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Progress on development of a Single Regulatory Framework (SRF) to govern work with human and animal pathogens

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Issue

1. To inform the SMT and HSE Board on progress with taking forward Sir Bill Callaghan's recommendations to improve the way animal pathogens are regulated and for the development of a single regulatory framework (SRF); and to seek agreement for a revised approach and timetable for implementation of the SRF.

Timing

2. For approval at the SMT Meeting on 3 June 2009 to enable the paper to go to the HSE Board Meeting on 23 June 2009.

Background

3. This paper is to advise the Board of current progress on the development of the SRF and the proposed approach for the delivery and implementation of the new framework.

Recommendation

4. The SMT is asked to agree to the proposed twin-track approach that would see the delivery of the Legislative Reform Order by the agreed April 2010 date, with the SRF package to be delivered and implemented by October 2010.

Consultation

5. Policy, Legal Advisers Office, HID, Defra, PFPD

Health and Safety Executive Board		Paper No: HSE/09/??	
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Progress on the development of the Single Regulatory Framework (SRF) to govern work with human and animal pathogens

Purpose of the paper

1. To advise on progress with the development of a single regulatory framework (SRF) to govern work with human and animal pathogens; and to seek agreement for a revised approach and timetable for implementation of the SRF.

Background

2. Following the foot and mouth disease outbreak at Pirbright, Sir Bill Callaghan led a review of the regulatory regime for animal pathogens, taking into account that which exists for human pathogens. The Government – including the Devolved Administrations - accepted his recommended phased approach, leading ultimately to a single regulatory framework, with HSE as the enforcing authority. Phase 1, for HSE to formalise support to Defra and the Devolved Administrations for SAPO inspections, is now complete; Phase 2 saw changes made to the Specified Animal Pathogens Order (SAPO) to designate HSE as the inspection and enforcement body by means of Agency Agreements with Defra and the Devolved Administrations. These arrangements were successfully implemented and are working well.

3. We are now working on the third and most complex phase of the project which will deliver:

a. the SRF comprising a single set of regulations[1] to govern work with human and animal pathogens based on a Legislative Reform Order (LRO) to provide HSE with the vires to make regulations in relation to animal pathogens;

b. a common set of containment measures based on advice from ACDP (HSE is leading the work);

c. appropriate cost recovery and integrated notification systems.

The Project Board that comprises senior representatives from HSE and Defra oversees the Callaghan Implementation Project. Sir Bill Callaghan set an aspiration for delivery of the full SRF by April 2010, but recognised that this would be extremely challenging.

4. Stakeholders have welcomed proposals for the introduction of a single set of regulations. They support a permissioning regime that replaces the incongruities of the current sets of legislation with a risk-based approach that is demonstrably rational. However, they recognise that the detail is complex and that

[1] Biological Agents and Genetically Modified Organisms (Contained Use) Regulations 2010 (BA&GMO (CU) Regs 2010)

there are many issues to resolve to turn these principles into workable, fit for purpose regulations. Continuing dialogue with stakeholders will be key to resolving these issues.

Argument

5. The phasing of the project was designed to reduce the risks of delivery. Successfully completing phase 1 and 2 has ensured that HSE has the powers and established working arrangements to carry out inspection and enforcement functions under SAPO on behalf of Defra and the Devolved Administrations.

6. However, completing phase 3 is proving more difficult. Much of the complexity surrounds bringing together three separate legislative regimes[2] that stem from EU directives that are both prescriptive and specific to the individual component regimes. The first draft of the BA&GMO (CU) regulations raised a wide range of important legal, technical and policy issues that need resolution (see Annex 1 for further detail).

7. In the light of this, the Callaghan Project Board and HSE senior managers re-assessed current project plans aimed at delivering the SRF for April 2010. They concluded that it is possible to continue to press ahead with the original deadline but this would not give time to resolve adequately the issues raised. They felt that, whilst there may be reputational issues in not delivering to the aspirational timescale, these were heavily outweighed by the risk of delivering a regime that is not fully fit-for-purpose and which does not command support of the stakeholders. The Project Board therefore propose to adopt an approach that would put full implementation back six months to October 2010.

Twin-track approach to implementation of the SRF

8. The original plan was to introduce the LRO and Regulations at the same time. Following advice from HSE Lawyers, we now propose to adopt a twin-track approach to implementation of the SRF by decoupling the LRO from the new Regulations and accompanying guidance. This approach has the following **advantages**:

a) the LRO, giving HSE the vires on animal pathogens, can be delivered by April 2010 and this is an essential legal milestone preparing the ground for the SRF;

b) the LRO process is long but relatively simple if decoupled from the Regulations e.g. we will only have to set out the main features of the Regulations rather than spell them out in detail;

c) work on the LRO and Regulations can be undertaken in parallel and because the resource peaks with these work streams occur at different times we can manage resource deployment more effectively;

d) delaying the Regulations will allow for an extended consultation period on the SRF commencing in late 2009, running for four months, avoiding the summer recess and peak holiday period and will subsequently provide time to review fully stakeholder views and test additional drafts post consultation.

[2] Control of Substances Hazardous to Health (CoSHH) Schedule 3, Genetically Modified Organisms (Contained Use) Regulations (GMO(CU) Regs; Specified Animal Pathogens Order (SAPO)

9. The **disadvantages** of a delay are:

a) the potential reputational risks associated with failing to deliver the full package by April 2010 – but risks from poor implementation are much greater;

b) two separate periods of consultation and two regulatory impact assessments (RIA) will be needed, one for the LRO and one for the Regulations – but the resource impacts can be managed internally;

c) there is a risk of criticism about lack of transparency if we fail to give sufficient detail to Parliament about how the new power in HSWA will be used - but legal advice is that this is likely to be low risk;

d) extending the life of the project for a further six months means the current project resource is required for that period to ensure the SRF delivers to the revised schedule – but we will defer other lower priority work to make space for this.

Recommendation

10. To agree to the proposed twin-track approach that would see the delivery of the LRO by the agreed April 2010 date, with the SRF package delivered and implemented by October 2010.

Consultation

11. PFPD, Legal Advisers Office, Defra, Policy, HID. Defra is represented on the Callaghan Project Board and has contributed to this paper. Subject to approval of the proposed approach, HSE and Defra will brief respective Ministers simultaneously.

Costs and Benefits

12. A partial impact assessment is in the process of being completed for the LRO. A full cost/benefit analysis will be completed in due course as part of the full RIA for the regulations and implementation package.

13. The benefits of the proposed approach would be that the LRO, extending HSWA to provide Ministers with the vires to make regulations in relation to animal pathogens, will be made by the agreed date of April 2010. The subsequent implementation of the SRF package by October 2010 will deliver a fully fit-for-purpose and workable regulatory regime for dutyholders that will assist in easing the current regulatory burden, and in line with Callaghan recommendations and Government response to the IUSS Select Committee Report.

Financial/Resource Implications for HSE

14. There would be a small amount of additional costs for Defra and the Devolved Administrations from extending Phase 2 beyond April 2010 and thus the period of payment to HSE for SAPO inspections under the subsequent Agency Agreements. The current inspection costs payable to HSE, as agreed with Defra and the Devolved Administrations, for 09/10 totals £195,550 (£153,000 - Defra, £10,000 - Wales and £32,550 - Scotland). Extending the implementation date of the SRF to October 2010 would increase the HSE inspection costs to £295,550 (£231,000 - Defra, £15,000 - Wales and £49,550 - Scotland).

15. Current project resource from the Project Implementation Team, including workstream leaders, and Defra would be required for the extended period, which currently includes Policy, Biological Agents Unit, LAO, PFPD and Defra. Decoupling the LRO and Regulations would also require two separate periods of consultation and two regulatory impact assessments having a subsequent impact on resource requirements.

16. HSE do not currently charge for the assessment of notifications and inspections submitted under CoSHH in relation to activities with biological agents. The SRF will introduce cost recovery to this sector. There is therefore a small income impact in that HSE will not now introduce cost recovery for work done under COSHH until October 2010.

Paper Clearance:

Gordon MacDonald, Director, HID - SCS

Annex 1

Issues/concerns relating to current April 2010 implementation date

- Fully address important issues in relation to LRO and regulatory definitions, common hazard group definitions, combined containment measures for human and animal pathogens, combined Approved List (requiring HSE/ACDP approval) for human and animal pathogens, Competent Authority issues, Transfer of Functions from Devolved Administrations back to Westminster etc..;

- The BA (CU) Regs implement two European Directives. These directives have differing provisions. To have a common approach, it may be necessary to add to the minimum provisions in the Directives i.e. gold-plating. This necessary "gold-plating" needs to be reviewed and justified to determine if it is essential to deliver a SRF. This will naturally impact on the development of other workstreams;

- This timescale provides no opportunity to test the impact of the full SRF package with key stakeholders from the range of sectors, through a series of well-developed scenarios, prior to formal consultation;

- The current timescale allows for less than the minimum 12-week consultation period; BERR has advised that a longer period is more appropriate due to the impact of the new framework on dutyholders; the consultation period and limited time to react to the consultation response would make this date no longer viable

- Consultation is scheduled to take place from August to September. Past experience suggests that, as this coincides with the academia/research summer recess (key sector), stakeholders are likely to have a negative view of the timing of the consultation and the response rate would be low;

- The possibility of maintaining a 12 week consultation period has been considered, however, this would lead to limited time to make amendments post consultation and would impact on the parliamentary process for implementation of the new Regulations by the common commencement date;

- If stakeholders feel that a single set of regulations is too unwieldy and unworkable, the current timetable provides no additional time to consider alternative approaches e.g. combining SAPO with COSHH regulations and leaving GMO (CU) regulations separate.

- Necessity to hold further stakeholder events, particularly for the clinical/diagnostic sector, on cost recovery proposals and notification requirements.