Northern Biological Safety Officers Meeting

Tuesday 27th April at 10:30am in the Cuillin Room
Charles Stewart House 9-16 Chambers Street University of Edinburgh

Agenda

Coffee/tea available from 10:00am

1. Welcome and introduction
2. Structured discussion on single regulatory framework – based on draft seen November 2009:
    - Interpretation
    - Inconsistencies
    - New requirements (ie not in parent Directives) vs over-implementation

(see attached sheet for further detail on issues as an aid to discussion)

3. Local implementation:
    - Committee structure(s)
    - Role of the BSO (local and organisational)
    - Risk assessment forms and formats
    - Record keeping
4. Likely impact:
    - Cost – notifications and inspections/investigations
    - Administration – locally and centrally
    - Training/awareness raising
    - Checking compliance
5. Need for stakeholder engagement – who and how?
6. Responses to recent consultations:
    - Legislative Reform Order
    - Amendment of Contained Use Regulations
    - Amendments to ATCSA – Schedule 5 pathogens
7. Updates from Steering Group:
    - Minutes of last meeting
    - Steering group activities – steering group membership
    - Agenda for next meeting
8. Date/location of next meeting – November 2010, University of Manchester
9. Any other business

Issues for discussion

Interpretation

Biological agent – same definition as used in COSHH (includes cell cultures) but extended to include animal pathogens (and animal cell cultures) which have an approved categorisation ie only those listed on the Approved List whereas human pathogens do not have to be listed to be covered under the legislation.

How will cell cultures be classified - eg how much evidence will be required to justify Class 1 classification – will it be in line with current ACDP/SACGM guidance and how is that used currently?

Contained use of biological agents – activities include culture, storage, transport, destruction and disposal but no mention of "incidental exposure" or carrying out activities with material that may contain biological agents as in COSHH Schedule 3. However, there is reference in connection with minimum containment required for such activities in Schedule 5 but no mention of the type of assessment required for work of this kind or anything else in the preceding regulations that places such material within scope of the legislation.

Also noted that regulations do not apply to the destruction and disposal of biological agents – not clear about rationale for this exclusion when it does apply to GMMs and whether this is intended to just exclude clinical waste incinerators/alternative treatment plants or to include what happens in the laboratory too.

Connected programmes - how can we make best use of these to limit number of notifications required, especially of Class 2 work.

Diagnostic service – similar definition to COSHH but extended to include veterinary treatment – appear to be exempt from need to notify individual activities unless process will propagate, concentrate or otherwise increase exposure to agent – how will this be interpreted ie not initial isolation of agents but only subsequent work in reference labs? Could argue that most initial microbiological investigations will propagate agents so what would be exempt?

Do need to notify first use of premises – will this be retrospective or apply only to new labs?

Micro-organisms – now specifically includes prions but would this be better defined as prion proteins capable of causing disease as this could cause confusion for those handling normal prion proteins.

Notification – now asked to give name and contact details of the employee with specific responsibility for supervision and safety of the contained use (as opposed to giving details of the employee of the notifier with responsibility for supervision and safety) – so is this just the contained use that is being notified, in which case is this the PI?

Premises – new definition – how does this apply to large campus sites spread over a number of roads – can we still notify as one site?

Relevant animal – looks like it is partially taken from the definition used in the Animal Health Act – but what does a four-footed animal that is not a mammal mean – does this include reptiles and amphibians and if so, where does that leave snakes. Full definition in AHA goes on to say "fish, reptiles, crustaceans and other cold-blooded creatures".

Inconsistencies

Notification periods – different timescales for GM and BA work. Would be it be simpler to align for different classes of work albeit this would extend period required for BA work as currently set out in COSHH.

Retention of risk assessments – only required for GM activities; would it be a burden to have the same requirement for BA assessments, especially as some infections may turn out to be latent? NB: exposure records not in current draft but hopefully will be in final draft (requirement of BAD) – this requires keeping records of exposure to certain agents for 40 years.

Notification of Class 3 or 4 activities – CA must consider representations made in respect of GM work but not BA work.

Additional notification provisions – can continue with GM and animal pathogen activities to the extent needed to destroy them (if required to cease work by HSE) but not BAs.

Derogation – appear to be able to do this for GMMs and BAs but it is not clear how this would work with animal pathogens which do not have any relevant Community legislation to refer to ie nothing in a Directive that sets out containment required for work with animal pathogens.

Emergency plans – different approaches/information required depending on whether GMM, BA or animal pathogen. And what is the definition of "slight risk" in relation to biological agents.

GMP/GOSH – looks like a combination of what is in COSHH and GM(CU) but no mention of vaccination; slight difference of approach as regards controlling exposure GMMs and BAs (to lowest level practicable *vs* prevent or adequately controlled)

New requirements *vs* over-implementation

Notification of premises – now need to give details of CL3 and CL4 labs within premises

Notification of subsequent Class 2 activities using BAs – only first use required in COSHH (and BAD). NB: this was proposed when COSHH was last amended and was deemed too costly/burdensome by both consultees and HSE economists resulting only those HG2 agents currently listed in Part V of Schedule 3 needing subsequent use notification ie risk based.

Biological safety committee – need to establish a committee to advise on Class 3 or 4 work with biological agents.

Design notification for CL4 facilities – will there be a standard format to use to supply relevant information and at what stage should such information be notified?

Risk assessment for contained use of w/t biological agents – there is currently no prescribed format. Could the suggested format given be more closely aligned with GMM approach to facilitate design of in-house forms. And what to certain questions mean, eg circumstances of contained use and amount of BA involved?