, e.g. was a non-digestate amended similar soil tested as control, was toxin detected in that? Such aspects are important, and further information should be considered, if available.

- Toxin is heat labile, however little data is given, and no information on external effects on stability is presented (pH will affect toxin heat stability but is not mentioned). No real data is given in section 3.4.4.3 on the possible effects of feedstock pasteurisation on toxin, and the statement of 'significant denaturation' is insufficient to support a substantive judgement.

- Survival of organisms/spores during anaerobic digestion (AD). Again section 3.4.4 appears to cover pre and post AD pasteurisation. Does PAS 110 covers pasteurisation pre-AD, or pre or post AD? Pre-AD pasteurisation should deliver a significant reduction in vegetative cells of C.*botulinum*, but no data is given in the review. Spores will be affected to a much lesser degree, but very limited data is given in the review (3.4.4).

- Comments on the effects of carbon dioxide in digesters needs to be substantiated with data.

<u>Minor points/suggestions</u>

p 1.1 2nd paragraph, 4th sentence - include reference to toxins?
p 1.3.1 last paragraph - delete 'other' in front of 'wildlife'
p. 1.4 Table 1.1 - explain TPA = "Tonnes per Annum"? Figure for Sewage Sludge - - os there a '0' missing after the '3'?
p 2.1 2nd para - it would be useful to add estimates of LD50 for cattle and sheep given that they are the species in which the largest number of cases of botulism have been occurring.
p 2.3.1.2 - add reference to detection by Elisa as recently developed by VSD of Dard - Dr Hywel Ball and colleagues?
P.2.3.3 - line 2 persistence *and growth* of C.*botulinum*?
p. 2.5.5 last para - 'fat in on' - delete on?
P.3.2.3.4 - Poultry manures (i.e. manure without litter) are rarely if ever associated with botulism - carcases or part carcases are unlikely to be present under good management. Ensuring that all carcases are found in litter-based systems is a greater challenge.

Qv. Can Members identify any additional microbiological food safety issues not considered to date that should be brought to the attention of WRAP?

22. As mentioned in the earlier response of the ACMSF[6], WRAP should consider the need to further demonstrate that possible risks from TSE agents have been sufficiently assessed. Although only category 3 animal by-products from animals passed as fit for human consumption are permitted for use in composting and anaerobic digestion (along with limited category 2 material which is not a TSE risk), given public concerns raised over BSE and the use of meats in animal feeds, public acceptability of the proposal to use meats as a component of food plant fertilizer should be considered.

23. One possible aspect that should be revisited is the emerging risk from non-O157 VTEC organisms. Clearly this topic has been brought to the fore by recent events in Germany with O104 infections, but there are a number of other VTEC serogroups that are of relevance in this respect. The risks from these non O157 serogroups are likely to be in addition to the existing O157 VTEC risk (which has been considered) , although the cumulative quantitative additional risk from non-O157 VTEC is unlikely to exceed the estimate of risk from O157 VTEC. This would effectively give a doubling of the potential risk attributed to VTEC in the current version of the assessment. This would probably not impact upon the overall conclusions.

Qvi. Can Members identify any particular data gaps that should be prioritised in future research programmes in order to allow additional potential microbiological food safety risks associated with digestate use to be more fully quantified?

24. It would be helpful to establish actual rates of process compliance so that quantified bypass measures could be incorporated into the risk assessment. In general commercial use, what are the quantified non-compliances with component processes including input selection, incomplete anaerobic digestion/partial decomposition, moisture content, temperature during anaerobic digestion and pasteurisation temperature and duration?

25. It would be valuable to generate further data from pilot plants with known defined pathogen inputs and actual measurement of reductions achieved to provide further data for validation of the model? The report has already highlighted that current gaps in the data impact upon the ability to perform quantitative risk assessment for *C.botulinum,* and does makes some useful suggestions as to areas that might usefully be addressed.

26. The suggested areas for further research would indeed allow a more precise assessment of risk. Additional areas to consider include:

- In relation to the *C. botulinum* review, some of the uncertainty is related to the variable microbiology of these systems - perhaps work on the

[6] http://www.food.gov.uk/multimedia/pdfs/committee/responsetowrap.pdf

production of complex seed cultures (similar to those marketed for silage production or competitive exclusion products used in poultry) would go some way to reduce this variability and, may, even improve the efficiency of energy production in these system while at the same time reduce the likelihood of pathogen growth and toxin production.

- Recent work by Agri-Food and Biosciences Institute, Stormont (Dr Hywel Ball and colleagues) has led to the development of improved techniques currently applied to the diagnosis of animal botulism. Consideration should be given to seeing whether these techniques might be beneficial in improving the health assurance of the AD industry.

Qvii. Do Members consider the proposed risk management recommendations (biofertiliser matrix) adequately reduce the residual microbiological food safety risks associated with the proposed uses of pasteurised and non-pasteurised digestate in UK agriculture. (Taking account of the available data on pathogen loadings in pasteurised and unpasteurised digestate and assessed risks).

27. The biofertilizer matrix is helpful in summarising the information in a manner that is easy to assimilate and it should prove a good straightforward checklist. The suggested matrix appears logical for the hazards covered.

28. Overall, the proposed risk management recommendations are likely to reduce residual food safety risks, provided that satisfactory compliance with these proposed recommendations can be maintained. However, given the role that has been highlighted for pasteurisation in the assessment, the use of unpasteurised digestate on Category 3 fresh produce should be reconsidered.

29. Within the matrix, plants used to derive seeds for sprouting should be considered and whether or not the feedstock that may be used for such purposes needs to be pasteurised.

30. The risk management strategy might be strengthened by outlining measures to ensure compliance with the necessary processes within anaerobic digestate production and application.