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HEALTH AND SAFETY COMMISSION

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

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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. DEFRA wish to extend the tender to cover 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 2003. The revised agreement was submitted by HSE in accordance with the deadline set by DEFRA but there has been a delay on the part of DEFRA resulting in the agreement being signed later than anticipated.

Recommendation

3. HSE continues to inspect the contained use activities, and extends its remit to include the deliberate releases of GM micro-organisms in a clinical setting.

Background

4. Powers of enforcement are currently provided under s116 of the Environmental Protection Act (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 2003. A new agreement to cover contained use and deliberate release has been drafted to take effect from 1st April 2003 for a further three years.

5. For the last three years, the Central Science Laboratory, York (CSL), has carried out the inspection of “deliberate releases”. CSL specialises in plant health, and the inspectors come from an agricultural background. To date, all trials carried out have involved release of GM plants. CSL do not have any experience in inspection in a clinical environment, which is why DEFRA have asked HSE to cover this work. HSE currently inspects GM vaccine and gene therapy trials that are conducted under “contained use” conditions. The proposed inspections of deliberate releases in a clinical setting will look at worker protection and environmental safety issues. HSE 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. The contained use aspect of the tender is a continuation of existing work endorsed by the HSC in 2000. The deliberate release aspect will be 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 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 the extension to cover releases in a clinical setting 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 is 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 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. They 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 10 years, and for about 19 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, Northern Ireland.

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 micro-organisms 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, Welsh Assembly Government and Northern Ireland and this programme further promotes joined up government working relationships.

Financial/Resource Implications for HSE

12. The contract is worth £177,494 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 (35 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
- authorise the Chair to sign the agreements for England on behalf of HSC