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HEALTH AND SAFETY EXECUTIVE

Senior Management Team

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 GENETICALLY MODIFIED MICROORGANISMS 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; and inspection of “deliberate releases” of genetically modified organisms (GMOs) in clinical settings, such as vaccine and certain gene therapy trials

Timing

2. Urgent. The current agency agreement between the Secretary of State and HSC expires on 30 June 2009. The revised agreement is submitted by HSE in accordance with the deadline set by DEFRA.

Recommendation

3. The SMT is asked to agree that:

- HSE continues to inspect the environmental aspects of contained use activities in relation to larger genetically modified organisms under the Environmental Protection Act 1990 and the deliberate releases of genetically modified microorganisms used in clinical settings; and

- HSE authorises the Chair of the HSE Board to sign the agreement for England and later, on behalf of the Executive, the agreements with the Scottish Executive and the National Assembly for Wales.

Background

4. The Environmental Protection Act (EPA) 1990, section 114 provides powers to appoint inspectors to enforce 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 larger GMOs. The Commission asked the Health and Safety Executive to carry out the functions on its behalf. HSE fulfilled this obligation through inspection of "contained use" work activities at specified premises with work involving "larger genetically modified organisms" (GM plants and GM animals).

5. This agreement expired on 31st March 2006, was subsequently renewed extending the HSE inspection remit to include inspections of similar work undertaken as part of "deliberate release" consents under the Genetically Modified Organisms (Deliberate Release) Regulations 2002, in clinical settings. The aim of these inspections is to ensure that the risks to both the environment and human health identified in the trial application are minimised and within the limitations and conditions of the original consent. The current agreement has been extended and runs until 30th June 2009

6. HSE's intention is to tender for this work as part of a renewed agency agreement in respect of both the arrangements for inspection/enforcement of the environmental aspects of larger GMOs and also the deliberate release into the environment of GMOs used in clinical applications, in line with HSE's core business for a further 3 years.

7. The GMO(Deliberate Release) 2002 regulations require that prior to granting consent for such activities, the Secretary of State must seek agreement from HSE that they are content in respect of risks to human health. This requirement is irrespective of HSE's inspection role. Therefore in undertaking this role, HSE liaises closely with the Department of Health's Gene Therapy Advisory Committee (GTAC), and the Medicines and Healthcare products Regulatory Agency which advise on ethical and patient safety aspects of such trials, respectively.

Argument

8. HSE are recognised as having longstanding expertise in the regulation of the contained use of GMOs and have been asked to tender to continue inspections. 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. In line with HSE's strategy, this area of work is a clear example of bringing together health and safety and other portfolios i.e. the environment together in terms of organisation and delivery; and an acknowledged need for balance in managing the interfaces between HSE and other regulators. In accord with 'Better Regulation' and 'Hampton' principles, there are clear benefits to both the dutyholder to comply with one regulator that covers aspects of the work they undertake; and to HSE

as the regulator, as they already carry out inspection and enforcement with the same dutyholders under the GMO (CU) Regulations in relation to human health and the environment. To ensure this work dovetails with HSE's core business, a review of the links to HSE's overall strategy is also undertaken prior to the proposal to tender being submitted.

9. Both the 'contained use' and 'deliberate release' aspects of the tender are a continuation of existing work endorsed by the HSC in 2003 and 2006. The most significant changes to the agreement are:

- The new agreement intends to reduce the number of larger genetically modified organisms (LGMO) contained use inspections, from 25 to 16 per annum, based on HSE's inspection experience of good levels of compliance to date; and increase the number of inspections of deliberate release clinical studies, from 5 to 10 per annum, based on an increase in the number of applications received by Defra. These will generally be carried out in centres already registered with HSE;

- The consent for clinical applications of GMOs will include the need for HSE to be contacted to arrange an inspection prior to the clinical trial commencing;

- Specific qualifications of the HSE staff involved in the work have been replaced by the competencies required for those undertaking and supervising the inspections.

10. 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.

11. HSE has carried out GMO based inspections for environmental risks for the past 16 years, and for about 25 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 2005 (as amended).

Consultation

12. PFPD, Policy Group, Legal Advisors Office, Defra, Scottish Executive, Welsh Assembly Government. The costings for the renewal agreement with Defra cover England as well as Scotland and Wales (as agreed between Defra and

the devolved administrations) and identify the elements allocated to each. The Scottish Executive and the National Assembly for Wales have indicated (through Defra) that they want HSE to continue with the existing arrangements and undertake similar inspection functions in Scotland and Wales respectively. Consequently separate agency agreements are in the process of being drawn up with the devolved administrations. It is not intended to submit separate papers to the SMT for these agreements and the Chair of the HSE Board will be asked to sign these off on behalf of HSE in due course.

Presentation

13. This contract continues and builds on HSE's expertise in the field of inspection of activities involving genetic modification 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

14. There is already a well established working relationship with other parts of Government including Defra, Scottish Executive and the National Assembly for Wales. This is a formalised arrangement in respect of the Genetically Modified Organisms (Contained Use) Regulations 2005, as amended, such that HSE and the Secretary of State for the Department for Environment, Food and Rural Affairs are the competent authority in England and Wales. In practice, these functions are delegated to officials of the Executive and Defra. In Scotland, the competent authority for the Genetically Modified Organisms (Contained Use) Regulations 2005, as amended comprises the Scottish Ministers, who have delegated their functions to the Scottish Government, and HSE. Although not part of the competent authority, the National Assembly for Wales are 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

15. The agency agreement has been costed at 'full economic cost' and provides total recovered costs of £119,292 over the 3-year period. In addition, a contingency element of up to £59,915 has been included in the agreement, which will provide additional resources 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 228 staff days, plus a contingency element of 120 staff days. This is 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.

16. 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

17. The work involves enforcement of environmental legislation.

18. There is likely to be a continuation in research involving the generation and use of larger GMOs over the next three years commensurate with 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. Another area that has seen continuing 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.

Action

19. The SMT is asked to agree the recommendations in paragraph 3.

AGREEMENT BETWEEN THE SECRETARY OF STATE AND THE HEALTH AND SAFETY COMMISSION ON INSPECTION AND ENFORCEMENT RELATING TO THE ENVIRONMENTAL ASPECTS OF CONTAINED USES OF LARGER GMOs, AND DELIBERATE RELEASES INTO THE ENVIRONMENT OF GENETICALLY MODIFIED MICROORGANISMS USED IN CLINICAL APPLICATIONS

1. This agreement is made between the Secretary of State for Environment, Food and Rural Affairs ("The Secretary of State") and the Health and Safety Executive ("the Executive") under Section 13(4) of the Health and Safety at Work etc Act 1974 ("the 1974 Act"). It relates to functions exercisable by the Secretary of State which in the opinion of the Secretary of State for Work and Pensions can be appropriately performed by the Executive in connection with the Executive's functions.

IT IS AGREED THAT

2. The Executive shall, subject to paragraph 3, perform on behalf of the Secretary of State the functions specified in paragraph 1 of Annex A, being the Secretary of State's enforcement functions under Part VI of the Environmental Protection Act ("the 1990 Act").

3. The functions are to be exercised in relation to the release and marketing of genetically modified organisms under the 1990 Act and the Genetically Modified Organisms (Deliberate Release) Regulations 2002 and the GMO (Deliberate Release and Risk Assessment)(Amendment) Regulations 1996. In relation to the import and acquisition of genetically modified organisms, functions are to be exercised under the 1990 Act and the Genetically Modified Organisms (Contained Use) Regulations 2005 (as amended).

4. Subject to the terms and conditions set out in Annex A and the initial programme of work set out in Annex B, acceptance of this invitation shall:

(a) constitute an agreement between the Secretary of State and the Executive under section 125(1) of the 1990 Act and section 13(1)(b) of the Health and Safety at Work, etc Act 1974 ("the 1974 Act"); and

(b) activate for the purposes and duration of the agreement the delegation by the Secretary of State to the Executive of the relevant functions.

5. References in this agreement to any Act or subordinate legislation are references to that Act or subordinate legislation as amended, extended or applied

IN WITNESS whereof the Seal of the Secretary of State for Environment, Food and Rural Affairs has been affixed this _____ day of _____ 2009, and the Common Seal of the Health and Safety Executive has been affixed this _____ day of _____ 2009.

THE SEAL OF THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS is authenticated by:

Authorised by the said
of Secretary of State

THE COMMON SEAL OF THE HEALTH AND SAFETY EXECUTIVE is authenticated by:

Chair of the Health and
Safety Executive

Annex A

TERMS AND CONDITIONS

Functions

1. The relevant functions are those specified in section 125(2) of the 1990 Act namely:

   (i) the service and withdrawal of prohibition notices (section 110);

   (ii) the appointment of inspectors (section114(1));

   (iii) the authorisation of inspectors to prosecute before a magistrates' court (section 114(4));

   (iv) the service of notices requiring persons to furnish information (section 116);

   (v) dealing with any cause of imminent danger to the environment (section 117);

   (vi) the institution of proceedings (section 118(10));

   (vii) the power to arrange for the remedying for harm (section 121).

2. The Executive will exercise its relevant functions in accordance with the following undertakings.

Appointment of inspectors

3. The Executive shall:

   (a) inform the Secretary of State of the competencies and instruments of appointment of inspectors under section 114 of the 1990 Act for the purposes of the agreement;

   (b) appoint under section 114 of the 1990 Act such numbers of inspectors as appear sufficient for the purpose of carrying the agreement into effect and inform the Secretary of State of the arrangements for their deployment; and

   (c) inform the Secretary of State of any proposed changes to the deployment of the inspectors appointed for the purpose of the agreement.

4. Inspectors appointed under the arrangements shall have the powers set out in sections 115 and 117 of the 1990 Act.

5. Where an action has been brought against a person appointed by the Executive as an inspector in accordance with Paragraph 2 in respect of an act done in the enforcement or purported enforcement of the Order, the Secretary of State will indemnify that person against the whole or part of any damages and costs or expenses which he may have been ordered to pay or may have incurred, if the Secretary of State is satisfied that the inspector honestly believed that the act complained of was within his powers and that his duty as an inspector required or entitled him to do it.

Programme of work

6. The Executive shall perform the relevant functions in accordance with a costed three-year programme of work and the Secretary of State's requirements for environmental protection. The agreed programme of work is at Annex B. The programme may be updated and revised to cover changed requirements in line with the arrangements described in paragraph 6, in addition to which the strategy for deliberate release inspections of clinical trials will be reviewed after one year. Separate Agreements, to include an agreed programme of work, will be put in place with the devolved administrations.

7. In October 2009 and annually thereafter, the Secretary of State and the Executive shall review the programme of work for the financial year beginning in the following April. Any changes to the proposed programme will reflect the Secretary of State's current requirements for environmental protection and any additional requirements for inspection and enforcement. The programme will also, as appropriate, include details or take account of:

   (a) the expected number of planned inspection visits and the procedure to be used for prioritising them as well as the capacity of inspectors to respond to urgent needs;

   (b) the staff, management and training arrangement for the inspection team, including the grade of each member of it, and the proportion of his or her time allocated to the relevant functions;

   (c) the development of inspection procedures and instructions, including the procedures and warrants necessary for the exercise of rights of entry to and inspection of premises and the taking of samples under section 115 of the 1990 Act;

   (d) proposed arrangements for liaison with and support from other bodies and inspectorates;

   (e) proposed arrangements for liaison with the Secretary of State's officials and for attendance at meetings of the Advisory Committee on Releases to the Environment;

(f) proposed arrangements for dialogue, nationally and internationally, with scientists, technologists and professional societies and other organisations on matters relating to environmental aspects of inspection and enforcement in connection with the relevant functions; and

(g) proposals for support and advice to the Secretary of State on the development of standards, technical guidance and publications in connection with environmental aspects of the relevant functions.

Reports to the Secretary of State

8. The Executive shall submit to the Secretary of State at the end of April 2010 and annually thereafter, a report on the work carried out in fulfilment of the agreement during the preceding financial year. It will give an account of the work done under the costed programme of work for that year, and will include in particular the number of inspection visits paid, information on prosecution and other enforcement action taken, and a description of any problems identified which might require action in the future.

9. The Executive shall keep the Secretary of State fully informed on the investigation of any serious incidents or dangerous occurrences which have policy or prosecution implications or which might be widely publicised.

Exchange of information

10. The Secretary of State shall provide to the Executive such information as either of them may at any time reasonably require for the purpose of performing the functions specified in the agreement, and the Executive shall provide to the Secretary of State such information as he may at any time reasonably require in connection with the performance of those functions.

Financial arrangements

11. The Secretary of State shall pay the Executive the full amount of the costs incurred in performing the relevant functions, in so far as they are included in the approved programme of work. The Secretary of State's total liability for the three-year programme shall be £119,292 plus a contingency limit of £59,915, divided as follows:

- £37,784 plus contingency of £19,285
- £40,092 plus contingency of £19,970
- £41,416 plus contingency of £20,660

12. The costs assume that the programme of inspections will be maintained at a constant level over three years and include a 3.5% inflationary element. An allowance has been included for inspections in Scotland and Wales, which Defra shall continue to fund on behalf of the devolved administrations. The work programme is set out in Annex B.

13. The Secretary of State shall be responsible for additional liabilities only where he has consented to that additional expenditure in writing before it was incurred. The Executive shall notify the Secretary of State as soon as possible if the agreed sum for any year in relation to the costed programme of work is likely to be inadequate.

14. The Secretary of State's total liability in the period of 12 months from the commencement of this agreement, and in any subsequent period, shall be limited to the amount, if any, agreed by him in writing in accordance with the arrangements set out in paragraph 6, 10, 11 and with the other terms and conditions of the agreement, except that any costs relating to enforcement action and appeals shall be in addition to the costs specified.

15. The Executive shall produce such accounts, documents, records or explanation as the Secretary of State may reasonably request relating to expenditure in connection with the agreement.

16. The Secretary of State shall make payments to the Executive annually in arrears against invoices submitted to Defra's ASD Division. They will be within the limits of the agreed budget or for such higher sums as have been given prior approval.

General

17. The Executive shall not disclose to a third party information, reports or results relating to work carried out under the agreement, except for the purposes of enforcement action; in compliance with a legal obligation to disclose for example under the provisions of the Environmental Information Regulations 1998; or in compliance with a court order, or in accordance with HSE's policy on open government, without the agreement of the Secretary of State.

Period of agreement

18. The agreement shall come into effect as from 1 July 2009 and shall terminate on 31 March 2012, unless it is terminated early on the expiry of six months written notice given at any time by either party to this agreement to the other, or immediately with the consent of both parties.

Annex B

AGREEMENT BETWEEN THE SECRETARY OF STATE AND THE HEALTH AND SAFETY EXECUTIVE ON INSPECTION AND ENFORCEMENT RELATING TO THE ENVIRONMENTAL ASPECTS OF CONTAINED USES OF LARGER GMOs, AND DELIBERATE RELEASES INTO THE ENVIRONMENT OF GENETICALLY MODIFIED MICROORGANISMS USED IN CLINICAL APPLICATIONS

PROGRAMME OF WORK

1. This document sets out the programme of work from the commencement of the agreement signed by the Secretary of State and the Health and Safety Executive. The period covered by this programme shall terminate on 31 March 2012 but the programme is subject to review and may be amended to meet changed requirements.

2. Responsibility for the day-to-day management of the specified tasks rests with HSE under the supervision of the Head of the Biological Agents Unit. The staff undertaking the specified tasks shall be drawn from the list of staff set out in Appendix 3 hereto such list to be updated as necessary to reflect staff changes from time to time.

3. The Department's nominated officer for this agreement shall be Mr David Sherlock, GM Team, Area 8A, LMB, 17 Smith Square, London, SW1P 3JR

4. The Department shall pay HSE the costs of undertaking the specified tasks in accordance with the programme, subject to a total liability of £119,292 plus a contingency limit of £59,915.

WORK PLAN

1. The plan of work is intended to cover that part of the work of HID SI4, Biological Agents Unit, is concerned with:

(a) the Genetically Modified Organisms (Deliberate Release) Regulations 2002, in relation to inspection of consented activities involving clinical applications of vaccine or gene therapy trials and

(b) environmental aspects of the contained use of genetically modified organisms covered by the Environmental Protection Act (EPA) 1990, and in particular Section 108(1)(a), as applied by the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996

2. Release sites will be inspected in connection with consents for vaccine or gene therapy trials granted by the Secretary of State. All such trials should be inspected,

with 10 cases allowed for in the annual budget subject to adjustment in the light of the number of consents actually issued. This element of the programme will be reviewed after one year so that HSE can provide feedback on the workload involved and an assessment can be made as to how effectively this is operating.

3. Planned inspections of sites in relation to the import and acquisition of genetically modified organisms which are larger than micro-organisms (plants and animals) at sites subject to Section 108(1)(a) of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Risk Assessment) (Records and Exemption) Regulations 1996 will continue. Inspections will be targeted at centres in the higher risk category, by intelligence gathered during the notification process for the contained use regulations, from published papers, from Defra licences and from any requested by Defra. In relation to the import and acquisition of genetically modified organisms, functions are to be exercised under the 1990 Act and the Genetically Modified Organisms (Contained Use) Regulations 2005, as amended.

4. When HSE inspectors visit premises for their own contained use inspections, they should also carry out any inspections on our behalf of the environmental aspects of contained use of larger GMOs, with the intention of maximising efficiency. The number of proposed inspections per annum is 13 for England, 2 for Scotland and 1 for Wales, with additional visits carried out if required by the competent authorities, to be covered by the contingency fund.

5. The areas of work covered by this agreement relate to the Environmental Protection Act 1990 as follows:

- scheduled inspections of release or contained use sites or in connection with GMOs, including tests, inspections, information gathering and taking and examination of samples under S. 115 or 116 of the 1990 Act, etc. for the purposes of:

    (a) inspecting and advising on compliance with the conditions attached to consents to release or market GMOs granted in accordance with S. 111 and 112 of EPA 1990;
    (b) determining the adequacy of environmental risk assessments and associated records made in connection with contained use (i.e. importation or acquisition) of GMOs under S. 108 of the EPA 1990.

- scheduled or unscheduled inspections of release or contained use sites or in connection with approved GMO products for the purposes of investigating or dealing with unforeseen incidents or occurrences, and including:

    (a) the service and withdrawal of prohibition notices under S. 110 in connection with proposals for import, acquisition, release or marketing of GMOs;
    (b) dealing with any cause of imminent danger of damage to the environment in accordance with S. 117;
    (c) instituting and pursuing proceedings for offences committed under S. 118;

(d) remedying harm in accordance with S. 121 in connection with offences committed under S. 118;
(e) any tests, inspections, information gathering and taking and examining of samples required to support activities (a) to (d);
(f) investigating public complaints to determine if any offence has occurred.

6. In addition HSE will continue its activities relating to the assessment of applications for release of GMOs and GMMs considered by the Advisory Committee for Releases to the Environment (ACRE) and its working groups including the development of related guidance.

7. HSE will also collect information under the Cartagena Protocol on the transboundary movements of Class 3 and 4 GMOs and pass that information to the Biosafety Clearing House and the EC, via Defra.

8. Appropriate staff, training, travel and subsistence costs incurred in carrying out the duties required under this agreement will be met by Defra

9. The details of the programme and the costings are given in Appendix 1. The agreed protocol for the clinical trial inspections has been set out in full at Appendix 2. The staff qualified to undertake inspection, etc. and the contact points for the different aspects of the work are given in Appendix 3. Their qualifications and experience are given in Appendix 4.

APPENDIX 1

PRICE SCHEDULE

FORM OF TENDER AND PRICE SCHEDULE

Costings are worked out for delivery of the inspection programmes, including management costs, supervision, and travel and subsistence (T&S). Costs are worked out on a daily rate, using Full Economic Costs (FEC) by grade. The T&S component is added to the staff costs, and is on the basis of a *pro rata* split between HSE and DEFRA.

Costs given below are for 2009 –2012. An inflationary element of 3.5% has been added to the 2nd and 3rd years, to give the total price.

Daily FEC costs for:	**09/10**	**10/11**	**11/12**
Band 1 Specialist Inspector	674	697	722
Band 2 Specialist Inspector	590	611	632
Band 3 Specialist Inspector	505	523	541
Band 4 Administrator	400	413	428
Band 5 Administrator (Regulatory Contact Officer)	351	363	376
Band 6 Administrator	306	317	328

Staff days offered for management, training given/received and maintenance of databases:

		09/10	**10/11**	**11/12**
Band 1	2 days	1348	1394	1444
Band 2	5 days	2950	3055	3160
Band 4	5 days	2000	2065	2140
Band 6	5 days	1530	1585	1640
Overall costs (including T&S)		7828	8099	8384

Staff days offered for contained use inspections in England - (inc. time for visit preparation, inspection visit, report working and follow-up action):

13 visits to contained use facilities:

		09/10	10/11	11/12
Band 2	2.5 days	1475	1527	1580
Band 3	14 days	7070	7322	7574
Band 5	5 days	1755	1815	1880
Band 6	2 days	612	634	656
Overall costs (including T&S)		10912	11298	11690

Staff days offered for contained use inspections in Scotland - (inc. time for visit preparation, inspection visit, report working and follow-up action):

2 visits to contained use facilities:

		09/10	10/11	11/12
Band 2	0.5 days	295	305	316
Band 3	3 days	1515	1569	1623
Band 5	0.5 days	175	181	188
Band 6	0.5 days	153	158	164
Overall costs (including T&S)		2138	2213	2291

Staff days offered for contained use inspections in Wales - (inc. time for visit preparation, inspection visit, report working and follow-up action):

1 visits to contained use facilities:

		09/10	10/11	11/12
Band 2	0.5 days	295	305	316
Band 3	1.5 days	757	784	811
Band 5	0.5 days	175	181	188
Band 6	0.5 days	153	158	164
Overall costs (including T&S)		1380	1428	1479

The split between England, Wales and Scotland may be adjusted within the overall total to respond to actual inspection requirements.

Staff days offered for Deliberate Release inspections in connection with consents to release GMOs in vaccine or gene therapy trials - (inc. time for visit preparation, inspection visit, report working and follow-up action):

10 inspection visits (2 per site):

		09/10	10/11	11/12
Band 2	2 days	1180	1222	1264
Band 3	15 days	7575	7845	8115
Band 6	1 day	306	317	328

Overall costs (including T&S)	9061	9384	9707

Staff days offered for work involving liaison with the Competent Authority, dialogue with scientists and professional bodies on matters relating to the inspection and enforcement function, and production of technical guidance supporting the inspection function:

		09/10	**10/11**	**11/12**
Band 2	5 days	2950	3055	3160
Band 3	5 days	1515	2615	2705
Overall costs (including T&S)		4465	5670	5865

Conferences and Training

Where specific training is required to fulfil the contract, arising from developments in technology, this will be carried out in the most cost efficient manner. Individual inspectors would attend necessary training, and information would be cascaded within the group.

Attendance at relevant conferences may be required to keep abreast of technical developments.

	09/10	**10/11**	**11/12**
Overall costs (including T&S)	2000	2000	2000

Contingency Time and Costs

A contingency element is included to allow for increased inspection demand, for example following an expansion in deliberate releases, or to cover extra time required for formal investigations and enforcement.

These costs will only be incurred in agreement with DEFRA.

		09/10	**10/11**	**11/12**
Band 2	10 days	5900	6110	6320
Band 3	20 days	10100	10460	10820
Band 5	5 days	1755	1815	1880
Band 6	5 days	1530	1585	1640
Overall costs (including T&S)		19285	19970	20660

TENDER BID

(Excluding contingency time)

	09/10	10/11	11/12
TOTAL COSTS	£37784	£40092	£41416
TOTAL TENDER BID		£119,292	

CONTINGENCY PLAN

(ONLY TO BE USED IN AGREEMENT WITH THE COMPETENT AUTHORITY)

	09/10	10/11	11/12
TOTAL COSTS	£19285	£19970	£20660
TOTAL CONTINGENCY COSTS		£59915	

APPENDIX 2

HSE's Intervention Strategy for Premises Undertaking Clinical Trials of GM Vaccines or Gene Therapy Agents Under Deliberate Release Legislation

Aims of Inspections

1) One of the main aims of inspection of consent holders undertaking clinical trials of GM vaccines or gene therapy agents under deliberate release legislation will be to ensure that the trial is carried out in a way which is compliant with the limitations and the conditions of the consent to release the organism. In particular, the inspections will aim to ensure that the risks to both the environment and human health are those identified in the application and are minimised. However, the issues scrutinised during the inspection will depend on the nature of the trial, the information provided in the application and the conditions of consent for that trial. HSE's approach to undertaking the inspection will be in the manner set out below.

Which Deliberate Releases to Inspect

2) **All** consent holders undertaking clinical trials of GM vaccines or gene therapy agents under deliberate release consents will be inspected. Where the GM vaccine or gene therapy product is to be administered in the home, the strategy for inspection will be to assess compliance with the conditions of the consent through discussion with the clinical investigator overseeing the trial, rather than visiting individual dwellings.

Timing of Inspections

3) We will carry out initial inspections **before** the trial begins and a second inspection during the course of a trial. The aim of the initial inspections will be to discuss procedures and protocols, particularly those related to monitoring, and to inspect the facilities. This will be arranged by contacting the consent holder when consent is issued to set up an inspection before work commences or during the trial.

4) In theory, inspection before the trial begins may not be possible in all cases as the work can begin as soon as consent is issued. In this event, inspection will be carried out during the trial. However, in practice, centres will need to recruit volunteers to take part in trials, and this should provide the opportunity to inspection prior to commencement of the trial. In order to avoid this scenario, the conditions of the consent issued by the Secretary of State need to reflect that work can not start until HSE has been approached and an inspection undertaken. Information obtained during this pre-trial inspection will be reported back to Defra/SE/WA, and may inform the timing and nature of follow-up visits.

5) A second inspection visit will be carried out during the trial. This will be either during the period when the vaccine is being administered, or during the follow-up work where monitoring for shedding is taking place. The visits will aim to ensure that the procedures for administration and for monitoring of shedding are being carried out in accordance with the consent. Consent holders are required to give details of how all procedures will be carried out, and the inspection will monitor compliance with the stated methods and procedures. Furthermore, where specific conditions are applied to the consent, compliance will be assessed.

Pre Inspection Activities

6) Prior to the initial inspection being carried out, HSE inspectors will review information provided in the application for consent to release the organisms, as well as any advice from ACRE and conditions attached to the consent to release.

7) The inspectors will contact the consent holders to arrange the inspection. This will include arranging to discuss protocols and procedures for all aspects of the trial, including follow-up and reporting back. They will also arrange to speak to staff administering the GMO and staff involved in sampling and monitoring, to ensure that there is the appropriate degree of understanding of the issues involved, and that training has been carried out.

Inspection Issues

8) During the inspection, a range of issues will be looked at. The degree of scrutiny of any particular area will vary between trials and will be based on the judgement of the inspection. The key issues that will be covered will include:

- Supply of GMO, including safe transport.
- Storage of the GMO.
- Preparation of the GMO for administration.
- Compliance with monitoring requirements detailed as part of the application or as a condition of consent. This will include: what samples are taken, timing of sampling, storage and transport of samples, how they are tested, sensitivity of tests used, competence of those carrying out testing and sampling etc. Contingency plans will be discussed, for example, procedures to be followed where unexpected levels of shedding are observed, etc.
- Facilities and areas used in the trial and their suitability. As well as considering the physical nature of the facilities, the location will be considered, for example, in relation to public corridors, waiting rooms etc.
- Cleaning regimes for areas to be used in the trial.
- Treatment of contaminated waste.
- Availability and use of personal protective equipment (where applicable).
- Information on risks to health and environment provided to patients and their families (ideally including speaking to patients).

- Information on risks to health and environment provided to staff, both directly involved in the trial and ancillary staff, such as porters and cleaners.
- Information provided to staff, patients and their families on hygiene measures or use and replacement for dressings.
- Mechanisms in place to ensure effectiveness of staff training and information provided to patients.
- Information on risk provided to staff, patients and their families.
- Contingency plans.
- Monitoring systems in place for general health of patients and any relevant symptoms in staff.
- Copies of monitoring data, specifically methodologies, consistency with application, adverse reactions, and ‘daily log’.

Post Inspection

9) Following the inspection HSE will provide a copy of inspection report and any letter/formal enforcement action sent to trial organisers to Defra/SE/WA. Copies will be forwarded electronically. Copies of any supporting documentation will be held on file by HSE, and copied, as appropriate to Defra/SE/WA. Where issues arise at inspection that require the attention of the Competent Authorities these will be communicated directly by telephone or E. mail, particularly if enforcement action is being considered.

Post Trial

10) Review any report or monitoring data provided from the trial as a condition of consent.

APPENDIX 3

STAFF UNDERTAKING DUTIES UNDER THE AGENCY AGREEMENT

Band 1	Head of Unit
Band 2	Biotechnology Portfolio Holder Intervention Programme Manager
Band 3	BAU Specialist Inspectors (11)
Band 4	Notifications & Consents Administration Manager
Band 5	Regulatory Compliance Officer Administration Manager
Band 6	Band 6 Administrators (2)

Any changes to this list will be notified to Defra and the devolved administrations.

APPENDIX 4

COMPETENCY AND TRAINING

1. All professional staff are required to have a level of understanding of biotechnology and microbiology sufficient to assess the risks to the environment and human health from the activities involving large genetically modified organisms and clinical applications of genetically modified organisms. During periods of staff development, individuals will be directed and supervised by experience colleagues, to ensure the necessary level of competence is demonstrated.

2. All inspection staff undergo a structured "in-house" training programme that includes training in inspection, investigation, enforcement, notification assessment, communication skills, IT skills and information management. Staff are required to undertake appropriate further training and professional development. This programme includes both internal and external course and meetings. Appropriate training records are maintained