

# UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

Confidence Building Measure Return for 2015
(covering data for 2014) for the
Convention on the Prohibition of the
Development, Production and Stockpiling of
Bacteriological (Biological) and Toxin Weapons
and their Destruction, 10 April 1972

Submitted to the United Nations on 27 March 2015

# Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
В			
C		$\sqrt{}$	$2010^{\dagger}$
E			
F		$\boxed{ \  \   } \\$	2011*
G			

Date: 27 March 2015

State Party to the Convention: United Kingdom of Great Britain and Northern Ireland

Date of ratification/accession to the Convention: 26 March 1975

National point of contact: Christopher Hayes

**BTWC Desk Officer** 

**Counter Proliferation Department** 

**Foreign and Commonwealth Office** 

<sup>†</sup>covering data for 2009

<sup>\*</sup>covering data for 2010

1. Name(s) of facility<sup>2</sup>

Defence Science and Technology Laboratory (Dstl), Porton Down

Declared in accordance with Form A Part 2(iii)

2. Responsible public or private organization or company

Ministry of Defence

3. Location and postal address

Dstl Porton Down Salisbury Wiltshire SP4 0JQ

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Largely financed by the MOD

5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)

2 BL4 labs, 335m<sup>2</sup> total

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

Research and development into protective measures as defence against the hostile use of micro-organisms and toxins

The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>&</sup>lt;sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)"

<sup>&</sup>lt;sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

1. Name(s) of facility<sup>2</sup>

Public Health England - Colindale

2. Responsible public or private organization or company

Public Health England, an executive agency of the UK Department of Health

3. Location and postal address

PHE Colindale 61 Colindale Avenue London NW9 5EQ

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

The UK Department of Health funds this activity as part of its finance of Public Health England's facility at Colindale, London NW9.

5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)

1 high containment unit (CL4): 30m<sup>2</sup>

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

This laboratory is used to provide diagnostic services for Herpes B; viral haemorrhagic fever infections: Lassa fever, Ebola, Marburg, Congo-Crimean haemorrhagic fever; avian influenza and SARS. To support diagnostic services a programme of applied diagnostic research and development is conducted.

<sup>&</sup>lt;sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>&</sup>lt;sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)"

<sup>&</sup>lt;sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

1. Name(s) of facility<sup>2</sup>

Public Health England – Porton

2. Responsible public or private organization or company

Public Health England, an executive agency of the UK Department of Health

3. Location and postal address

Public Health England Porton Down Salisbury Wiltshire SP4 0JG

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

The UK Department of Health funds this activity as part of its finance of Public Health England's facility at Porton Down.

5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)

2 high containment units (CL4): 59m<sup>2</sup> and 46m<sup>2</sup>

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

This laboratory is used to provide diagnostic services for Herpes B; diagnosis and research into various containment level 4 viruses including Lassa, Ebola, Marburg and other haemorrhagic fever viruses.

<sup>&</sup>lt;sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>&</sup>lt;sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)"

<sup>&</sup>lt;sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

# 1. Name(s) of facility<sup>2</sup>

National Institute for Biological Standards and Control

# 2. Responsible public or private organization or company

The Medicines and Healthcare Products Regulatory Agency, a Non-Departmental Public Body of the UK Department of Health

### 3. Location and postal address

Blanche Lane South Mimms Potters Bar Hertfordshire EN6 3OG

# 4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

UK Government (Health and Home Office)

University of Wisconsin, US (Bill and Melinda Gates Foundation)

BARDA (Biomedical Advanced Research and Development Authority, US)

University of Lausanne (Switzerland)

EU Seventh Framework programme collaborative project, FP7 ANTIBOTABE 28012010 SEC 2009.4.3.1. (Neutralization of CBRN effects following a terrorist event)

National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) – UK

# 5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)

Two containment level 4 units, each of 59 m<sup>2</sup>

# 6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

In general, the activities are related to development of assays and testing of reagents. During 2014 active projects involving the following organisms were undertaken:

<sup>&</sup>lt;sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>&</sup>lt;sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)"

<sup>&</sup>lt;sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

- Highly pathogenic influenza virus reagent development, protection studies.
- Bacillus anthracis vaccine testing, reagent development, development of in vitro assays to detect anthrax toxin neutralising antibodies.
- Botulinum toxins (serotypes A-G) control, standardisation and assay development for toxins and anti-toxins. Evaluation of new generation of humanized recombinant antibodies against botulinum toxins.

1. Name(s) of facility<sup>2</sup>

NIMR Containment 4 Building C

2. Responsible public or private organization or company

National Institute for Medical Research

3. Location and postal address

The Ridgeway Mill Hill London NW7 1AA

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Medical Research Council

5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)

One BSL4 containment unit of 298 m<sup>2</sup>

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

Research and diagnostics on highly pathogenic avian influenza virus

<sup>&</sup>lt;sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>&</sup>lt;sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)"

<sup>&</sup>lt;sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

1. Name(s) of facility<sup>2</sup>

The Pirbright Institute

2. Responsible public or private organization or company

Biotechnology and Biological Sciences Research Council (BBSRC)

3. Location and postal address

The Pirbright Institute Pirbright Woking Surrey GU24 0NF

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

BBSRC, EU, Department for Environment, Food and Rural Affairs (Defra)

5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)

No ACDP\* Level 4 containment 282 m<sup>2</sup> ACDP Level 3 containment 3024m<sup>2</sup> of SAPO<sup>†</sup> Level 4, ACDP 2 laboratory excluding plant 4327m<sup>2</sup> of SAPO4 ACDP2 animal accommodation including plant

\*Advisory Committee on Dangerous Pathogens

<sup>†</sup>Specified Animal Pathogens Order

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

Diagnosis and surveillance of exotic animal diseases and research into control measures for those diseases: Foot and mouth disease, bluetongue, swine vesicular disease, African Horse Sickness, Capripox, African swine fever, Peste des Petits Ruminants, Rinderpest and Chickungunya.

<sup>&</sup>lt;sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>&</sup>lt;sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

<sup>&</sup>lt;sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

1. Name(s) of facility<sup>2</sup>

Animal and Plant Health Agency (APHA)

2. Responsible public or private organization or company

Department for Environment, Food and Rural Affairs (Defra)

3. Location and postal address

Woodham Lane Addlestone Surrey KT15 3NB

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Most funding is through Defra.

5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)

SAPO\* Level 4 (Defra):

 $2 \text{ x Avian Influenza laboratories } 1 = \text{each } 100 \text{ m}^2$ 

 $1 \text{ x Newcastle Disease Virus laboratory} = 100 \text{ m}^2$ 

1 x Rabies virus laboratory =  $100 \text{ m}^2$ 

1 suite of Serology laboratories capable of increasing to SAPO level 4, but which usually runs at  $ACDP^{\dagger}$  level  $2=200~m^2$ 

1 x Animal facility consisting of 14 individual rooms divided into 2 suites mainly used for Avian Influenza and Newcastle Disease statutory diagnosis testing and research =  $800\text{m}^2$ 

\* Specified Animal Pathogens Order

<sup>†</sup> Advisory Committee on Dangerous Pathogens

The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>&</sup>lt;sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)"

<sup>&</sup>lt;sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

# 6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

Diagnosis, statutory testing and applied research on the epidemiology and pathology of the disease of farmed, domesticated livestock (cattle, sheep, pigs and poultry) and wild animal reservoirs. Bacteria and viruses in ACDP hazard groups 1-4, GM class 1-4 and SAPO groups 2-4.

1. Name(s) of facility<sup>2</sup>

Merial Animal Health, Biological Laboratory

2. Responsible public or private organization or company

Private company: Merial Animal Health, a SANOFI company

3. Location and postal address

Ash Road Pirbright Surrey GU24 0NQ

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Private finance

- 5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)
  - 5 SAPO\* Level 4 containment units (manufacturing laboratories and QC testing laboratories for the production of foot and mouth disease and bluetongue disease vaccines)
- 6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

Production of inactivated foot and mouth disease antigen and vaccines, and bluetongue disease antigen

\* Specified Animal Pathogens Order

<sup>&</sup>lt;sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>&</sup>lt;sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2

<sup>&</sup>lt;sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

# **Not Applicable**

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents<sup>1</sup> on a State Party's territory:

Biosafety level 3 <sup>2</sup>	yes / no
Biosafety level 2 <sup>3</sup> (if applicable)	yes / no

Any additional relevant information as appropriate:	

<sup>&</sup>lt;sup>1</sup> Microorganisms pathogenic to humans and/or animals

In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

### National Biological Defence Research and Development Programmes Declaration

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

Yes

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme.

Two Forms A, Part 2 (ii) are provided detailing programmes funded by the Ministry of Defence at (a) and the Home Office at (b).

#### (a) National biological defence research and development programmes

# **Description**

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The objectives of the UK MOD biological defence research and development programme reflect the National Security Strategy (NSS), Strategic Defence and Security Review (SDSR), the National Security through Technology White Paper and the Chemical, Biological, Radiological and Nuclear (CBRN) Protection Capability Management Plan (CMP).

The Vision of Defence Capability in this area has been defined as the delivery of cross Defence Lines of Development (DLoD) military capability to minimise the impact to operations of the CBRN threat, by managing risk and utilising a coherent basket of CBRN capabilities tailored to suit the context. The keys to success are the economies of resource and synergies that can be exploiting true cross DLoD capability development and Through Life Capability Management (TLCM). This will enable creative and innovative solutions to be delivered to mitigate clearly defined problems.

#### Hazard Assessment

CBRN Hazard Assessment maintains the ability to provide an effective assessment of the current and developing CBRN hazard and is thus the bedrock on which sound CBRN defence is built. It requires the evaluation of the range of potential biological and toxin agents that might be utilised by a potential aggressor. The information generated helps define defence strategy, concepts and doctrine, as well as identifying the required performance of protective equipment. Therefore Hazard Assessment is an essential enabler to the CBRN capability.

The studies undertaken necessarily involve activities such as consideration of the agents' potency and dissemination characteristics, their aerobiology and the way in which they might be utilised by an aggressor in military and terrorist scenarios. This includes the potential impacts of genomics and proteomics. This work is essential to determine the challenge levels against which detectors, protective equipment and countermeasures must be effective. Current work includes studying the inhalation toxicity of a range of materials and the aerosol survival of pathogenic bacteria and viruses.

# **Detection and diagnostics**

The ability to detect the presence or release of biological and toxin warfare (BTW) agents across the battlespace is crucial in providing timely warning to military personnel to allow them to adopt the appropriate protective posture and avoid casualties. Work programmes have focussed on technologies for improved sample collection, non-specific detection (to detect particulate material), generic detection (to distinguish between biological and non-

biological materials) and specific identification (to identify the material). The objective is to develop point detection systems that are man portable and impose less logistic burden than current systems.

Technologies for the specific identification of BTW currently rely on the use of Biological Recognition Elements, such as antibodies and gene probes. The research programme has continued to develop specific antibodies - recombinant, monoclonal and polyclonal – to extend the range of potential BTW agents that can be identified. Testing is conducted in the laboratory by assessing the binding of the BTW agent to the generally immobilised antibody, monitored either through a linked colour change (e.g. Dipsticks) or electronically (biosensors).

Gene probe-based technology offers highly sensitive and specific assays for the identification of BTW agents like bacteria and viruses. Work is continuing in order to accelerate and simplify the methodology thus rendering it suitable for military use. Rapid PCR systems have been developed so that this technology can be used in field situations. In addition, similar technologies are also being investigated for use in medical diagnostic systems.

The research programme has continued to assess whether biological mass spectrometry technology could offer unambiguous detection and identification of BTW agents with a significant reduction in whole life costs.

### Protection

The dissemination of BTW agents by an aggressor is likely to result in the production of particulate aerosols. Effective individual and collective protection (COLPRO) requires the prevention of the inhalation of this particulate challenge or its contact with the skin of personnel. Individual Protective Equipment (IPE) consists of a respirator and suit while collective protection systems provide isolation from a BW agent challenge in the form of whole buildings, rooms, ships or vehicles.

Current research focuses on providing IPE with effective levels of protection but with significantly reduced physiological loading compared with in-service equipment. This involves the development of new materials, integrating the materials into protective suit ensembles, and assessing the performance of the ensembles using non-pathogenic microorganisms.

COLPRO research aims to design systems that provide the required levels of protection but pose a lower logistical burden on the user. This includes assessing the potential of Commercial off the Shelf (COTS) systems to meet the requirements of UK Armed Forces, including rapid strike, lightweight and low power requirements as well as incorporating protection into general purpose tentage.

### **Medical Countermeasures**

The Medical Countermeasures (MedCM) programme seeks to determine the efficacy of vaccines, antibiotics, antivirals and antitoxins for the prevention of disease caused by BW agents.

The current suite of in-service MedCM offers a capability which does not protect against all BW agents. In some cases, no licensed MedCM are available and in others the in-service provision provides protection against lethality but not incapacitation. Opportunities for using COTS MedCM are extremely limited. Where no COTS solutions exist, and there is a

realistic prospect of identifying feasible candidate MedCM, additional research has been performed to establish 'proof-of-principle' for potential interventions. Before COTS products or other medical interventions can be recommended, evidence base for their use in the treatment of personnel exposed to CBR agents has been assessed.

Programmes have continued to devise vaccines against tularemia (caused by Francisella tularensis) and melioidosis/glanders (caused by Burkholderia pseudomallei/mallei). In the case of Francisella tularensis a programme is continuing to assess Lipopolysaccharide subunit vaccines in collaboration with academia and industry. For Burkholderia pseudomallei/mallei the focus is to devise a sub-unit vaccine. Polysaccharides and proteins are currently being evaluated to test the optimal combination. A similar sub-unit vaccine approach is being employed for the development of vaccine candidates for Q-fever (caused by Coxiella burnetii). These vaccines will be tested using inhalation challenge models of disease.

Assessment of candidate anti-toxins against ricin, botulinum and SEB has continued, assessing efficacy, safety and acceptability.

The programme to explore the development of broad-spectrum BW countermeasures has continued, including therapies against *Brucella*, VEEV and Filoviruses. It has three broad elements: to investigate the up-regulation of the innate immune system, for example through immunomodulator stimulation; to determine whether there are cross-protective antigens or common mechanisms of virulence shared by different BW agents; and, to identify broad spectrum antimicrobials. Antibiotics and anti-virals which are newly emerging from industry are being tested to investigate whether they are effective against a wide range of candidate BW agents.

Projects to identify how animal models of disease can be replaced with in vitro assays, cell or organ culture systems are continuing.

### Hazard Management

The ability to decontaminate personnel, materiel and infrastructure once an aggressor has dispersed BTW agents is a key element to hazard management and restoring operational tempo. Research aims to develop low logistic burden approaches for decontamination of BTW agents based on liquid formulations, strippable coatings, and reactive gases. Validated test methodologies for determining the efficacy of these decontamination processes are also being developed in parallel.

### Arms Control

Dstl staff at Porton Down provide technical advice on CBW non-proliferation to the Ministry of Defence and the Foreign and Commonwealth Office as well as to other Government Departments involved in formulating and implementing UK policy on non-proliferation matters. Over the years, this has included working towards and participating in: the Review Conferences of the BTWC; the Ad Hoc Group of Governmental experts tasked with identifying and examining potential verification measures; the Special Conference of States Parties held in September 1994; the BTWC Ad Hoc Group; and, the annual Meetings of Experts and of States Parties during the intersessional programmes of work following the Fifth, Sixth and Seventh Review Conferences.

Dstl staff assist in collating data for the UK Confidence Building Measures returns and provide technical advice towards the formulation and execution of policy on export control legislation, covering items related to biological weapons proliferation in foreign countries.

Dstl staff also assist the Department of Energy and Climate Change (DECC) in its role as the UK National Authority for the Chemical Weapons Convention, providing technical support over declarations, licensing, and inspections. Dstl operates the UK's Single Small Scale Facility at Porton Down, which has been declared under the CWC.

Dstl staff are also involved in supporting the UK Biological Engagement Programme, part of the UK contribution to the Global Partnership, which seeks to promote safe, secure and responsible application of dual use biological science internationally.

# 2. State the total funding for each programme and its source.

The UK national biological defence research and development programme is concerned with the provision of effective measures for the UK and its Armed Forces against the threat that biological weapons may be used against them. The total UK expenditure on research and development on biological defence for the protection of the UK and its armed forces against micro-organisms and toxins in the fiscal year, April 1<sup>st</sup> 2014 - March 31<sup>st</sup> 2015 is forecast to be £50.0M. This includes £18.0M for work as project support to the procurement of armed forces biological defence equipment.

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes

# 4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

During the fiscal year April 1st 2014 to March 31st 2015, a total of 87 extramural contracts were placed. Of these 21 extramural contracts on research and development aspects relating to biological defence were in place with universities and other academic institutions, and 66 extramural contracts with other bodies, which are either government funded or industrial companies. Funding for these extramural contracts during the fiscal year totalled approximately £7.4M. This represents 14.8% of the total UK expenditure in the fiscal year on research and development on biological defence. The duration of individual contracts varies from a few months to three or four years, and in a few cases they include periods of work at Dstl. The precise institutions and companies are constantly varying as they are selected according to the needs of the defence programme and the availability of the necessary specialist skills.

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

Contracts are let on specific research topics in support of the main research programme carried out at Dstl.

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).

Policy for biological and chemical defence is determined by the Ministry of Defence with the Director of Chemical, Biological, Radiological and Nuclear Policy (CBRN Pol) as the focus. The Arms Control and Counter-Proliferation Policy (ACP) Division determines MOD policy on CB arms control. The goals and individual objectives of the research programme are determined by the Ministry of Defence (MOD), with the Dstl Programmes Directorate

(CBR Programme) being responsible for managing the planning, contracting and delivery of the research programme. Joint Forces Command (JFC) Capability SP Head is responsible for the development of CBRN Defence capability and is the customer focus for the output from the research programme. Acquisition of tri-service CBRN protective equipment is carried out by the CBRN Integrated Project Team (CBRN IPT) and the Medical and General Supplies IPT is responsible for the acquisition of CBRN medical countermeasures. Research at Dstl, Porton Down is undertaken in response to the requirements of these customers within MOD, and Dstl provides technical and policy advice as appropriate.

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

The only UK facility which has a substantial proportion of its resources devoted to the national biological defence research and development programme is Dstl, Porton Down, for which a declaration is made on Form A Part 2 (iii).

# (b) National biological defence research and development programmes

#### **Description**

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The Home Office (HO) co-ordinates the CONTEST programme. The research undertaken under this programme is aimed at enhancing the UK's capability to minimise the risk of a CBRN terrorist incident.

2. State the total funding for each programme and its source.

£781,134.64 – Direct government funding

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

No

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

Not applicable

- 5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
  - Detection and analysis of biological materials
  - Development and assessment of protective equipment against biological materials
  - Hazard assessment and decontamination of biological agents
  - Developing an understanding of the impact and spread of biological materials
- 6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).

Contractors report through controlling Government departments to the HO-led CBRN Oversight Board.

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

The only facility that falls into this category is Dstl, Porton Down, for which a declaration is made on Form A Part 2 (iii).

### National biological defence research and development programmes

# **Facilities**

# 1. What is the name of the facility?

Defence Science and Technology Laboratory, Porton Down

# 2. Where is it located (include both address and geographical location)?

Dstl Porton Down Salisbury Wiltshire SP4 0JQ

The geographical location is shown in the attached map (Figure 2). G13 Access Road, centre of south boundary, Latitude  $50^{\circ}$  07-N, Longitude  $01^{\circ}$  40-W.

### 3. Floor area of laboratory areas by containment level:

$BL2\ 1600m^2$ )	
)	Biological defence research and development
BL3 $1050 \text{ m}^2$ )	element
)	
BL4 335 m2 )	

### 4. The organizational structure of each facility.

The organisational structure of Dstl is shown in Figure 1. The facility provides research for all aspects of defence, including CBRN. The total number of Dstl staff at Porton Down on 27 February 2015 was 1780 (1695 permanent and 85 temporary) and 15 military. The permanent staff fall into the following categories:

Administration	114
Engineers	105
Managerial	230
Professional	275
Scientific	665
Technical	306
TOTAL	1695
Military personnel	15

For the biological defence research and development element, the numbers are as follows:

# (i) Total number of personnel

### (ii) Division of personnel

Military

Civilian	139
(134 permanent and 5 temporary)	

3

## (iii) Division of civilian personnel (permanent) by category:

Administration	1
Engineers	0
Managerial	16
Professional	11
Scientific	102
Technical	4
TOTAL	134

### (iv) List the scientific disciplines represented in the scientific/engineering staff.

Aerobiology, aerosol physics, mathematics, chemistry, chemical engineering, physics, bacteriology, biology, biophysics, bioinformatics, virology, genetics, immunology, medicine, veterinary science, microbiology, biochemistry, molecular biology, physiology, pharmacology, neuropharmacology, psychology, toxicology, engineering, electronics, ergonomics, hydrodynamics, information science, materials science, operational analysis, operational research, information technology, CB defence science.

# (v) Are contractor staff working in the facility? If so, provide an approximate number.

A small number of contractors work on the programme from time to time. Other contractor staff carry out building and maintenance work and some administrative functions.

# (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Porton Down is one of the sites of the Defence Science and Technology Laboratory (Dstl), which is part of the Ministry of Defence. Some work, approximately 9%, is carried out for other governmental and commercial customers.

### (vii) What are the funding levels for the following programme areas:

Research	£32.0 M		
Development	£18.0 M		

Test and Evaluation This is carried out as required to support research

and development. Not separately funded in UK.

(viii) Briefly describe the publication policy of the facility:

Staff at Dstl are encouraged to publish their work in the scientific literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

Attached as Annex.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms<sup>1</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.

The work of Dstl, Porton Down has been reported under Question 1 of Form A Part 2 (ii). Projects currently underway include:

- a. The assessment of the hazard posed by micro-organisms and toxins when used by an aggressor as BW.
- b. Research into systems to facilitate collection, detection, warning, and identification of BW agents. This work includes the evaluation of collection and detection systems in outdoor studies using microbiological simulants and research into the composition of naturally occurring biological aerosols.
- c. Research to establish the protection afforded by materials and CBRN defence equipment against BW agents. This work includes the evaluation of military equipment both in the laboratory and in outdoor studies using microbiological simulants.
- d. Research into formulations and techniques for decontaminating microbiologically contaminated equipment using suitable simulants.
- e. Rapid identification of micro-organisms and toxins by the use of monoclonal antibodies and gene probes.
- f. Studies on the mechanism of action and treatment of toxins.
- g. Therapies for bacterial and viral infections.
- h. Studies on the mechanisms of pathogenicity of viruses and bacteria and the development of improved vaccines.

<sup>&</sup>lt;sup>1</sup> Including viruses and prions.

## BIOLOGICAL DEFENCE RESEARCH PUBLICATIONS FOR Dstl PORTON DOWN 2014

Ascough S, Ingram RJ, Chu KK, Reynolds CJ, Musson JA, Doganay M, Metan G, Ozkui Y, Baillie L, Sriskandan S, Moore SJ, Gallagher TB, Dyson H, Williamson DE, Robinson JH, Maillere B, Boyton FJ & Attmann DM (2014). Anthrax lethal factor as an immune target in humans and transgenic mice and the impact of HLA polymorphism on CD4+ T cell immunity. *PLoS Pathogens* 10(5):e1004085

Begley DW, Fox D 3<sup>rd</sup>, Jenner D, Juli C, Pierce PG, Abendroth J, Muruthi M, Safford K, Anderson V, Atkins K, Barners SR, Moen SO, Raymond AC, Stacy R, Myler PJ, Staker BL, Harmer NK, Norville IH, Holzgrabe U, Sarkar-Tyson M, Edwards TE & Lorimer DD (2014). A structural biology approach enables the development of antimicrobials targeting bacterial immunophilins. *Antimicrob Agents Chemother* 58(3):1458-1467

Bukreyev AA, Chandran K, Dolnik O, Dye JM, Ebihara H, Leroy EM, Muhlberger E, Netesov SV, Patterson JL, Paweska JT, Saphire EO, Smither SJ, Takada A, Towner JS, Volchkov VE, Warren TK & Kuhn, JH (2014). Discussions and decisions of the 2012-2014 International Committee on Taxonomy of Viruses (ICTV) Filoviridae Study Group, January 2012-June 2013. *Arch Virol* 159(4):821-830

David J, Sayer NM & Sarkar-Tyson M (2014). The use of a three-dimensional cell culture model to investigate host-pathogen interactions of *Francisella tularensis* in human lung epithelial cells. *Microbes & Infection* 16(9):735-745

Ford DC, Ireland PM, Bullifent HL, Saint RJ, McAlister EV, Sarkar-Tyson M & Oyston PCF (2014). Construction of an inducible system for the analysis of essential genes in *Yersinia pestis*. *J Microbiol Methods* 100:1-7

Ford DC, Joshua GWP, Wren BW & Oyston PCF (2014). The importance of the magnesium transporter MgtB for virulence of *Yersinia pseudotuberculosis* and *Yersinia pestis*. *Microbiology* 160:2710-2717

Ireland PM, Marshall L, Norville L & Sarkar-Tyson M (2014). The serine protease inhibitor Ecotin is required for full virulence of *Burkholderia pseudomallei*. *Microb Pathog* 67-68:55-58

Ireland PM, McMahon RM, Marshall LE, Halili M, Furlong E, Tay S, Martin JL & Sarkar-Tyson M (2014). Disarming *Burkholderia pseudomallei*: Structural and functional characterisation of a disulfide oxidoreductase (DsbA) required for virulence *in vivo*. *Antioxid Redox Signal* 20(4):606-617

Kuhn JH, Andersen KG, Bào Y, Bavari S, Becker S, Bennett RS, Bergman NH, Blinkova O, Bradfute S, Brister JR, Bukreyev A, Chandran K, Chepurnov AA, Davey RA, Dietzgen RG, Doggett NA, Dolnik O, Dye JM, Enterlein S, Fenimore PW, Formenty P, Freiberg AN, Garry RF, Garza NL, Gire SK, Gonzalez JP, Griffiths A, Happi CT, Hensley LE, Herbert AS, Hevey MC, Hoenen T, Honko AN, Ignatyev GM, Jahrling PB, Johnson JC, Johnson KM, Kindrachuk J, Klenk HD, Kobinger G, Kochel TJ, Lackemeyer MG, Leroy EM, Lever MS, Mühlberger E, Netesov SV, Olinger GG, Omilabu SA, Palacios G, Panchal RG, Park DJ, Patterson JL, Paweska JT, Peters CJ, Pettitt J, Pitt L, Radoshitzky SR, Ryabchikova EI, Saphire EO, Sabeti PC, Sealfon R, Smither SJ, Sullivan NJ, Swanepoel R, Takada A, Towner JS, van der Groen G, Volchkov VE, Volchkova VA, Wahl-Jensen V, Warren TK, Warfield KL, Weidmann M, Nichol ST, Fackner DF & Shestopalov AM (2014). Filovirus RefSeq Entries: Evaluation and Selection of Filovirus Type Variants, Type Sequences, and Names. *Viruses* 6(9):3663-3682

Kuhn JH, Bào Y, Bavari S, Becker S, Bradfute S, Brauburger K, Rodney Brister J, Bukreyev AA, Caì Y, Chandran K, Davey RA, Dolnik O, Dye JM, Enterlein S, Gonzalez JP, Formenty P, Freiberg AN, Hensley LE, Hoenen T, Honko AN, Ignatyev GM, Jahrling PB, Johnson KM, Klenk HD, Kobinger G, Lackemeyer MG, Leroy EM, Lever MS, Mühlberger E, Netesov SV, Olinger GG, Palacios G, Patterson JL, Paweska JT, Pitt L, Radoshitzky SR, Ryabchikova EI, Saphire EO, Shestopalov AM, Smither SJ, Sullivan NJ, Swanepoel R, Takada A, Towner JS, van der Groen G, Volchkov VE, Volchkova VA, Wahl-Jensen V, Warren TK, Warfield KL, Weidmann M & Nichol ST (2014). Virus nomenclature below the species level: a standardized nomenclature for filovirus strains and variants rescued from cDNA. *Arch Virol* 159(5):1229-1237

Kuhn JH, Lofts LL, Kugelman JR, Smither SJ, Lever MS, van der Groen G, Johnson KM, Radoshitzky SR, Bavari S, Jahrling PB, Towner JS, Nichol ST & Palacios G (2014). Reidentification of Ebola Virus E718 and ME as Ebola Virus/H.sapiens-tc/COD/1976/Yambuku-Ecran. *Genome Announc* 2(6): e01178-14

Gillard JJ, Laws TR, Lythe G & Molina-París C (2014). Modeling early events in *Francisella tularensis* pathogenesis. *Front Cell Infect Microbiol* 4:169

Gutherie HC, Martin KR, Taylor C, Spear AM, Whiting R, Macildowie S, Clasper JC & Watts SA (2014). A pre-clinical evaluation of silver, iodine and Manuka honey based dressings in a model of traumatic extremity wounds contaminated with *Staphylococcus aureus*. *Injury* 45(8):1171-1178

Hamblin KA, Armstrong SJ, Barnes KB, Davies C, Wong JP, Blanchard JD, Harding SV, Simpson AJ & Atkins HS (2014). Liposome-encapsulation of ciprofloxacin improves protection against highly virulent *Francisella tularensis* Schu S4 strain. *Antimicrob Agents Chemother* 58(6):3053-3058

Hamblin KA, Wond JP, Blanchard JD & Atkins HS (2014). The potential of liposome-encapsulated ciprofloxacin as a tularemia therapy. *Front Cell Infect Microbiol* 4:79

Hashim Z, Green M, Chung PH, Suhing K, Protti A, Botnar R, Khanbeigi RA, Thanou M, Dailey LA, Commander NJ, Rowland C, Scott J & Jenner D (2014). Gd-Containing Conjugated Polymer Nanoparticles: Bimodal nanoparticles for Fluorescence and MRI Imaging. *Nanoscale* 6:8376-8386

Male AL, Oyston PCF & Tavassoli A (2014). Self-assembly of *Escherichia coli* phage shock protein A into higher-order, rod like structures. *Advances in Microbiology* 4:353-359

Martinez E, Cantet F, Fava L, Norville I & Bonazzi M (2014). Identification of OmpA, a *Coxiella burnetii* protein involved in host cell invasion, by multi-phenotypic high-content screening. *PLoS Pathogens* 10(3):e1004013

Moule MG, Hemsley CM, Seet Q, Guerra-Assuncao JA, Lim J, Sarkar-Tyson M, Clark TG, Tan PB, Titball RW, Cuccui J & Wren BW (2014). Genome-wide saturation mutagenesis of *Burkholderia pseudomallei* K96243 predicts essential genes and novel targets for antimicrobial development. *MBio* 5(1):e00926

Nelson M & Loveday M (2014). Exploring the innate immunological response of an alternative nonhuman primate model of infectious disease; the common marmoset. *J Immunol Res* 2014:913632

Newstead S, Gates AJ, Hartley MG, Rowland C, Williamson ED & Lukaszewski RA (2014). Control of intracellular *Francisella tularensis* by different cell types and the role of nitric oxide. *J Immunol Res* 2014:694717

Norville IH, Hartley MG, Martinez E, Cantet F, Bonazzi M & Atkins TP (2014). *Galleria mellonella* as an alternative infection model for *Coxiella burnetii*. *Microbiology* 160:1175-1181

Norville IH, Hatch GJ, Bewley KR, Atkinson DJ, Hamblin KA, Blanchard JD, Armstrong SJ, Pitman JK, Rayner E, Hall G, Vipond J & Atkins TP (2014). Efficacy of liposome-encapsulated ciprofloxacin in a murine model of Q fever. *Antimicrob Agents Chemother* 58(9):5510-5518

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Scott AE, Ngugi SA, Laws TR, Corser D, Lonsdale CL, D'Elia RV, Titball RW, Williamson ED, Atkins TP & Prior JP (2014). Protection against Experimental Melioidosis following Immunisation with a Lipopolysaccharide-Protein Conjugate. *J Immunol Res* 2014:392170

Scott AE, Burtnick MN, Stokes MG, Whelan AO, Williamson ED, Atkins TP, Prior JL & Brett PJ (2014). *Burkholderia pseudomallei* capsular polysaccharide conjugates provide protection against acute melioidosis. *Infect Immun* 82(8):3206-13

Smither SJ, Eastaugh LS, Steward JA, Nelson M, Lenk RP & Lever MS (2014). Post-exposure efficacy of Oral T-705(Favipiravir) against inhalational Ebola virus infection in a mouse model. *Antiviral Res* 104:153-155

Thompson IJ, Mann ER, Stokes MG, English NR, Knight SC & Williamson D (2014). Specific activation of dendritic cells enhance clearance of *Bacillus anthracis* following infection. *PLoS One* 9(11):e109720

Tree JA, Flick-Smith H, Elmore MJ, Rowland CA (2014). The impact of 'omic' technologies on assessing the host immune response to biodefence agents. *J Immunol Res* 2014:237043

Williamson D (2014). Approaches to Modelling the Human Immune Response in Transition of Candidates from Research to Development. *J Immunol Res* 2014:395302

Fatoyinbo HO, McDonnell MC, Hughes MP (2014). Dielectrophoretic sample preparation for environmental monitoring of microorganisms: Soil particle removal. *Biomicrofluidics* 8(4):044115

Bishop AH (2014). Germination and persistence of *Bacillus anthracis* and *Bacillus thuringiensis* in soil microcosms. *J Appl Microbiol* 117(5):1274-82

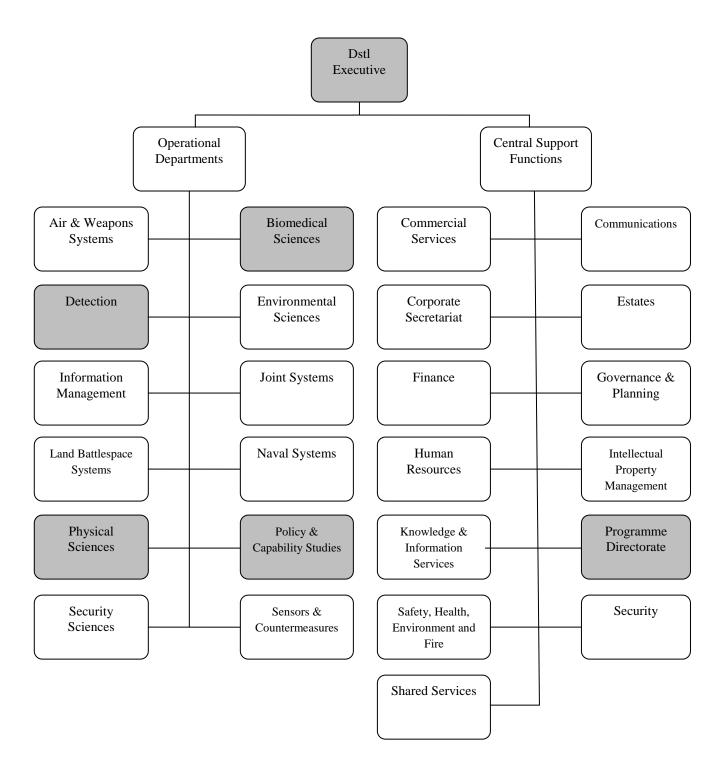
Bishop AH (2014). Expression of prtA from *Photorhabdus luminescens* in *Bacillus thuringiensis* enhances mortality in lepidopteran larvae by sub-cutaneous but not oral infection. *J Invertebr Pathol* 121:85-88

Bishop AH, Robinson CV (2014). *Bacillus thuringiensis* HD-1 Cry-: development of a safe, non-insecticidal simulant for *Bacillus anthracis*. *J Appl Microbiol* 117(3):654-62

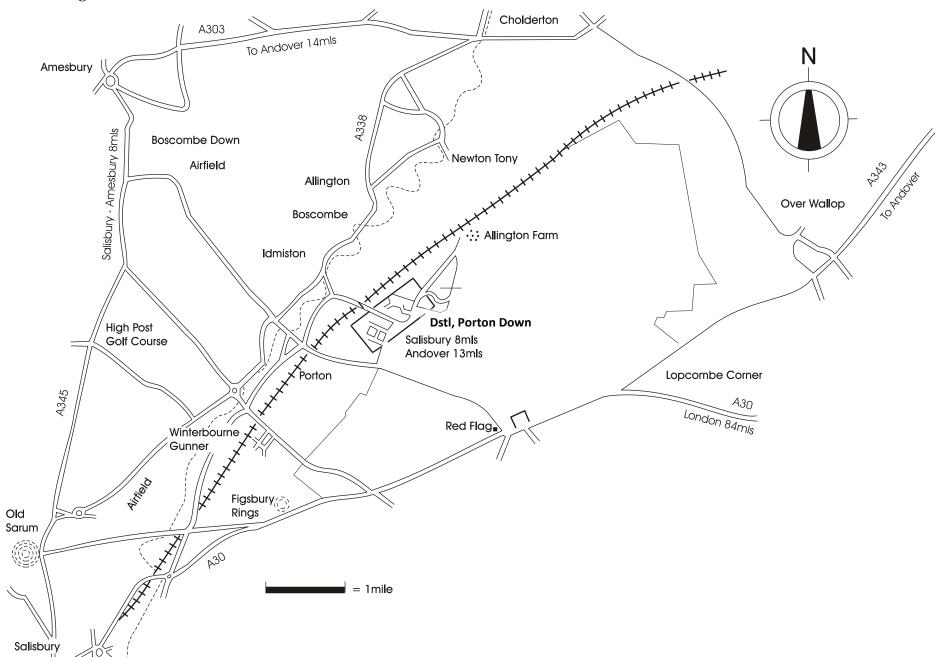
Bishop AH, Rachwal PA (2014). Identification of genes required for soil survival in *Burkholderia thailandensis* by transposon-directed insertion site sequencing. *Curr Microbiol* 68(6):693-701

Bishop AH, Rachwal PA, Vaid A (2014). Identification of genes required by *Bacillus thuringiensis* for survival in soil by transposon-directed insertion site sequencing. *Curr Microbiol* 68(4):477-85

Figure 1: Organisational Structure of Dstl (Departments contributing to the Biological Defence Programme are shown in grey)



**Figure 2: Routes to Dstl Porton Down** 



# Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1.	Time of cognizance of the outbreak	16 November 2014
2.	Location and approximate area affected	Single poultry premises in East Riding of Yorkshire
3.	Type of disease/intoxication	Highly Pathogenic Avian Influenza H5N8
4.	Suspected source of disease/intoxication	Contact with infected wild birds
5.	Possible causative agent(s)	Highly Pathogenic Avian Influenza H5N8
6.	Main characteristics of systems (symptoms)	Mild clinical signs in fattening ducks
7.	Detailed symptoms, when applicable	
_	respiratory	
_	circulatory	
_	neurological/behavioural	
-	intestinal	
-	dermatological	
-	nephrological	
-	other	Egg drop in affected sheds
8.	Deviation(s) from the normal pattern as regards	
-	type	No HPAI outbreaks since 2008
-	development	
-	place of occurrence	
-	time of occurrence	
-	symptoms	
-	virulence pattern	
-	drug resistance pattern	
-	agent(s) difficult to diagnose	
-	presence of unusual vectors	
-	other	New emerging strain of HPAI

(H5N8) not seen in Europe before 2014 9. Approximate number of primary cases 1 10. Approximate number of total cases 1 11. Number of deaths 0 12. Development of the outbreak Suspicion reported on 7 November 2014 and disease confirmed on 14 November 2014 by UK Chief Veterinary Officer 13. Measures taken Culling all birds at the premises, Control measures in line with EU Regulations (restriction zones, surveillance of susceptible species) and cleansing/disinfection of premises

# Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1.	Time of cognizance of the outbreak	24 October 2014
2.	Location and approximate area affected	Single backyard premises in South Wales
3.	Type of disease/intoxication	Contagious Agalactia
4.	Suspected source of disease/intoxication	Contact with infected goats in South West France
5.	Possible causative agent(s)	Mycoplasma agalactiae
6.	Main characteristics of systems (symptoms)	None
7.	Detailed symptoms, when applicable	
	respiratory circulatory neurological/behavioural intestinal dermatological nephrological other	
8. - - - - -	Deviation(s) from the normal pattern as regards type development place of occurrence time of occurrence symptoms virulence pattern drug resistance pattern	No outbreaks since prior to 2005
-	agent(s) difficult to diagnose	Isolation of the pathogenic agent is required to confirm disease
-	presence of unusual vectors other	
9.	Approximate number of primary cases	1

10.	Approximate number of total cases	1
11.	Number of deaths	0
12.	Development of the outbreak	Animals were tested for non-compliance with import certificate
13.	Measures taken	Culling all (4) animals at the premises, and cleansing/disinfection

Background information on UK outbreaks of infectious diseases in humans, animals and plants can be obtained via:

https://www.gov.uk/government/collections/notifications-of-infectious-diseases-noids

http://www.publichealthagency.org/directorate-public-health/health-protection/notifications-infectious-diseases

http://www.hps.scot.nhs.uk/publichealthact/NotifiableInfectiousDiseaseData.aspx

https://www.gov.uk/government/collections/notifiable-diseases-in-animals

http://www.oie.int/wahis\_2/public/wahid.php/Countryinformation/Countryreports

https://secure.fera.defra.gov.uk/phiw/riskRegister/plant-health/whats-new.cfm

https://www.ippc.int/en/countries/united-kingdom/pestreports/

Other infectious disease outbreaks were considered for inclusion in the UK Form B submission, particularly two imported cases of Ebola virus disease (EVD) in healthcare workers who had been deployed to Sierra Leone. It was concluded that they did not meet the criteria for reporting under CBM B since they were associated with a widely recognised natural outbreak, followed a normal pattern associated with symptomatic EVD; and were not unexplained (it could be anticipated that there might be a small number of cases in the UK resulting from the response in West Africa).

### Encouragement of publication of results and promotion of use of knowledge

### Nothing new to declare.

Previous submission (2010, covering data for 2009):

UK policy is that basic research in biosciences, and particularly that related to the Convention, should generally be unclassified and applied research is also unclassified to the extent possible without infringing on national and commercial interests.

It is UK policy to encourage research scientists funded by the Government to publish the results of their work in scientific journals readily available to the scientific community. This applies to the publication of the results of research carried out in the research centres and laboratories subject to exchange of information under Confidence Building Measure A.

Insofar as publication of research on outbreaks of diseases covered by Confidence Building Measure B is concerned again it is UK policy to encourage research scientists funded by the Government to publish the results of their studies.

Examples of relevant scientific journals and other scientific publications include the following:

American Journal of Tropical Medicine and Hygiene

Analyst

Antimicrobial Agents and Chemotherapy

Antiviral Research

Applied and Environmental Microbiology

**Applied Biosafety** 

Archives of Virology

Avian Pathology

**Bioinformatics** 

Biosensors and Bioelectronics

**BMC Genomics** 

**BMC** Infectious Diseases

**BMC** Microbiology

**BMC Proceedings** 

Clinical and Vaccine Immunology

Developmental and Comparative Immunology

**Emerging Infectious Diseases** 

**Epidemiology and Infection** 

Eurosurveillance

**Expert Review of Vaccines** 

FEMS Microbiology Letters

Foodborne Pathogens and Disease

Government Veterinary Journal

Indian Journal of Experimental Biology

Infection and Immunity

Influenza and Other Respiratory Viruses

Institute for Animal Health Biology of Animal Infections Series

International Journal of Antimicrobial Agents

International Journal of Experimental Pathology

International Journal for Parasitology

Journal of Aerosol Science

Journal of Bacteriology

Journal of Comparative Pathology

Journal of Food Protection

Journal of General Virology

Journal of Immunological Methods

Journal of Medical Microbiology

Journal of Molecular and Genetic Medicine

Journal of the Royal Society Interface

Journal of Veterinary Diagnostic Investigation

Journal of Virological Methods

Journal of Virology

Lancet

Letters in Applied Microbiology

Methods in Molecular Biology

Microbial Pathogenesis

Microbiology

Molecular Immunology

Nature

Nature Biotechnology

Outlooks on Pest Management

Parasite Immunology

Parasitology Research

Philosophical Transactions of The Royal Society B-Biological Sciences

PLoS Neglected Tropical Diseases

PLoS One

Proceedings of the National Academy of Sciences

Proteomics

The EMBO Journal

The Veterinary Journal

Transactions of the Royal Society of Tropical Medicine and Hygiene

Transboundary and Emerging Diseases

Trends in Immunology

Trends in Microbiology

Trends in Parasitology

Vaccine

Veterinary Immunology and Immunopathology

Veterinary Microbiology

Veterinary Research

Viral Immunology

Virology

Virology Journal

Virus Research

### Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I		Yes	Yes	No
(b) Exports of micro- organisms and toxins	Yes	Yes	Yes	Yes
(c) Imports of micro- organisms and toxins	Yes	Yes	Yes	Yes
(d) Biosafety and biosecurity	Yes	Yes	Yes	Yes

For further details of relevant legislation, regulations and other measures see the following (those amended since last year are highlighted in italics):

- (a) The Biological Weapons Act 1974:
  - http://www.legislation.gov.uk/ukpga/1974/6/contents

The Anti-Terrorism, Crime and Security Act 2001 (ATCSA):

- http://www.legislation.gov.uk/ukpga/2001/24/contents
- http://www.legislation.gov.uk/uksi/2007/926/contents/made
- http://www.legislation.gov.uk/uksi/2007/929/contents/made
- http://www.legislation.gov.uk/uksi/2012/1466/contents/made

The Academic Technology Approval Scheme (ATAS):

- https://www.gov.uk/academic-technology-approval-scheme
- (b) UK Export Control legislation:
  - https://www.gov.uk/overview-of-export-control-legislation

Latest amendment to the Export Control Order (2008):

• http://www.legislation.gov.uk/uksi/2014/1069/contents/made

### **UK Strategic Export Control Lists**

 https://www.gov.uk/government/publications/uk-strategic-export-control-lists-theconsolidated-list-of-strategic-military-and-dual-use-items-that-require-exportauthorisation

Latest version reflects Commission Delegated Regulation (EU) No 1382/2014 amending Council Regulation (EC) No 428/2009:

- http://eur-lex.europa.eu/legalcontent/EN/TXT/?qid=1420476234258&uri=OJ:JOL\_2014\_371\_R\_0001
- (c) Relevant amendments in 2014 to Plant Health Orders:

# England:

- http://www.legislation.gov.uk/uksi/2014/2385/contents/made
- http://www.legislation.gov.uk/uksi/2014/979/contents/made

#### Wales:

- http://www.legislation.gov.uk/wsi/2014/2368/contents/made
- http://www.legislation.gov.uk/wsi/2014/1463/contents/made
- http://www.legislation.gov.uk/wsi/2014/1186/contents/made
- http://www.legislation.gov.uk/wsi/2014/521/contents/made

#### Scotland:

• http://www.legislation.gov.uk/ssi/2014/140/contents/made

#### Northern Ireland:

• http://www.legislation.gov.uk/nisr/2014/172/contents/made

### England and Scotland (Forestry):

- http://www.legislation.gov.uk/uksi/2014/2420/contents/made
- (d) Health and Safety at Work etc. Act 1974:
  - http://www.legislation.gov.uk/ukpga/1974/37/contents

Health and Safety at Work (Northern Ireland) Order 1978:

• http://www.legislation.gov.uk/nisi/1978/1039

The Control of Substances Hazardous to Health Regulations 2002:

- http://www.legislation.gov.uk/uksi/2002/2677/contents/made
  - The associated Approved List of Biological Agents:
  - http://www.hse.gov.uk/pubns/misc208.pdf

The associated Control of Substances Hazardous to Health Approved Code of Practice and Guidance (L5) was revised and an amended version published:

• http://www.hse.gov.uk/pubns/books/15.htm

The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003:

• http://www.legislation.gov.uk/nisr/2003/34/contents/made

The Genetically Modified Organisms (Contained Use) Regulations 2014:

• http://www.legislation.gov.uk/uksi/2014/1663/contents/made

The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001:

• http://www.legislation.gov.uk/nisr/2001/295/contents/made

The Specified Animal Pathogens Order 2008:

- http://www.legislation.gov.uk/uksi/2008/944/contents/made
- http://www.legislation.gov.uk/uksi/2009/3083/contents/made

The Specified Animal Pathogens (Wales) Order 2008:

- http://www.legislation.gov.uk/wsi/2008/1270/contents/made
- http://www.legislation.gov.uk/wsi/2009/3234/contents/made

The Specified Animal Pathogens (Scotland) Order 2009:

- http://www.legislation.gov.uk/ssi/2009/45/contents/made
- http://www.legislation.gov.uk/ssi/2009/394/contents/made

The Specified Animal Pathogens (Northern Ireland) Order 2008:

- http://www.legislation.gov.uk/nisr/2008/336/contents/made
- http://www.legislation.gov.uk/nisr/2010/24/contents/made

The Anti-Terrorism, Crime and Security Act 2001 (ATCSA):

- http://www.legislation.gov.uk/ukpga/2001/24/contents
- http://www.legislation.gov.uk/uksi/2007/926/contents/made
- http://www.legislation.gov.uk/uksi/2007/929/contents/made
- http://www.legislation.gov.uk/uksi/2012/1466/contents/made

Further information and guidance on biosafety and biosecurity measures in the UK:

• http://www.hse.gov.uk/biosafety/information.htm

Further information on UK domestic controls to prevent the proliferation of nuclear, chemical and biological weapons, and their means of delivery has been submitted under UN Security Council Resolution 1540 requirements and can be found via:

- http://www.un.org/en/sc/1540/national-implementation/national-reports.shtml
- http://www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml
- http://www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml

Form F

# Declaration of past activities in offensive and/or defensive biological research and development programmes

#### Nothing new to declare.

Previous submission (2011, covering data for 2010):

### 1. Date of entry into force of the Convention for the State Party.

26 March 1975

### 2. Past offensive biological research and development programmes:

**Updated Information:** 

The UK provided information on its past offensive programme in 1992. Since that point the CBM F has not been updated. In the past year information has become available, as part of regular reviews of retained files held at The National Archives, which reveals some experimental work on anti-livestock biological warfare, which has not been previously acknowledged in the UK's CBM submissions. The UK is therefore taking this opportunity to update the information provided in its CBM Form F. Our original Form F is being reproduced in this year's return.

The Porton Experiments Sub-Committee was established in September 1940 as a sub-committee of the War Cabinet to investigate the feasibility of the means of biological warfare. Until then there had been no systematic scientific investigation in the UK into offensive and defensive biological warfare. Those engaged in UK efforts worked from the assumption that only by a full examination of the methods of attack would it be possible to develop effective means of defence. Work started at Porton Down within the Chemical Defence Experimental Station (CDES) in November 1940 to assess the feasibility of BW, to define the necessary defensive measures and to acquire the means to retaliate in kind in the event of use of BW against the UK or its allies.

As part of this work in January 1941, the UK noted the possibilities for attacks on livestock using saboteurs and aircraft as the means of delivery of the causative agents. At the then current state of knowledge of human and animal diseases, it was believed that the spreading of the latter appeared to be the more formidable weapon. It was subsequently proposed that preparatory measures for retaliation with animal diseases should be initiated or continued by the Ministry of Agriculture and Fisheries at its Weybridge and Pirbright stations or elsewhere. The diseases under investigation were Foot and Mouth Disease (FMD), Rinderpest, Glanders and Swine Fever.

Experiments were conducted in 1941 and 1942 to test the survival of Swine Fever virus on certain foodstuffs, particularly cakelets, and when sprayed on grass. Similar programmes were undertaken for FMDV and Rinderpest virus. Research was also done to investigate defensive measures against these agents. Work on glanders involved some initial studies on virulence, growth and survival of the causative agent, as well as defensive measures.

<sup>&</sup>lt;sup>1</sup> Pirbright in Surrey was the Ministry of Agricultures and Fisheries' Foot and Mouth Disease Research Station. Weybridge, also in Surrey, was the Ministry's Veterinary Laboratory.

It seems that no further progress was made on developing these agents into practical weapons in the 1940 to 1942 period. Although experimental work with FMDV and Rinderpest virus in cattle cakes was undertaken, no evidence has been found to indicate that there were any stockpiles produced to match the anthrax charged cattle cakes, which were the sole means of providing a BW retaliatory capability during the Second World War.

Original Form F:

### **BIOLOGICAL AND TOXIN WEAPONS CONVENTION: UK CBM FORM F 1993**

Declaration of past activities in offensive and/or defensive biological research and development program

### 1. Date of entry into force of the Convention for the State Party

The UK signed the Biological Weapons Convention in April 1972 and ratified in March 1975. The 1974 Biological Weapons Act implements the Convention's provisions.

### 2. Past offensive biological R&D programs

- Yes

#### - Period(s) of Activities:

The UK had a modest programme to provide a capability to retaliate in kind should UK force be attacked by BW which started in 1940 and ceased in the late 1950s.

- Summary of the R&D activities indicating whether work was performed concerning production, test, and evaluation, weaponisation, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

United Kingdom concern about the possible future menace of the use of biological weapons (BW) began in the 1920s and continued through the 1930s with the establishment in 1936 of a sub-committee of the Committee for Imperial Defence, with a mandate "to report on the practicality of the introduction of bacteriological warfare and to make recommendations on the countermeasures which should be taken to deal with such an eventuality." This led to the establishment in 1940 of the Biology Department, Porton (BDP).

From 1940 to 1946 the UK focus for BW studies was the Biology Department, Porton (BDP) which though located within the then Chemical Defence Experimental Station was a small autonomous organisation (up to about 45 people at its largest) set up to assess the feasibility of BW, to define the necessary defensive measures and to acquire the means to retaliate in kind in the event of use of BW against the UK or its allies. The latter part of this mandate involved carrying out trials using anthrax spores disseminated from bombs on Gruinard Island in 1942 and 1943. The success in demonstrating this method of release of spores was followed by the start of a conjoint United Kingdom, United States and Canadian development of a retaliatory capability based on cluster bombs with anthrax charged munitions, the so called N-bomb project. This project had not come to fruition by the end of the war, and the War Cabinet's requirement for a retaliatory capability in World War II was fulfilled by the development of a modest anti-livestock aircraft-delivered BW capability based on anthrax spores in cattle cakes. A stockpile of 5,000,000 cattle cakes was produced by BDP in 1942-3 and was stored at Porton. This weapon was never employed.

In the immediate post-war period the cattle cake stockpile was destroyed by autoclaving and burning; a few cardboard boxes each holding 400 cakes were retained as curiosities in the culture collection of the then Microbiological Research Establishment (MRE) at Porton until they were destroyed in 1972 at the time of the signature of the Biological Weapons Convention.

Whilst some research on offensive aspects continued for a few years after World War II, by 1957 the UK had abandoned work on an offensive capability. Subsequent work was on biological defence and included assessment of hazards should BW be used against the UK.

- 3. Past defensive biological R&D programmes
- Yes
- Period(s) of Activities:

1940-Present

- Summary of the R&D activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

BW defence was pursued from 1940 by BDP, notably in evaluation of respiratory protection, immunisation, anti-biotic therapy, and decontamination. By 1946 the BDP had become the Microbiological Research Department (MRD). In 1951 the MRD moved to a separate building in from within what had now become the Chemical Defence Experimental Establishment (CDEE). It was still known as MRD until 1957 when it became the Microbiological Research Establishment (MRE), under which title it continued until 1979.

Defensive studies were carried on from 1946 at MRD and then at MRE. The programme involved work on pathogenicity and virulence, aerobiology and experimental inhalation infection, detection and warning of BW aerosols, rapid identification of BW agents and rapid diagnosis of infectious diseases, prophylaxis, toxins, physical protection for individual and collective use, and decontamination. Most of this work was done at Porton but in the period 1948-1955 field trials with pathogens were performed on the high seas off the Bahamas and off the Scottish coast, initially to determine the feasibility of conducting trials at sea and latterly to acquire data on the behaviour of microbial aerosols under realistic conditions. Although such work was begun during the period when offensively motivated R&D was also being pursued, the data acquired was relevant to defence.

In the late 1960s and 1970s the proportion of MRE effort devoted to BW defence was gradually reduced as a result of reductions in defence funding offset by increases in civil research and microbiology. In the late 1970s it was decided that BW defence should be carried out at the then Chemical Defence Establishment (CDE) on a much reduced scale, resulting in defence sector economies and benefits from the wholesale commitment of MRE to public health microbiology. MRE was transferred to the Public Health Laboratory Service of the Department of Health in 1979. It is now the Centre for Applied Microbiology and Research in the Public Health Service. Accordingly, on 1 April 1979, a new Defence Microbiology Division (DMD) was set up within CDE as the focus of UK research on BW defence. The impact of genetic engineering, molecular biology, and biotechnology began to be felt in the early 1980s and has been highlighted in the UK papers submitted to all three Review Conferences of the Convention. These scientific and technological developments brought about a reassessment of the potential hazard posed by living biological and toxin

weapons to the UK Armed Forces, and of continuing progress towards better detection and protection. In the latter areas it was recognised that the emerging biological technologies would make a significant contribution within the integrated research programme of CDE to counter the CBW threat. In April 1991, CDE was renamed the Chemical and Biological Defence Establishment (CBDE) to reflect more accurately the scope of the Establishment's work.

# **Declaration of vaccine production facilities**

### 1. Name(s) of facility

Novartis Vaccines and Diagnostics Limited

# 2. Location (mailing address)

Gaskill Road Speke Liverpool L24 9GR

# 3. General Description of the types of diseases covered

During 2014, only Influenza vaccines were manufactured at this facility: two distinct types for the market, Fluvirin and Agrippal (seasonal influenza strain presentations).

Northern & Southern Hemisphere Influenza vaccine: Cultivation of egg adapted influenza virus. Three strains incorporated within the vaccine (Trivalent), trade name Fluvirin or Agrippal.

Cultivation in eggs of attenuated influenza strains produced by 'Reverse Genetics' and classical reassortant techniques. For seasonal strains, the work was undertaken at containment biosafety level 2.

Attenuated influenza virus strains in reverse genetic form are designated as GMOs and an appropriate manufacturing licence (GM consent) has been granted from the UK Competent Authority. IAPO (Importation of Animal Pathogens Order 1980) does not apply to these strains due to attenuation at the genetic level.

Note: the manufacturing facility at Liverpool, bulk manufactures the influenza vaccine at site 4 with eggs supplied from site 6. The fill finish operations to manufacture individual influenza vaccine doses occurs at a sister facility located at Rosia in Italy.

# **Declaration of vaccine production facilities**

# 1. Name(s) of facility

MedImmune UK Ltd

# 2. Location (mailing address)

Plot 6 Renaissance Way Boulevard Industry Park Speke Liverpool L24 9JW

# 3. General Description of the types of diseases covered

Influenza vaccine

# **Declaration of vaccine production facilities**

# 1. Name(s) of facility

Public Health England – Porton

# 2. Location (mailing address)

Public Health England Porton Down Salisbury Wiltshire SP4 0JG

# 3. General Description of the types of diseases covered

Anthrax vaccine manufacture