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HEALTH AND SAFETY COMMISSION

AGENCY AGREEMENT WITH DEFRA FOR THE INSPECTION AND ENFORCEMENT RELATING TO THE ENVIRONMENTAL ASPECTS OF CONTAINED USES OF LARGER GENETICALLY MODIFIED ORGANISMS (LGMOs) AND DELIBERATE RELEASES INTO THE ENVIRONMENT OF GMOs USED IN CLINICAL APPLICATIONS

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Cleared by Board Member: on 10 April 2006

Cleared by Justin McCracken, DCE: on 13 April 2006

Issue

1. Renewal of the arrangements to inspect and enforce contained use work activities involving "larger genetically modified organisms" (GM plants and GM animals) under the Environmental Protection Act 1990; and inspection of "deliberate releases" of GMOs in clinical settings, such as vaccine and certain gene therapy trials.

Timing

2. Urgent. The previous agency agreement between the Secretary of State and HSC expired on 31 March 2006. The revised agreement is submitted by HSE in accordance with the deadline set by DEFRA.

Recommendation

3. HSE continues to inspect the contained use activities, and the deliberate releases of GM microorganisms in a clinical setting.

Background

4. The Environmental Protection Act (EPA) 1990, section 114 provides powers to appoint inspectors to enforce over the requirements of Part VI of the EPA 1990. Under s125 of the EPA (1990) the functions of inspection and enforcement may be delegated, and in March 2000, such an arrangement was made with the Health and Safety Commission in relation to the environmental aspects related to the contained use of GMOs. The

Commission asked the Health and Safety Executive to carry out the functions on its behalf and this agreement expired on 31st March 2006. A new agreement to cover contained use and deliberate release has been drafted to take effect from 1st April 2006 for a further three years.

5. In the last agreement for 2003-2006, HSE were awarded the contract from the Central Science Laboratory, York (CSL), to carry out the inspection of “deliberate releases” of GMOs. Although CSL specialises in plant health, and the inspectors come from an agricultural background, CSL did not have any experience of inspection in a clinical environment. Defra subsequently awarded HSE the contract to cover this work, and wish HSE to continue under the new tender. HSE currently inspects GM vaccine and gene therapy trials that are conducted under “contained use” conditions under the Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended). The inspections of deliberate releases in a clinical setting will look at worker protection and environmental safety issues. HSE already currently liaises closely with the Department of Health’s Gene Therapy Advisory Committee (GTAC), which advises on ethical (patient safety) aspects of such trials.

Argument

6. Both the ‘contained use’ and ‘deliberate release’ aspects of the tender are a continuation of existing work endorsed by the HSC in 2003. The deliberate release aspect is limited to a small number of trials each year (approximately 5 each year). These will generally be carried out in centres already registered with HSE.
7. HSE has been asked to continue to carry out the deliberate release inspections as we are recognised as having longstanding expertise in the regulation of the contained use of GMOs. DEFRA recognises that this is an appropriate use of ‘joined up government’, as there is clear synergy between HSE’s current areas of responsibility and this newly developing area. Biotechnology continues to be a rapidly growing area, and is expected to play a central role in the new economy. Clinical applications are likely to eventually move into the mainstream of medical practice, and the Government recognises that careful regulation is appropriate in the early stages to ensure that public confidence is maintained. It should be noted that clinical applications of GM technology have not been subjected to the same opposition campaigns as agriculture and food uses. If HSE did not continue to cover this area of work it is not obvious who else would have the expertise to do so. The Medicines & Healthcare Products Regulatory Agency (MHRA) have an inspection function covering clinical trials, however this is purely from a ‘product purity’ / patient safety perspective. MHRA do not, however, inspect phase 1 trials of the type covered by this contract.
8. HSE has carried out GMO based inspections for environmental risks for the past 13 years, and for about 22 years for human health risks. HSE therefore has the infrastructure in place to deal with the administrative duties required, including a database of centres which are required to notify use of premises and activities under the GMO (Contained Use) Regulations 2000.

Consultation

9. PEFD, Defra, Scottish Executive, Welsh Assembly Government. The costings for the renewal agreement with Defra cover England, Scotland and Wales and identify the elements allocated to each. In consultation and agreement with Defra, both the Scottish Executive and the National Assembly for Wales, as devolved administrations, are content for HSE to continue with the existing arrangements. As their agreement needs to be formally and legally sought, separate Agency Agreements are in the process of being drawn up with both devolved administrations. It is not intended to submit separate papers to the Commission for these agreements and the Chair will be asked to sign these off on behalf of the Commission in due course.

Presentation

10. This contract continues and builds on HSE's expertise in the field of inspection of activities involving GM activities. The deliberate release of genetically modified microorganisms in clinical applications may attract some media attention. Ministers are keen to ensure that a robust inspection regime is in place.

Costs and Benefits

11. There is already a well established working relationship with other parts of the Competent Authority including Defra, Scottish Executive and the Welsh Assembly Government. HSE and the Secretary of State for the Department for Environment, Food and Rural Affairs are the competent authority in England and Wales for the Genetically Modified Organisms (Contained Use) Regulations 2000, as amended; and the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005. In practice, these functions are delegated to officials of the Executive and Defra. In Scotland, the competent authority comprises the Scottish Ministers, who have delegated their functions to the Scottish Executive, and HSE. Although not part of the competent authority, the National Assembly for Wales will be sent copies of notifications of activities intended to take place in Wales and invited to comment. This programme further promotes joined up government working relationships.

Financial/Resource Implications for HSE

12. The contract is worth £115,073 over 3 years, including staff costs, T&S, and any specific training requirements. All costs will be recovered on a "full economic cost" basis. A contingency element has been included in the bid, which will provide extra money to cover increases in numbers of releases, or time involved in any investigation and enforcement action. A call-off bid covering legal costs is also included. The total resource involved over the period of the contract is 1.8 staff years, plus a contingency element of 0.5 staff years. This for the unit as a whole and does not represent a full-time commitment for individuals as the staff involved deliver this contract as part of their wider responsibilities.

13. A contingency element for staff time involved in enforcement action is included (40 days for each year). If this is not used for enforcement, this could be diverted to additional inspections if required by the competent authority.

Environmental Implications

14. The work involves the enforcement of environmental legislation.

15. There is likely to be an increase in research involving the generation and use of larger GMOs over the next three years; and an increase in the development of animals as models for human disease. This area poses a higher level of risk as they have the potential to act as novel reservoirs of disease and would be a priority area for inspection.

16. Another area that has seen a lot of development over the last few years is the production of plants carrying viral/pest genes. This area possibly represents the highest environmental risk, due to scientific uncertainty, and again would be a priority area for inspection.

Other Implications

17. None.

Action

18. That HSC should agree to:

- entering into the new agency agreement in respect of both the arrangements for inspection/enforcement of the environmental aspects of larger GMOs and the deliberate release into the environment of GMOs used in clinical applications, in line with HSE's core business and
- authorising the Chair to sign the agreement for England and later, on behalf of the Commission, the agreements for the Scottish Executive and the National Assembly for Wales.

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