ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

ACMSF RESPONSE TO THE WRAP RISK ASSESSMENT ON THE USE OF SOURCE SEGREGATED COMPOSTS IN AGRICULTURE

At the March 2010 meeting the Committee considered Waste and Resources Action Programme (WRAP): risk assessments on the use of source segregated composts in agriculture (paper ACM/976[1] and three presentations: introduction on WRAP, update of the VLA's 2002 risk assessment which estimated risks to grazing livestock from food-borne pathogens and risk assessment for the use of source – segregated composts in UK agriculture).

A sub-group of committee members were asked to discuss the risk assessments in more detail and their comments (see Annex 1) were approved as the Committee's response to WRAP at its 23 September 2010 meeting.

Secretariat
November 2010

[1] http://www.food.gov.uk/multimedia/pdfs/committee/acm976wrap.pdf

Summary of comments on ACMSF/976 WRAP Risk Assessment

This summary has been written and approved by the ACMSF subgroup that considered the WRAP Risk Assessment in detail.

Overall, the group found the risk assessment approaches robust, despite not being constructed in a way that is typical of currently published microbiological risk assessments. The approaches used are over-complex for the majority of hazards; this impacts on the transparency of the risk assessments rather than the robustness. Transparency of the assessments could have been improved by utilizing a simpler (e.g. qualitative risk assessment) approach and undertaking more detailed analyses for those hazards where this approach didn't provide an adequate level of certainty that the risk was acceptable. However, the conclusions reached for the majority of hazards addressed can be considered valid.

A more thorough assessment is required for the hazards *E. coli* O157 and *C. botulinum*, where the exposure was estimated to be close to the 'safe daily dose'. In these cases a 100-fold safety factor may not be appropriate, but it can't be clear from the approach used what the actual risk is. Unlike materials that are considered to have an accumulative effect, regularly exposing people to doses just below what is considered an infective dose may result in an unacceptable risk of illness, particularly when the consequences of illness can be severe, as is the case with these hazards. The application of the ALARP principle here is not appropriate.

There are also gaps in the initial hazard identification stage, with the group identifying spore-forming bacteria, fungi, encysted parasites (e.g. *Cryptosporidium* spp.), TSEs, as other organisms of concern that should be considered. The risk assessments should also reflect the reality, as best as possible, of the level of by-pass that is inherent in the system being modelled, as this may have a significant impact on the risk characterization. Risk management measures can then be proposed to address any unacceptable risks identified, rather than assuming a potentially unachievable measure of total compliance with legislation in the actual estimation of the risk.

Annex 1

WRAP Risk Assessments on use of source segregated composts in agriculture

Comments have been framed to reflect the specific questions posed by the FSA via ACM/976[2].

"Do Members consider the approaches used in both risk assessments are appropriate and sufficiently rigorous to fully assess the microbiological safety risks associated with application of PAS 100 compliant composts to food producing land?"

The approaches used are unnecessarily complex. This has the effect of decreasing transparency by increasing the need to dig deeper to filter out key assumptions, despite the fact that the authors are careful to state these where they are made. Due to the complexity of multi-hazard, multi-vehicle and multi-receptor risk assessment, a qualitative approach taken in the first instance, with quantitative approaches applied in more focused scenarios, would have improved transparency. It doesn't help that the two risk assessments follow different methods (for different initial purposes), nor that the "Update of 2002…" really needs to be considered with the original.

However, in terms of the risk assessment methodologies used, we found these to be generally sound, as well as the logic applied in assigning values and, in most cases, the assumptions made.

As is the temptation with quantitative risk assessments, we found (particularly in the case of the "Update of 2002 RA") that they are over precise in both inputs and outputs given the likely (unquantified and in many cases unquantifiable) uncertainties, giving rise to likely over-interpretation of the outputs and a false confidence in the results. For example an estimate of 4.7 $\log_{10}$ reduction of pathogens by composting is updated to 4.62 $\log_{10}$– surely the uncertainties involved make this a pointless revision. In both assessments the outputs would be more credible as a ranking of relative risks rather than the more absolute statements made.

On whether the risk assessments fully assess micro safety risk? Covered also in the next question, but where the risks are calculated to be acceptably small in a robust, conservative qualitative or semi-quantitative assessment, the answer is yes. Where the exposure would appear, as in the case of *E. coli* O157 and *C. botulinum* in the source segregated compost RA, to be close to the 'safe daily dose', we would expect to see a more thorough assessment undertaken of the particular scenario (either qualitative or quantitative). It is unclear what the 100-fold margin of safety actually means in terms of risk here, and the application of the ALARP principle to these risks seems inappropriately applied here as there hasn't been an appropriate

[2] http://www.food.gov.uk/multimedia/pdfs/committee/acm976wrap.pdf

evaluation of the effectiveness/cost-benefit of risk management options, at least not in this document.

Key to a useful risk assessment is the identification of the appropriate hazards. Both studies principally focus on viruses and vegetative bacteria, and may have benefitted from the inclusion of a wider range of microbial hazards. For example, much less attention has been given to bacterial & fungal spores and the cysts of parasites which may be more resistant to the composting process and so represent a greater risk to health. Again, a broader, less quantitative approach, may have been a good mechanism for screening a wider range of hazards (on paper) to then allow for more detailed focus on those deemed most significant.

While it is neither necessary nor practicable to consider every possible potential pathogen, there is then a requirement to demonstrate that representative organisms from each appropriate group have been considered. The rationale for the selection of such representatives should be transparent and explicit. This might also usefully consider TSE agents. If the authors consider that the range of pathogens encompassed within the current documents is sufficiently wide, then they need to make and justify that assertion clearly.

In general, however, the organisms give a basis on which to assess some of the key microbiological food safety hazards and risks.

"Do Members consider the risk ratio approach to be appropriate to assess microbiological risks?"

This approach is more appropriate to toxicological assessments where the notion of a TDI has more merit, at least in a regulatory sense, but compared to microbiological hazards also in a mechanistic one where chronic affects are assumed from the contaminants concerned.

The risk ratio in the source segregated compost report provides some useful information on the relative risk to health posed by the different pathogens considered. However, absolute risk has also been expressed in terms of the chance (per year) of having an infected animal on a farm and the number of infections likely to arise nationally each year in the "Update of 2002 risk assessment" report. The report on source-segregated composts only considers the daily dose to safe daily dose (risk ratio) and might be strengthened by the addition of absolute risk data in terms of likely numbers of infected cases. Equally, in the catering waste study, this data was not expressed for enteric pathogens or *C. botulinum*. In the former case, this may be significant given the incorporation of re-growth into the pathway.

There must always be some caution regarding the basis of "safe daily dose" estimates in relation to microbial pathogens. It is important to note that infectious dose data should be regarded as providing a guide to relative infectivity, rather than an absolute measure of infective dose. It is now quite

apparent that dose-response modelling in the hazard characterisation of pathogens is an intricate subject, involving complex interactions between the pathogen, the containing matrix and the host. Each of these elements in turn has a number of parameters that may influence this process. The so-called "single-hit" hypothesis has been proposed that states that infection may result ultimately from the survival of a single, viable, infectious pathogenic organism. This implies that, no matter how low the dose, there is always, at least in a mathematical sense, and possibly very small, a non-zero probability of infection and illness. Obviously, this probability increases with the dose, but not necessarily in a linear fashion. For example organisms are rarely distributed in a uniform fashion within their containing matrix. The presence of "clumps" of organisms may increase the likelihood of infection, even at lower mean concentrations. The danger of over simplistic interpretation of infectious dose data is not a mere theoretical curiosity, as was dramatically demonstrated in the large *Salmonella* outbreak associated with the consumption of contaminated chocolate from a major UK manufacturer. However, the authors of the report have built a considerable safety margin into their calculations in this respect.

"Do Members feel their recommendations for further development of the original catering waste risk assessment have been adequately addressed?"

- the response to recommendations concerning the pathogens assessed may be regarded as partial rather than comprehensive. In particular, the risk associated with different parasites, fungi and spore forming bacteria could be explored in greater detail.

- the question of process by-pass, the size of the problem and associated risks does not seem to be addressed explicitly.

"Do Members agree with the conclusions derived for the assessed scenarios with regard to microbiological risks to the food chain?"

The conclusions derived from the assessed scenarios seem reasonable. The main concern is scenarios not fully assessed (such as Cryptosporidium contamination). Although, the report draws on comparisons with existing processes to justify the lower risks e.g. enteric pathogen levels in composted catering waste vs stored manures, it is important to estimate the absolute level of risk from consuming ready to eat vegetable crops to which this waste may be applied. Furthermore, the comparison to sewage sludge is irrelevant in this context as the harvest intervals for sewage sludge application are prescribed whereas those for composted catering waste are not.

"In relation to microbiological food safety, do Members agree with the overall conclusion that the risks associated with the use of PAS 100 compliant composts in agriculture are low?"

The overall conclusion, that the risks associated with the use of PAS 100 compliant composts in agriculture are low, seems reasonable and justified by the risk assessments performed. Notwithstanding this, the report on source segregated waste does indicate an increased risk for HEI with regard to the hazard of *E. coli* O157. This may merit further investigation. Likewise, the risks regarding *C. botulinum* to cattle also needs further exploration.

In addition, it is possible for issues to arise from either process failure and/or bypass, but those are issues of regulation and monitoring, rather than risks associated with the process *per se.*

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

As outlined above, WRAP should consider the requirement to consider spore-forming bacteria and fungi, encysted parasites and TSEs, and to explicitly demonstrate that representative organisms from each appropriate group have been considered. The rationale for pathogen selection should be clearly stated.

"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 compost use to be more fully quantified?"

Potential gaps include the identification of specific pathogens most resistant to the composting process and the actual size of the process by-pass problem.

Other Comments:

Whilst both reports are comprehensive and detailed, the respective "Executive Summaries" are too long and difficult to assimilate. These summaries might be improved by robust précis and the extensive use of bullet points.

In addition, as some consumers might be surprised that animal food waste was being used in compost, it would be helpful to see the outcome of the consultation carried out by Defra into the consumer's view on animal food waste being used in compost.