Department for Environment Food & Rural Affairs

HSE

MEMORANDUM OF UNDERSTANDING BETWEEN THE SECRETARY OF STATE FOR THE DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS AND THE HEALTH AND SAFETY EXECUTIVE IN RELATION TO THE CONDUCT OF SERVICE PROVISION FOR THE INSPECTIONS OF LARGER GENETICALLY MODIFIED ORGANISMS IN CONTAINED USE AND GM MEDICAL AND VETERINARY TRIALS REFERENCE: 29163

1 SEPTEMBER 2021

SECTION 1

Memorandum of Understanding

This Memorandum of Understanding (**"MoU"**) is between the following parties:

(1) The Secretary of State for Environment, Food and Rural Affairs (Defra) ("Secretary of State" or "Service Receiver"); and

(2) The Health and Safety Executive ("HSE" or "Service Provider").

Each a "Party" and together referred to below as the "Parties".

WHEREAS:

Background

a. An Agency Agreement (the "Agency Agreement") dated 17th April 2018 made between the Secretary of State and HSE under section 13(4) of the Health and Safety at Work etc. Act 1974 ("the 1974 Act") and Section 125(1) of the Environmental Protection Act 1990 ("the 1990 Act") establishes that HSE will perform inspection and enforcement functions. The purpose of this MoU is to set out the framework whereby HSE will supply inspection and enforcement services to the Service Receiver in relation to the environmental aspects of contained uses of larger genetically modified organisms (LGMOs), and deliberate releases of genetically modified organisms used in GM medical and veterinary trials. It also sets out how HSE will discharge the functions described in the Agency Agreement. It deletes, replaces and supersedes all previous MoUs between parties. There is a continuing need for the MoU given the on-going statutory inspection and enforcement function.

b. By agreement within this MoU, the Service Provider will provide certain services and enforcement functions under Part VI of the 1990 Act on behalf of the Secretary of State.

c. This MoU is not intended to create a binding legal obligation between the Parties. However, the Parties will observe the terms of this MoU as if it were legally binding, and it shall be construed in accordance with English law.

IT IS AGREED AS FOLLOWS:

1. Interpretation

1.1 "Confidential Information" means any information which has been designated as confidential by either Party in writing or that ought to be considered as confidential (howsoever it is conveyed or on whatever media it is stored) including information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person or trade secrets or Intellectual Property Rights of either Party and all personal data and sensitive personal data within the meaning of the Data Protection Act 2018 but does not include information which:

a. was public knowledge at the time of disclosure (otherwise than by breach of clause 6 (Confidential Information));
b. was in the possession of the receiving Party, without restriction as to its disclosure, before receiving it from the disclosing Party;
c. is received from a third party (who lawfully acquired it) without restriction as to its disclosure; or
d. is independently developed without access to the Confidential Information.

1.2 In this MoU unless otherwise expressly provided, or unless the context otherwise requires:

a. references to the singular include the plural and vice versa;
b. references to words denoting any gender shall include all genders; and
c. references to the Parties and individuals include their respective successors in title, permitted assigns and legal personal representatives.

1.3 In this MoU any reference to any statute or statutory provision shall, unless the context otherwise requires, be construed as a reference to that statute or provision as from time to time amended, consolidated, modified, extended, re-enacted or replaced.

1.4 The Annexes form part of this MoU and will have effect as if set out in full in the body of this MoU.

1.5 In the case of conflict or ambiguity the order of precedence for this MoU and the documents attached to or referred to in this MoU will be as follows:

a. the Agency Agreement;
b. the body of this MoU;
c. the Annexes to this MoU.

2. Services and Functions to be performed

2.1 The Agency Agreement describes the functions that HSE can perform on behalf of the Secretary of State, including the appointment of inspectors and sets out the relevant legislation underpinning the inspectors' powers and functions. The Secretary of State can exercise functions under the 1990 Act having given written notice to HSE. The MoU covers the arrangements for the payment of costs to HSE in performing their functions.

2.2 The enforcement functions will be undertaken by HSE in the manner described in Annex A. HSE shall perform on behalf of the Secretary of State the programme of work and the work plan specified in Annex B.

2.3 This MoU will be kept under review by both Parties to identify any new opportunities for joint working, should they arise. Should the MoU require amendment to factor in these new opportunities, it will be through mutual agreement.

3. Specification and terms and conditions

3.1 The specification of the services and terms and conditions are set out in Annex A and the initial programme of work (the "Programme") is set out in Annex B. Any material changes or variations, including any additional work must be detailed in a written addendum in accordance with Clause 3.2 of the Terms and Conditions (Annex A).

4. Duration/Expiry/Termination

4.1 The MoU shall come into effect as from 1 September 2021 and shall terminate on 31 March 2023, unless it is extended for any further period(s) on the same terms and as mutually agreed between the Parties. The MoU or any extension to it may be terminated early on the expiry of six months written notice given at any time by either Party to this MoU to the other, or immediately with the consent of both Parties.

4.2 In the event that notice of termination is given or agreed between the Parties in respect of the Agency Agreement, such notice shall be treated as notice of termination in respect of

the MoU, and the MoU shall cease to have effect immediately upon termination of the Agency Agreement.

5. Data protection and information management

5.1 Information obtained and provided by the Parties must be managed in accordance with the relevant information management legislation including but not limited to:

a. Freedom of Information Act 2000 (FOIA);
b. Environmental Information Regulations 2004 (EIR);
c. References to "GDPR" within the document are references to "the UK GDPR" as defined by regulation 2 of the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019;
d. Public Records Act 1958 and 1967;
e. Privacy and Electronic Communications Regulations 2003 (PECR);
f. Re-use of Public Sector Information Regulations 2015; and
g. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation).

5.2 The Parties will have their own obligations and will discharge their duties independently, taking responsibility for their own decision making. The respective roles and responsibilities that Defra and HSE will play in managing the processing of personal data are described in more detail in Annex G.

5.3 For law enforcement purposes and to comply with Part 3 of the Data Protection Act 2018 please refer to *Investigations for law enforcement purposes* in the HSE *Privacy Policy Statement*.

6. Confidential Information

6.1 Each of the Parties understands and acknowledges that it may receive or become aware of Confidential Information belonging to the other Party whether in the course of the performance of the obligations under this MoU or otherwise.

6.2 Except to the extent set out in this clause or where disclosure is expressly permitted elsewhere in this MoU, each Party must:

a. treat the other Party's Confidential Information as confidential and safeguard it accordingly;
b. not disclose the other Party's Confidential Information to any other person (except their employees, agents and professional advisers to the extent to which such disclosure is necessary for the purposes contemplated under this MoU, and subject to procuring that such persons are made aware of, and comply with, these obligations of confidentiality).

6.3 The obligations of confidentiality imposed by paragraphs 6.1 and 6.2 continue in force notwithstanding termination of this MoU. They do not apply to any Confidential Information to the extent that it is required to be disclosed by a requirement of law placed upon the Party making the disclosure (including any requirements for disclosure under the Freedom of Information Act 2000 and/or the Environmental Information Regulations 2004. They are subject to any government requirements as to transparency which may apply to the Parties from time to time.

6.4 The Parties must not use the Confidential Information under this MoU for commercial purposes without the prior written agreement of the Party supplying the Confidential Information.

7. **Dispute Settlement**

7.1 It is the responsibility of the Parties in the first instance to attempt to resolve any dispute between the Parties arising out of or in connection with this MoU and, if no resolution is reached within a reasonable period of time, the dispute should be referred to the Heads of Department or other senior officials of both parties for resolution.

8. **Miscellaneous**

8.1 This MoU does not confer any rights on any third party. Nothing in this MoU shall be interpreted as limiting, superseding or otherwise affecting either Party's normal operations in carrying out its statutory, regulatory or other duties.

SIGNATORIES

The duly authorised representatives of the Parties affix their signatures below:

Signed for and on behalf of the Secretary of State for Environment, Food and Rural Affairs

Name

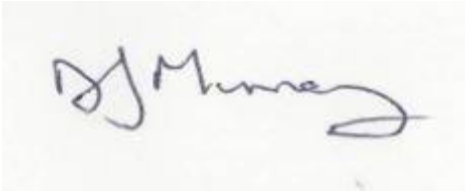
John Forecast

Role - Senior Category Manager, Defra Group Commercial (DgC)

Date - 01/09/2021

Signed for and on behalf of the Health and Safety Executive

Name



David Murray

Role - Director Planning Finance and Procurement

Date - 28/08/2021

Annex A

AGREED TERMS AND CONDITIONS

1.0 Undertakings

1.1 HSE will exercise its relevant functions as set out in the Agency Agreement agreed between the Parties.

2.0 Appointment of inspectors

2.1 HSE 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 MoU;
b. appoint under section 114 of the 1990 Act such numbers of inspectors as appear sufficient for the purpose of carrying the MoU 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 MoU.

2.2 Inspectors appointed under the 1990 Act shall have the powers and functions set out in the Agency Agreement.

2.3 Where an action has been brought against a person appointed by HSE as an inspector in accordance with the Agency Agreement in respect of an act done in the enforcement or purported enforcement of the 1990 Act, HSE may recover from the Secretary of State, the whole of any costs or expenses that have been reasonably incurred by HSE or by an inspector and reimbursed by HSE, where the court was satisfied that the inspector acted in good faith and that there were reasonable grounds for doing so.

3.0 Programme of work

3.1 HSE shall perform the relevant functions in accordance with a costed two-year programme of work and the Secretary of State's requirements for environmental protection. The agreed Programme of work is set out in Annex B. The Programme may be updated and revised to cover any requirements that may change in line with the arrangements described in paragraph 3.2 of this Annex. A separate MoU and Agency Agreement, to include an agreed programme of work, will be put in place with the Devolved Administrations of Scotland and Wales.

3.2 The Parties agree that material changes to the Programme will be by mutual consent, made by a written addendum to this MoU and 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 and members of the inspection team to respond to urgent needs;

b. the staff, management and training arrangements for the inspection team, including the grade of each member of it, and the proportion of their 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 (ACRE);
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.

4.0 Charges and Liabilities

4.1 The Service Provider will perform the specified tasks described in Annex B. The Service Receiver will perform those tasks identified in Annex B and shall make payments to the Service Provider upon satisfactory completion of the tasks in accordance with the terms in Annex C. For the avoidance of doubt, the payments the Service Receiver shall pay the Service Provider is, subject to a maximum amount of £62,604.00.

4.2 Except as provided in Clauses 2.3 and 4.1 above, each Party shall bear its own costs and expenses incurred in complying with its obligations under this MoU.

4.3 Except as provided in Clauses 2.3 and 4.1 above, both Parties shall remain liable for any losses or liabilities incurred due to their own or their employees' actions and neither Party intends that the other Party shall be liable for any loss it suffers as a result of this MoU.

5.0 Reports to the Secretary of State

5.1 HSE shall submit to the Secretary of State, at the end of May in each year the MoU applies, a report on the work carried out in fulfilment of the MoU 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, should there be any further Agency Agreements, MoUs or an extension to this MoU, might require action in the future.

5.2 HSE shall keep the Secretary of State promptly and fully informed about the investigation of any serious incidents or dangerous occurrences which have policy or prosecution implications, or which might be widely publicised.

6.0 Post Inspection Undertakings

6.1 Any letter or formal enforcement action sent to dutyholders in relation to the environmental aspects of contained uses of larger genetically modified organisms

(LGMOs), and deliberate releases of genetically modified organisms used in GM medical and veterinary trials, will be copied electronically to the Service Receiver/ duly appointed representatives of Scottish Ministers (SG), Defra and duly appointed representatives of Welsh Ministers (WG). Copies of any supporting documentation will be held on file by HSE and copied, as appropriate, to the Service Receivers upon request. Where issues arise at inspection that require the attention of the Service Receiver, these will be communicated by HSE by telephone or email direct to the appropriate Service Receiver/Devolved Administration, particularly if enforcement action is being considered.

7.0 Exchange of information

7.1 Each Party shall provide to the other Party such information as either of them may at any time reasonably require for the purpose of performing, or in connection with the performance of, the functions specified in the MoU.

8.0 Service Levels and Performance Management

8.1 Key Performance Indicators (KPIs) are essential to manage HSE's performance in delivering the Secretary of States' requirements in a fair and practicable way. KPIs are realistic, achievable, measurable and will be reported on at annual review meetings the first review being in May 2022.

8.2 Each Party will appoint Service Level Managers to this Agreement whose role will be to ensure the essential requirements of the Agreement are delivered to meet or exceed the Party's minimum quality and safety standards as further referred to in the matrix of KPIs in Annex B.

Annex B **Key Performance Indicators and Programme of Work**		
KPI	**Output**	**Measured**
KPI 1 – Timeliness and Responsiveness	Where the Parties agree any project or programme of work HSE and the Secretary of State will use reasonable endeavours to assure any timeline is maintained. Where Defra raise any service request HSE will respond within pre-agreed response times.	HSE will deliver projects and programmes to agreed timelines and respond to service requests or issues arising to the agreed schedule of response times.
KPI 2 – Assessment of Document quality	HSE provides accurate reports as per Annex A, paragraph 5 of this MoU.	HSE will provide reports to expected HSE quality standards and in line with agreed timescales – measured by data quality checks by the Intervention Programme Manager and summarised at annual HSE/Defra Review meetings.
KPI 3 – Performance against budgeted cost	HSE provides the required service as set out in the pricing schedule (Annex C).	HSE provides the service within the budget. Assessed as part of the annual HSE/Secretary of State Review meetings.
KPI 4 – Remedial actions	Where the Secretary of State require HSE to undertake any remedial action or activity and HSE agrees remediation is required and the liability for this is exclusively HSE's, the Parties will agree the timeline for the corrective action and perform within the agreed timeframe.	Remedial action is provided to timeframe agreed between Parties.
KPI 5 – Health and Safety in Service Delivery	Near misses are reported and recorded in accordance with each organisations' H&S policy for near misses, as well as to the Service Review Group. All staff wear appropriate PPE wherever necessary.	Near misses report.

KPI 6 – Risks and Issues Log	Service Level Managers in the Secretary of State and HSE will maintain a Risk and Issues Log for all projects and programmes of work and alert each other in the event that any risk matures and creates an issue.	Risks and issues to the projects and programmes of work are effectively managed by the parties and as reported in the annual performance meetings.

Annex B continued

Programme of Work

1. SPECIFICATION OF REQUIREMENTS

1.1 This document sets out the programme of work from the commencement of the MoU signed by the Secretary of State and the Health and Safety Executive. The period covered by this programme shall terminate, unless extended or terminated early, on 31 March 2023 but the programme is subject to review and may be amended to meet changed requirements.

1.2 Responsibility for the day-to-day management of the specified tasks rests with HSE under the supervision of the Head of the Microbiology and Biotechnology Unit. The staff undertaking the specified tasks shall be drawn from the list of positions set out in Annex E. A list of nominated HSE and Defra contacts will be agreed, maintained and updated.

2. WORK PLAN

2.1 The work planned covers:

a. inspections of research and development trials for human and veterinary medicinal products containing or consisting of GMOs, which have received consent to proceed; and
b. inspections of environmental aspects of the contained use of LGMOs covered by the 1990 Act, and in particular Section 108(1)(a), as applied by the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996.

2.2 All release trials will be subject to inspection. Three inspections are allowed for in the annual budget for Great Britain, subject to adjustment in the light of the number of consents actually issued. Inspections may not in each case require visits to trial establishments but at a minimum, the relevant trial establishment's procedures must be examined to ensure consent holders are complying with consent conditions. This element of the Programme will be reviewed so that HSE can provide feedback on the workload involved in relation to release inspections and an assessment can be made as to how effectively this is operating.

2.3 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 1990 Act and the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) 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 the Service Receiver's licences and from any requested by the Service Receiver. 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 2014 (SI 214/1663), as amended.

2.4 When possible, HSE will combine inspection visits for the Service Receiver for the purposes of this MoU with visits for HSE's own purposes, with the intention of maximising efficiency. The number of proposed LGMO inspections per annum is

13 for England, 2 for Scotland and 1 for Wales, with additional visits carried out if required and funded by the Service Receiver.

2.5 The areas of work covered by this MoU relate to the 1990 Act 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 the 1990 Act;
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 1990 Act.

- 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 of the 1990 Act 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 of the 1990 Act;
c. instituting and pursuing proceedings for offences committed under S. 118 of the 1990 Act;
d. remedying harm in accordance with S. 121 in connection with offences committed under S. 118 of the 1990 Act;
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.

2.6 HSE will continue its activities relating to the assessment of applications for release of GMOs and genetically modified micro-organisms (GMMs) considered by ACRE and its working groups. This includes the development of related guidance.

2.7 HSE will also collect information under the Cartagena Protocol on the trans-boundary movements of Class 3 and 4 GMOs and pass that information to the Biosafety Clearing House, via the Service Receiver.

2.8 No funding requirement for staff training is foreseen in the pricing schedule at Annex C.

2.9 The details of the programme and the costings are given in Annex C. The agreed protocol for the medicinal trial inspections is set out in full at Annex D. The roles of staff for the different aspects of the work are given in Annex E. Their competency and training are given in Annex F.

2.10 Both Parties agree to bring forward the review date of the Programme of Work as necessary, to address any post EU exit issues. Should the MoU require review and amendment to factor in EU exit issues, it will be through mutual written

agreement with both Parties. The revised MoU would then run for two years from the date that the EU exit issues had been addressed unless terminated earlier in accordance with Clause 4.1 of Section 1 of this MoU.

Annex C

Pricing Schedule

1 Costings for delivery of the programme of work are calculated on an hourly basis, using Full Economic Costs (FEC). Travel and subsistence and HSE overhead costs are included in the hourly rate. From 01 April 2021 the FEC rate will be £188 per hour (£1,391.20 per day).

2 For budgeting purposes only, the overall annual cost is expected to be approximately £41,736.00. This is based on 24 days (£33,388.80) for the delivery of 16 inspections of contained use LGMO facilities, and 6 days (£8,347.20) for the inspection of up to 3 Deliberate Release clinical trial (subject to granting of consents).

3 If circumstances mean that the anticipated annual cost will be greater than 10% higher, the Service Provider will gain prior permission, before continuing with inspections, from the Service Receiver. This includes time for:

a. contained use inspections in England, Wales and Scotland;
b. Deliberate Release inspections;
c. staff days for liaison with the Service Receiver, dialogue with scientists and professional bodies and production of technical guidance.

4 The Department may make additional funding available in certain circumstances if these cannot be accommodated within the budget specified at 4.1. Such circumstances may include investigation of incidents, prosecutions or a larger than anticipated number of release consents to inspect. Any additional expenditure must be mutually agreed by the Parties by written addendum to this MoU.

Payment

5 All invoices should be sent, quoting a valid purchase order number (PO Number), to: gm-regulation@defra.gov.uk. You must be in receipt of a valid PO Number before submitting an invoice. Non-compliant invoices will be sent back to you, which may lead to a delay in payment. If you have a query regarding an outstanding payment, please contact gm-regulation@defra.gov.uk.

Annex D

THE HEALTH AND SAFETY EXECUTIVE'S INTERVENTION APPROACH FOR PREMISES UNDERTAKING CLINICAL TRIALS OF GM VACCINES OR GENE THERAPY AGENTS UNDER DELIBERATE RELEASE LEGISLATION

Inspection Aims

1. Inspection of consent holders undertaking clinical trials of GM medicinal products containing or consisting of GMOs under deliberate release legislation will seek to ensure that the trials are carried out in a way which is compliant with the limitations and the conditions of the consent to release the organisms. In particular, the inspections will seek to ensure that the risks to both the environment and human health identified in the risk assessment are minimised and adequate.

Inspections to be Undertaken

2. All consent holders undertaking clinical trials of GM medicinal products containing or consisting of GMOs under deliberate release legislation will be subject to inspection.

Inspection Format

3. The format of inspection will depend upon the nature of the trial and the risks posed by the GMOs. Inspections may not in all cases require visits to all trial sites. However, as a minimum the relevant hospital or clinic's procedures will be examined to assess compliance with consent conditions.

4. Where a site visit is not warranted or not appropriate, compliance with the conditions of consent will be assessed through discussion with the clinical investigator(s) overseeing the trial rather than visiting each individual site/dwelling. This will be supplemented through HSE's scrutiny of documentation and other information sought from those undertaking the trial (for example using checklists based on the information in the consent documentation). Scenarios where this assessment strategy may be applied include trials where the GMO is to be administered in the home and multisite trials where the work is managed centrally.

5. HSE will consider requests made by the Service Receiver about the approach to be employed on a case-by-case basis.

6. The key areas that will be assessed through inspection 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: the nature of the samples, timing of sampling, storage and transport of samples, how they are tested, sensitivity of tests used, and competence of those carrying out the work. Contingency plans will also be discussed, for example, procedures to be followed where unexpected levels of shedding are observed.

- 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'.

Inspection Timing

7. 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 for inspection prior to commencement of the trial.

8. An inspection visit to site may be required during the trial. For example, where risk management measures are required to minimise or prevent harm to human health and/or the environment, or where HSE has reason to believe there is a risk of the consent conditions not being followed. 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 will be required to give details of how procedures will be carried out, and the inspection will assess compliance with the stated methods and procedures. Where specific conditions are applied to the consent, compliance will be assessed.

9. Prior to inspection, 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. Inspectors will contact the consent holder to discuss and arrange the inspection process. This will include discussion of the protocols and procedures to be employed in the trial, the inspection format and follow-up and reporting output. The assigned HSE inspector 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.

Post-trial Undertakings

10. HSE will review any report or monitoring data provided from the trial as a condition of consent.

Annex E

ROLES OF MICROBIOLOGY AND BIOTECHNOLOGY UNIT STAFF UNDERTAKING DUTIES UNDER THE MoU

Band 1	Head of Unit
Band 2	Intervention Programme Manager Technical Policy lead
Band 3	Specialist Inspectors
Band 5	Regulatory Compliance Officer Administration Manager
Band 6	Administrators

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

Annex F

COMPETENCY AND TRAINING

1. All visiting 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 LGMOs and GM medical and veterinary trials. During periods of staff development, individuals will be directed and supervised by experienced colleagues, to ensure the necessary level of competence is demonstrated.

2. All visiting staff undergo a structured "in-house" training programme that covers relevant skills. These include areas such as inspection, investigation, enforcement, notification assessment, communication, IT and information management. In addition, staff also undertake appropriate further training and professional development. This programme includes both internal and external courses and meetings.

ANNEX G

Article 26 of the GDPR, Joint Controller Declaration

Purpose

1. The purpose of this annex is to explain the respective roles that Defra and HSE will play in managing the processing of personal data associated with inspections of LGMOs in contained use, or GM medical or veterinary trials under deliberate release legislation and on behalf of the Secretary of State. Defra and HSE are joint controllers of the personal data collected, as both parties (independently) determine the purposes and means of processing personal data as part of the functions defined in this MoU.

Data protection

2. Defra and HSE will comply with all relevant provisions of GDPR and the Data Protection Act 2018, as applicable.

3. Defra and HSE will act as joint controllers, in respect of any personal data pursuant to this MoU; they will process such personal data only to the extent necessary to meet the requirements of this MoU; and they will appoint external controllers/ processors as necessary.

4. Neither Defra nor HSE will transfer any personal data it is processing outside the United Kingdom.

5. Defra and HSE will ensure that they have appropriate technical and organisational procedures in place to protect any personal data they are processing. This includes protection against any unauthorised or unlawful processing and any accidental disclosure, loss, destruction or damage. Defra will promptly inform HSE, and vice versa, of any unauthorised or unlawful processing, accidental disclosure, loss, destruction or damage to any such personal data. Both parties will also take reasonable steps to ensure the suitability of their staff having access to such personal data.

Specific Defra responsibilities

6. Defra has the following specific responsibilities:

    i. Carrying out any required Data Protection Impact Assessment for any element of business or process change.

    ii. Following Defra Data Security Guidance to ensure that the necessary measures are taken to protect personal data.

    iii. Ensuring Defra staff are appropriately trained in how to use and look after personal data and follow approved processes for data handling.

    iv. Ensuring Defra staff have appropriate security clearance to handle personal data collected as part of this process.

    v. Ensuring secure transfer of personal data to HSE as necessary for fulfilment of HSE's regulatory functions.

    vi. Responding to Data Subject Access Requests (SARs) when required.

vii. Reporting any Personal Data breaches within Defra to their Data Protection Officer, who will determine in conjunction with the relevant Defra Data Protection Team whether the breach needs to be notified to the Information Commissioner's Office (ICO) and the data subjects.

viii. Maintaining any processing records for data held on Defra systems in compliance with Article 30 of the GDPR.

ix. If data held is found to be no longer accurate or up to date, they should notify the other party so that they can amend or erase it, as appropriate.

Specific HSE responsibilities

7. HSE has the following specific responsibilities:

i. Carrying out any required Data Protection Impact Assessment for any element of business or process change.

ii. Following HSE Data Security Guidance to ensure that the necessary measures are taken to protect personal data.

iii. Ensuring HSE staff are appropriately trained in how to use and look after personal data and follow approved processes for data handling.

iv. Ensuring HSE staff have appropriate security clearance to handle personal data collected as part of this process.

v. Ensuring secure transfer of personal data to Defra as necessary for fulfilment of Defra's regulatory functions.

vi. Responding to SARs when and where required in relation to personal data being processed as part of the regulatory function.

vii. Reporting any Personal Data breaches within HSE to their Data Protection Officer, who will determine in conjunction with the HSE Data Protection Team whether the breach needs to be notified to the ICO's Office and the data subjects.

viii. Maintaining any processing records for data held on HSE systems in compliance with Article 30 of the GDPR.

ix. Ensuring HSE staff taking enforcement measures adhere to standards set out under *Investigations for law enforcement purposes* in HSE's *Privacy Policy Statement*.

x. If data held is found to be no longer accurate or up to date, they should notify the other party so that they can amend or erase it, as appropriate.

Individual rights

8. The GDPR specifies rights for individuals over the processing of their data. These rights, and the processes individuals should follow when wishing to exercise their rights, are listed in both Defra's and HSE's privacy notice. Both parties should ensure they consult and comply fully with their respective privacy policies in the event of Data Subjects exercising any of their rights under data protection legislation. Both parties will handle and respond to a Data Subject's request in relation to the exercising of her/his rights under the GDPR, even if the s/he has

not followed the processes set out in the relevant privacy notice in making such a request, in accordance with the data protection legislation.

9. In response to any SAR, the controller that receives the request will undertake a proportionate and reasonable search of data it holds and respond to the SAR applicant within one month of receiving the original request, or within any extended time period as permitted by Article 12(3) of the GDPR. Each controller shall follow its own internal processes for handling SARs.

Personal data breach

10. Defra is responsible for reporting any personal data breach, as defined in Article 4(12) of the GDPR, occurring within their authority to their Data Protection Officer, who will determine in conjunction with the relevant Defra Data Protection Team, whether the breach needs to be reported to the ICO DPO. Defra will also inform HSE of the breach if there is any direct impact on HSE staff or other HSE interest.

11. HSE is responsible for reporting any personal data breach, as defined in Article 4(12) of the GDPR, occurring within their authority to their Data Protection Officer, who will determine in conjunction with the HSE Data Protection Team, whether the breach needs to be reported to the ICO DPO, HSE will also inform Defra of the breach if there is any direct impact on Defra staff or other Defra interest.

Liability for data processing

12. Should one party receive court action, relating to data processed under the Agreement, they are to inform the other party.

13. Should one party become subject to investigation by the ICO and/or receive any notice from them, under Part 6 of the Data Protection Act 2018 relating to data processed under this arrangement, they are to inform the other party.

14. If financial penalties are imposed by the ICO on a party in relation to any data processed under this Agreement and, if in the view of the ICO, one party is responsible for the breach of data protection legislation that resulted in the imposition of those penalties, that party shall be responsible for the payment of the penalties imposed. Where the ICO expresses the view that both parties were responsible then each party will bear such responsibility for any penalty imposed as is expressed by the ICO. If the ICO expresses no view as to responsibility, then each party shall bear responsibility for half of the penalty imposed.

15. If either HSE or Defra is the defendant in a legal claim before a court of competent jurisdiction by a third party, including a data subject in respect of data processed under this Agreement, the party determined by the final decision of the court to be responsible for the damage and/or distress shall be liable for the losses arising from such damage. Where both parties are liable, the liability will be apportioned between the parties in accordance with the decision of the court. If the court does not apportion liability between the parties then each party shall bear responsibility for half of the penalty imposed, unless it can prove that it is not in any way responsible for the event giving rise to the damage.

16. If either HSE or Defra receive from any person a claim for compensation for damage and/or distress, pursuant to Article 82 of the GDPR, in respect of data processed under this Agreement, the party which receives the claim will handle it according to their internal procedures. The party to this Agreement that receives

a such a claim will notify the other party to this Agreement of the claim if the other party is solely or jointly responsible for the event giving rise to the claim. If HSE and Defra are jointly responsible for the event giving rise to the claim, each shall bear responsibility for payment of such compensation to the claimant as it determines as being reasonable, subject to its being accepted by the claimant. The amount of compensation offered and paid by each party to the claimant might be different, depending on the circumstances of each case and the and the level of responsibility of each party for the event giving rise to the claim.

17. The provisions in paragraphs 15 and 16 do not prevent the parties coming to a mutual agreement as to the apportionment of financial responsibility for any losses, cost claims or expenses arising from the processing of data under this Agreement.

Data retention

18. Defra and HSE will retain personal data associated with inspections of LGMOs in contained use, or GM medical or veterinary trials in accordance with their respective organisational disposal and retention policies. Each party is responsible for ensuring appropriate technical and procedural functions are in place to ensure the secure and timely destruction of personal data.

The Freedom of Information Act 2000 and Environmental Information Regulations 2004

19. HSE and Defra are subject to the requirements of the Freedom of Information Act 2000 (FOIA) and the Environmental Information Regulations 2004 (EIRs) and shall assist and cooperate with each other to enable each party to comply with their obligations under this legislation. It is accepted that the party that receives an FOIA or EIRs request is responsible for making the final decision on disclosure in respect of any information in scope of a request that they hold. However, that party will consult the other party to this Agreement as outlined in paragraphs 20 and 21.

20. If a party receives a request for information that has been supplied by the other party ("the Information Supplier"), the party that has received the request for information will consult the Information Supplier as early as possible and before any information is disclosed in response to the request to enable sufficient time for the views of the Information Supplier, including any objections to disclosure, to be taken into account when determining whether the information is to be disclosed or withheld.

21. If a party receives a request for information that it holds and knows or believes the information is held by the other party, the party that received the request will inform the other party as early as possible and before any information is disclosed in response to the request. The purpose of this consultation is to ensure that each party is able to share with the other party any concerns about information that might be disclosed to the requester, that the party holding the information is able to take those concerns fully into account in its decision-making, and that the parties can co-ordinate their handling of requests for the same information.

Voluntary disclosures or publication of information

22. If a party decides to voluntarily disclose or publish information received from another party, it must obtain the written approval of the Information Supplier before disclosure occurs.

Data Protection Officers' Contacts

The contact details of the Joint Controller Data Protection Officers are:

Defra	HSE
Tim Beale Data Protection Officer Department for Environment, Food and Rural Affairs (Defra) Area 1E, Nobel House London SW1P 3JR Email: data.protection@defra.gov.uk	Sean Egan Data Protection Officer Health and Safety Executive 1.3 Redgrave Court Merton Road, Bootle Liverpool L20 7HS Email: DPO@hse.gov.uk

Schedule 1

Details of data sharing for LGMOs and Deliberate Release of GMOs in medical and veterinary trials

1.1 The contact details of the Department Data Protection Officer are:

HSE: Sean Egan (DPO@hse.gov.uk)

Defra: Tim Beale (data.protection@defra.gov.uk)

1.2 Details

Subject matter of the data sharing	*The processing is needed in order to support delivery of inspections of facilities working with larger genetically modified organisms (LGMOs) in contained use, and GM medical and veterinary trials. Defra grants consent for the deliberate release of GMOs in medical and veterinary trials.* *HSE conducts the inspections on behalf of Defra's Secretary of State and supplies advice and information to holders that consent to receive advice and information from HSE. On occasions where there has been a breach of the law, HSE will investigate and carry out enforcement action where necessary.*
Data Minimisation	*Defra collects the personal data as a record of the applicant/establishment as part of the application process for consent to 'release' GMOs in medical and veterinary trials.* *HSE collects personal data so that it can carry out inspections of the premises containing LGMOs on behalf of Defra's Secretary of State.* *The yearly reports to Defra are to inform them of the outcome of the inspections. The LGMO Report is anonymised but the Deliberate Release of GMOs in Medical and Veterinary Trials is not anonymised.*
Shared Personal Data – categories of personal data	*HSE and Defra officials: Names, work addresses and work contact details.* *LGMO notifications: Job role, business name and establishment address.* *Consent holders for Deliberate Release of GMOs in Medical and Veterinary Trials: Name and job role, work contact details and establishment address.*

Shared Personal Data - categories of Data Subject	*HSE officials, Defra officials, Consent holders.*
The purpose for which personal data is collected	*Defra will collect information as part of the application process and hold it for reference.* *HSE collect data from GM Notifications and identify possible sites that contain LGMOs.* *On behalf of Defra's Secretary of State, HSE inspectors will secure compliance with health and safety law at establishments working with LGMOs in contained use and GM medical and veterinary trials. The personal data enables HSE to write to consent holders, serve enforcement notices, vary licence conditions, prosecute etc.*
What is the legal basis/bases which is relied upon to share this data lawfully (in accordance with the GDPR and/or the Data Protection Act 2018) Please also clarify whether any of the Shared Personal Data qualifies as Special Category Data and the exemption the Department is relying on for processing	*Public task: the processing is necessary for HSE to perform a task in the public interest or for your official functions, and the task or function has a clear basis in law.* *HSE performs the public task on behalf of Defra's Secretary of State. An Agency Agreement between HSE and Defra provides the legal basis for HSE inspectors to undertake inspections of premises containing LGMOs in contained use and GM medical and veterinary trials. The MoU provides the detail of how this is achieved.*
Legal basis for the Department's processing of Shared Personal Data	*The legal basis is set out in 'The Genetically Modified Organisms (Contained Use) Regulations 2014', 'The Genetically Modified Organisms (Deliberate Release) Regulations 2002' and 'The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996'.*
Frequency of the data sharing	*Reports by HSE to Defra are shared once a year. Other data is shared on an ad hoc basis/when applications are received.*
Method and format of transferring the data Detail the agreed secure methods of transfer and the frequency	*Defra shares information via Government secure e-mail when applications are received. The reports which are prepared by HSE once a year are sent via a secure Government email system.*
Systems used in processing/limitation on data storage	*HSE processes inspection reports and other information electronically. HSE will retain the information on central record and information management systems (called COIN and CM9). HSE destroys most files when they are 10 years old, however exceptions apply and are specified in the business classification scheme and disposal policy.* *Defra will retain the information on a central record and information management system (called SharePoint).*

Systems used in processing/limitation on data storage *cont…*	*Defra appraises files when they are 7 to 10 years old (or as near as possible afterwards) and will not retain records for more than 20 years.*
Duration of the data sharing	*For as long as the MoU is in operation ie 1st September 2021 to 31st March 2023, unless the extended or renewed in accordance with the terms of the MOU.*
Monitoring and review of the Data Sharing Annex	*The effectiveness of the data sharing arrangement will be reviewed throughout the operation of the MoU as part of service level management, and when the MoU is renewed.*