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ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

Progress update on the Single Regulatory Framework (SRF) for animal and human pathogens

Issue

1. To inform members on the development and progress of the single regulatory framework for animal and human pathogens.

Single Regulatory Framework (SRF)

2. The Legislative Reform Order (LRO) that will amend Section 1 of HSWA to give Ministers the vires to make new regulations for animal pathogens under HSWA is currently with Parliamentary Counsel. Some initial issues were raised which are being considered and addressed by HSE Lawyers, in consultation with legal colleagues from Defra and the Devolved Administrations. Following this, the LRO will make its way through the lengthy parliamentary process.

3. There has been considerable progress on finalising the draft 'Biological Agents Contained Use Regulations'. The Project Team and HSE Lawyers are working on fine-tuning the regulations particularly in relation to notification requirements, cost recovery and the transitional arrangements.

4. Members will be aware that work is well advanced on the third and most complex phase of the project that will deliver the SRF comprising a single set of regulations. Much of the complexity surrounds bringing together three separate legislative regimes that stem from EU directives that are both prescriptive and specific to the individual component regimes. Initial drafts of the 'Contained Use Regulations' raised a wide range of important legal, technical and policy issues that need resolution. It is important to resolve these issues to turn these principles into workable, fit for purpose regulations.

5. Sir Bill Callaghan set an aspiration for delivery of the full SRF by April 2010, but recognised that this would be extremely challenging. Stakeholders have also supported a permissioning regime that will replace the incongruities of the current sets of legislation with a risk-based approach that is demonstrably rational. Since the last meeting, it been agreed, in consultation with HSE Senior managers and Defra, that the target date for full implementation be deferred for six months to October 2010.

6. Formal consultation on the single regulatory framework is scheduled for January 2010 and the 'consultation package' will include the Consultation Document, draft 'Contained Use Regulations', Guide to the CU Regs, and the Containment Guidance incorporating the amalgamated set of containment measures.

Integrated Notifications and Cost Recovery

7. Work continues on developing an integrated notification system with the main outcome being a system that is easily understood by dutyholders, easy to administer and supportive of Directive and regulator's requirements. This will include, amongst other issues, consideration of:
   - Premises notification that captures location, capacity and capability of containment level 3 and 4 laboratories
   - Activity notification that captures all necessary details of processes currently covered by CoSHH, GMO (CU) and SAPO
   - Clear differentiation in required detail between low and high hazard work to implement the minimum standards of the EU Directives
   - Consents/permissions process
   - Integrated electronic notification system
   - Security notification system in relation to work with pathogens included on the ATCSA 2001, Schedule 5 list
   - Challenges regarding gold-plating and/or under-implementation of EC Directives

8. This workstream is also addressing the notification requirements for the proposed six-month transitional period.

9. The cost recovery element of the SRF is being progressed in consultation with HSE's Financial Advisers, taking into account Government and HSE policy. In 'Managing Public Money' HM Treasury policy is to recover costs for publicly provided services. For dutyholders, they will be subject to cost recovery where regulatory activity delivers a direct benefit to them i.e. to allow the dutyholder to operate lawfully. It is HSE policy to cost recover for work of a permissioning nature including inspection and investigation that forms part of the permissioning regime. The cost recovery and fees element of the 'Contained Use Regulations' are currently being drafted to incorporate HSE and Government policy.

Stakeholder Engagement

10. HSE continue to inform and gather input from stakeholders during the development of the legal and regulatory framework. HSE held a key stakeholder event on 10 September 2009 to inform and gauge opinion about the new regulations and to discuss a series of scenarios to demonstrate the impact of the regulations, proposals for the integrated notification system, risk class categorisation and containment measures.

11. HSE are holding a series of focus groups throughout October and November with sections of our stakeholders to discuss the new single regulatory framework and its implications using the draft regulations as the basis for discussions.

Common set of containment measures

12. Members are provided with a copy of the latest draft, following discussions at the last of the working group meetings which took place on Friday October 2nd. The second part of this agenda item will provide an update on the status of the guidance and the amalgamated containment measures.

Devolved Administrations

13. Members are aware that the licensing regime under SAPO falls within the competence of the Devolved Administrations and specific arrangements are needed to enable HSE to enforce equivalent provisions in Wales and Scotland.

14. HSE has formal arrangements in place with Defra and the Devolved Administrations for Phase 2 and are undertaking inspection functions on behalf of Ministers under an Agency Agreement and associated Memorandum of Understanding.

15. Current activity focuses with the Devolved Administrations on ensuring that HSE have the vires to make new GB-wide regulations for animal pathogens through the implementation of the single regulatory framework. We are continuing to work closely with the Devolved Administrations to progress Phase 3 issues and to consider and address any legal and policy implications.

Action required

16. Members are invited to note the progress of the Project and its associated workstreams.

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ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

Latest draft of ACDP Biosafety guidance

Issue

1. A copy of the latest draft of the "Biosafety Guidelines" is provided for consideration (attached as Annex 1).

Background

2. Following the last meeting of the ACDP Containment Working Group, a further draft of the biosafety guidelines has been produced, taking into account Members' comments and subsequent discussion with legal representatives from HSE and Defra.

3. This latest draft comprises five sections, three appendices and two annexes. A further iteration of the hazard group definitions are also included following additional discussions with legal advisors.

4. Progress has also continued with the containment tables, including explanations of each control measure, and these continue to reflect the range of definitions in line with those proposed in the new CU 2010 regulations.

5. Following this meeting, the Secretariat will make final amendments and prepare the guidance for inclusion as part of the documentation package for the Autumn stakeholder engagements and consultation process.

Action

Members are asked to consider this latest near final draft of the biosafety guidelines and to endorse its content.