Revised forms for the submission of the Confidence-Building Measures

At the Third Review Conference it was agreed that all States Parties present the following declaration, later amended by the Seventh Review Conference:

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		X	2022
A, part 2 (i)		X	2022
A, part 2 (ii)	X		2022
A, part 2 (iii)		X	2022
B		X	2022
C		X	2022
E		X	2022
F	X		2022
G		X	2022

(Please mark the appropriate box(es) for each measure with a tick, and fill in the year of last declaration in the last column where applicable.)

Date: *13th April 2023*

State Party to the Convention: Ireland

Date of ratification/accession to the Convention: ratified 27 October 1972

National point of contact: Ronan McGurrin

Active promotion of contacts

The Third Review Conference agreed that States parties continue to implement the following:

"Active promotion of contacts between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis."

In order to actively promote professional contacts between scientists, joint research projects and other activities aimed at preventing or reducing the occurrence of ambiguities, doubts and suspicions and at improving international cooperation in the field of peaceful bacteriological (biological) activities, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention, and

- on other opportunities for exchange of scientists, joint research or other measures to promote contacts between scientists engaged in biological research directly related to the Convention,

including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

Confidence-Building Measure "A"

Part 1 Exchange of data on research centres and laboratories

Form A, part 1 (i)

Exchange of data on research centres and laboratories[1]

1. Name(s) of facility[2]
Department of Agriculture Food and the Marine Laboratories

2. Responsible public or private organization or company — Department of Agriculture Food and the Marine

3. Location and postal address — Backweston
Celbridge
Co. Kildare.

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

Central Government Expenditure

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

There are $556M^2$ of *CAT3* Laboratories.

$324M^2$ of *CAT3+ (Agriculture)* Laboratories are currently being commissioned for working with viral agents exotic to Ireland that affect domestic animals.

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

The **Department of Agriculture, Food and the Marine (DAFM) Laboratories** are the primary diagnostic facility for agents causing diseases in animals and plants in Ireland. Their *CAT3* laboratory facilities are located at Backweston, Celbridge, Co Kildare. A *CAT3+ (Agriculture)* facility is currently being commissioned.

The DAFM Laboratories act as the National Reference Laboratory for virus diseases such as Avian Influenzas, Newcastle Disease, Rabies, African Horse Sickness, Classical Swine Fever, African Swine Fever, Bluetongue, West Nile Fever, Aujeszky's disease, Equine Infectious Anaemia etc. and for bacterial diseases such as Salmonella, Campylobacter, Verocytotoxic *E.coli*, Bovine Tuberculosis, *M. paratuberculosis*, Bovine Brucellosis, Glanders, Dourine, Listeria, Staphylococci, Campylobacter etc. and Transmissible Spongiform Encephalopathies. The laboratories are also national reference laboratories for all five plant health disciplines (virology, bacteriology, nematology, mycology, entomology) and for honeybee health.

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

[2] 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)".

[3] In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

A diagnostic capability is maintained for a broader range of viruses and bacteria. Many of the protocols are accredited or undergoing accreditation procedures to the ISO 17025 Standard.

DAFM laboratories work with the above agents to provide testing facilities and comply with requirements of the EU Reference Laboratories (EURLs) relating to each particular agent. The EURLs provide regular training to staff in DAFM Laboratories.

Control and destruction of the above mentioned pathogens is carried out by internationally accepted norms.

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[4] on a State Party's territory:

Biosafety level 3[5]	Yes
Biosafety level 2[6] (if applicable)	No

Any additional relevant information as appropriate:

Department of Agriculture Food and the Marine Laboratories

324 M^2 of *CAT3+ (Agriculture)* Laboratories are currently being commissioned for working with viral agents exotic to Ireland that affect domestic animals.

University College Dublin, National Viral Reference Laboratory (NVRL)

University College Dublin, National Viral Reference Laboratory (NVRL), Belfield, Dublin

One high containment Class 3 (+) laboratory has been commissioned at the National Virus Reference Laboratory, University College Dublin (NVRL UCD). The NVRL BL3 + details are viewable on the Web at: https://nvrl.ucd.ie/

Molecular assays have been validated at the NVRL for the detection of a wide range of viral agents whose investigation requires BL3 containment. These include Orthopox, Lassa virus, Ebola, Marburg and emerging novel influenza strains such as Influenza A (H5N1) or Swine lineage Influenza A (H1N1). A testing protocol to investigate suspected smallpox infection utilising electron microscopy is also in place.

At the NVRL there is an ongoing programme to introduce "best practice" molecular methods to investigate the viral agents potentially associated with biological weapons such as the viral haemorrhagic fevers.

[4]Microorganisms pathogenic to humans and/or animals

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

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

Public Health Laboratory (PHL), Health Service Executive (HSE), Dublin

Public Health laboratory, HSE, Dublin at Cherry Orchard, Co. Dublin

PHL HSE Dublin provides National Reference laboratory services for Verocytotoxin *E.coli*, Campylobacter, & *C.difficile*. It has a BSL3 facility and employs routine culture along with molecular methodologies including PCR and genomic analysis. Both environmental (food & water ISO-17025) and clinical specimens (ISO-15189) are processed and detailed genomic characterisation is performed on these bacteria for surveillance and outbreak management. The PHL deals with a variety of public health threats within its public health microbiology scope as they arise, eg surveillance of water from heater cooler units used in thoracic surgery and COVID - SARS CoV2 community testing during this pandemic.

National Salmonella Reference Laboratory (INSL)

National Salmonella Reference Laboratory (INSL), National University of Ireland, Co. Galway

National Reference Laboratory for Salmonella, Shigella, Listeria and Carbapenemase-producing Enterobacteriales. This facility also possesses BCL3 containment laboratories. The INSL collects isolates of salmonella and associated data from all positive human faecal and blood samples, food samples and veterinary isolates in Ireland.

Galway Microbiology Reference Laboratory Services

The Galway Microbiology Reference Laboratory Service is based in Galway University Hospitals. The service provides National Reference Laboratory services for Salmonella, Shigella, Listeria and Carbapenemase-producing Enterobacterales. The laboratory also accepts other antimicrobial-resistant Gram-negative bacteria for characterisation on specific request. This facility possesses BCL3 containment laboratory. This is the only BCL3 facility in the hospital diagnostic laboratory system for the West and North West region. The Reference Laboratory securely stores all isolates received for a period of more than 1 year so that they are available in the event that further characterisation is required.

Irish Marine Institute

Irish Marine Institute, Oranmore, Co. Galway

The Irish Marine Institute has no laboratories that come to BSL 3 or above. There are five regional fisheries laboratories – the EU-designated National Reference laboratory for the monitoring of marine biotoxins (Regulation (EC) No. 882/2004) and co-ordination of the analysis of shellfish samples for the presence of marine biotoxins, as set out in Regulation (EC) No 853/2004.

Health Research Board (HRB) Clinical Research Facility, St James's Hospital Dublin

The Health Research Board has provided grant funding to the Wellcome Trust-HRB Clinical Research Facility at St James' Hospital, Dublin. The Clinical Research Facility has;

- a **CL2 Sample Processing Laboratory**: The Sample Processing Laboratory: 25m^2, opened in October 2013 is used for processing tissue (blood and urine) samples from human participants, and these may include tissues contaminated with infectious agents. Operates to the same standards as other hospital based CL2 laboratories.
- a **Pharmacy room**: The Pharmacy room dispenses oral investigational medicinal products (IMPs) and injectables for Phase I to Phase IV clinical trials. The pharmacy room is temperature mapped and alarmed to ensure all IMPs are stored correctly. They have temperature alarmed fridges and -80C freezers for storage of IMPs.

- **a Research Pharmacy CL2 clean room** within the Wellcome Trust-HRB Clinical Research Facility at St James' Hospital, Dublin. 25m^2, and it is used for compounding cytotoxic therapies and gene therapies that use viral vectors in hazard groups 1 and 2.

They are the only site in Ireland that has the expertise and capacity to deliver highly complicated gene therapy clinical trials. They have the ability to manufacture individually tailored gene therapies or advanced therapeutic preparations for St James's Hospital clinical trial patients. The ATIMP room is equipped with modern isolator technology in a cleanroom environment. The cleanroom operates as a Grade C (European G.M.P.) environment whilst the aseptic filling and preparation are carried out within either negative or positive (Grade A environment) isolators. A comprehensive validation programme for staff and equipment is in place, according to international guidelines. The unit is staffed by qualified and trained pharmacists and technicians and works closely with the main St James's hospital pharmacy. Activities are regulated by HPRA and/or HSE/HIQA.

Research Centres

Health Protection Surveillance Centre (HPSC)

The ***Health Protection Surveillance Centre (HPSC),*** is Ireland's specialist centre for surveillance of communicable diseases. The Director of the *HPSC* together with the Director of National Health Protection in the *Irish Health Service Executive* (HSE) form the National Focal Point for Ireland in respect of the International Health Regulations and are the National Contact Point for The European Commission's Early Warning and Response System for Communicable Diseases.

No known research on biocidal or plant protection active substances or products which could be construed as having a dual purpose was undertaken in Ireland during 2022.

The *HPSC* provides expert assistance as required in the investigation and management of outbreaks or incidents of communicable disease. The *HPSC* was established conjointly by Ireland's eight Health Boards and with the approval of the Minister for Health and Children in 1998. The *HPSC* works in partnership with health service providers and sister organisations in other countries to ensure that up-to-date information is available to contribute to the effective control of infectious diseases. Since July 2000 the *HPSC* is statutorily responsible for the collation, analysis and dissemination of notifiable diseases in Ireland. A report on all notifiable pathogens is produced weekly and sent to key partners. This information is also published on the *HPSC* website and in Epi-insight, the monthly bulletin from the *HPSC.* In addition, a report of all outbreaks of infectious diseases is produced on the *HPSC* website at http://www.hpsc.ie/hpsc/NotifiableDiseases/WeeklyOutbreakReport/

Science Foundation Ireland (SFI)

Science Foundation Ireland (SFI) contributes funding to support research activities in Higher Education Institutions. SFI mandates that all Higher Education Institutions in receipt of SFI funding warrant that any funded Research Programme is conducted in compliance with Irish and/or other applicable laws; and that the Research Programme is conducted in accordance with such ethical guidelines as may be issued by the Foundation, or any relevant industry or

other regulatory body, from time to time, including (without limitation) guidelines relating to the conduct of trials, clinical or otherwise, which involve members of the public or samples taken from them.

A link to the research centres funded by SFI is: http://www.sfi.ie/sfi-research-centres/. None of the SFI Research Centres are presently undertaking research involving "biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention".

National University of Ireland, Maynooth

The ***National University of Ireland, Maynooth*** was granted a Testing Facility Trial Permit to conduct biological control efficacy trials on the large pine weevil (Hylobius abietis) on pine stumps in 3 Coillte clearfell coniferous sites in Co. Galway, Co. Westmeath and Co. Tipperary & in the Biocontrol Laboratory, NUI Maynooth, Co Kildare in 2016. The trials had two nematode species (Heterorhabditis downsei K122) and (Steinernema carpocapsae EN03) and a fungus applied to the soil around the tree stumps as a suspension in water. DAFM inspect trial sites over the trailing season.

Environmental Protection Agency (EPA)

The ***Environmental Protection Agency (EPA)*** is the Competent Authority in Ireland for the implementation of the Genetically Modified Organism (Contained Use) Regulations (2001 to 2010) on the contained use of GMOs. There are 8 registered users of Class 3 GMMs. Two users, although registered are not using Class 3 GMMs and do not have Class 3 GMMs in storage.. These are all research activities none of which either wholly or in part are being conducted under / funded by any national biological defence research and development programmes. These Class 3 activities are subject to containment level 3 measures.

In addition, there are some 172 active Class 2 GMM activities, predominantly research activities, being carried out under containment level 2 measures.

The *EPA* has issued consents for the following Class 3 GMM projects:

- *Class 3 Genetically Modified Micro-organisms (GMMs), Mycobacterium tuberculosis complex organisms - M. bovis and M. tuberculosis; (Veterinary Sciences Centre in University College Dublin)*
- *Chimeric Hepatitis C virus (Institute for Molecular Medicine, Trinity College Centre for Health Sciences, St James Hospital Dublin)*
- *Recombinant Hepatitis C virus, GM variants of the Human Immunodeficiency Virus (HIV), the causative agent of the Acquired Immune Deficiency Syndrome (AIDS). (School of Medicine and Medical Science Centre for Research in Infectious Diseases in University College Dublin; and Trinity Biomedical Sciences Institute in Trinity College, Dublin).*
- *Recombinant Hepatitis B virus (Trinity Biomedical Sciences Institute in Trinity College, Dublin)*
- *Recombinant viruses of the Flaviviridae, Peribunyaviridae and Togaviridae families (Veterinary Sciences Centre, UCD)*

- *Recombinant SARS-CoV-2 Virus (Veterinary Sciences Centre, UCD, and Trinity Biomedical Sciences Institute, TCD)*

Part 2 Exchange of information on national biological defence research and development programmes

Form A, part 2 (i)

National biological defence research and development programmes Declaration

Ireland does not have a national biological defence research and development programme.

There is no research and development programme in Ireland aimed specifically at defence against biological and toxin weapons. There are many small programmes in Ireland aimed at combating infectious diseases in humans, animals and plants and these programmes include research on the mechanisms of pathogenicity, their natural incidence and the possibilities for boosting host defences against them. These programmes are primarily funded by the *Health Research Board (HRB), Science Foundation Ireland (SFI), Enterprise Ireland, Teagasc (the Irish Agriculture and Food Development Authority), the Department of Agriculture, Food and the Marine (DAFM), the Wellcome Trust, the EU* and a range of commercial interests.

The Defence Forces

The *Defence Forces (DF)* undertakes training in protection from bioweapons. All personnel on induction and on career level courses undergo basic CBRN (Chemical, Biological, Radiological and Nuclear) defence training. This includes a basic understanding of the characteristics and effects of biological agents. To counter the threat, personnel are taught drills to enable them to operate for periods in a contaminated environment. A small number of specialists, typically with university qualifications are trained in threat identification techniques.

The *Defence Forces Ordnance School* is responsible for training Explosive Ordnance Disposal (EOD) teams in Chemical, Biological, Radiological and Nuclear EOD (CBRN EOD), excluding atomic weapons. The role of these teams, within ways and means is to inhibit CB Explosive Ordnance and CBR Improvised Explosive Devices or Improvised Dispersal Devices from functioning in a manner that would release hazardous substances into the environment.

The Defence Forces Ordnance Corps operating in Aid to the Civil Power can provide a limited biological detection and mitigation response whereby EOD teams can conduct a number of field detection and identification tests to detect suspicious microbial activity in a substance of concern. The EOD Teams are also capable of detecting a limited range of bacteria and toxins, including Anthrax and Ricin.

The *Defence Forces Engineering Corps* also deploys a range of CBRN Decontamination equipment, configured for Chemical, Biological or Radiological/Nuclear roles and suitable for large-scale decontamination of vehicles, personnel or terrain. Two infantry units of the Army are equipped to deploy decontamination equipment within their respective Areas of Operation.

The *Defence Forces School of Military Engineering* has conducted a CBRN (Chemical, Biological, Radiological and Nuclear) Survive to Function Course for the *International Committee of the Red Cross (ICRC)* annually since 2015. The course is a key building block to a successful and sustainable humanitarian response in CBRN contaminated environments. The DF will continue to build on this initiative and develop the capacity and capability to deliver humanitarian assistance to those affected by CBRN events in the future.

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.

No

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

Form A, part 2 (ii)

N/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.

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

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

Yes/No

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

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

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

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.

Form A, part 2 (iii)

N/A

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?

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

3. Floor area of laboratory areas by containment level:

BL2 _____ (sqM)

BL3 _____ (sqM)

BL4 _____ (sqM)

Total laboratory floor area _____ (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel _____

(ii) Division of personnel:

Military _____

Civilian _____

(iii) Division of personnel by category:

Scientists _____

Engineers _____

Technicians _____

Administrative and support staff _____

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

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

(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?

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

Research _____

Development _____

Test and evaluation _____

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

(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.)

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[7] and/or toxins studied, as well as outdoor studies of biological aerosols.

[7] Including viruses and prions.

Confidence-Building Measure "B"

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern[8]

1.	Time of cognizance of the outbreak	**NIL**
2.	Location and approximate area affected	_____
3.	Type of disease/intoxication	_____
4.	Suspected source of disease/intoxication	_____
5.	Possible causative agent(s)	_____
6.	Main characteristics of systems	_____
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	_____
-	agent(s) difficult to diagnose	_____
-	presence of unusual vectors	_____
-	other	_____
9.	Approximate number of primary cases	_____
10.	Approximate number of total cases	_____
11.	Number of deaths	_____

[8] See paragraph 2 of the chapeau to Confidence-Building Measure B.

12. Development of the outbreak _____
13. Measures taken _____

Ireland has had no unusual outbreaks of infectious diseases or similar occurrence caused by toxins that deviate from the normal occurring in 2021.

The *State Veterinary Services/Department of Agriculture, Food and the Marine* (DAFM) reports animal diseases to the OIE (Office International des Épizooties). Plant diseases are monitored nationally by *Department of Agriculture, Food and the Marine* (DAFM) and are reported to the EU Commission via the EUROPHYT system and to the wider world via the EPPO reporting service.

Under the EU Zoonoses Directive 2003/99/EEC and Regulation 2160/2003, data on zoonoses monitoring activity in food and food animals in Ireland is submitted by *The Department of Agriculture, Food and the Marine (DAFM)* and the *Food Safety Authority of Ireland* to the *European Food Safety Authority (EFSA),* and data on zoonotic disease in humans is submitted by the *HPSC* to *ECDC.* The combined data submitted from across Europe are collated and analysed jointly by *ECDC* and *EFSA* in the production of annual summary reports on zoonoses. Legislation has been updated for control of plant diseases and for animal diseases in line with EU requirements e.g. S.I. 459 of 2020 – European Union (Plant Health) Regulations 2020.

Ireland has concentrated its efforts on raising awareness of possible threats among first responders, clinicians and public health personnel, strengthening surveillance of communicable disease and in expanding laboratory capacity to deal with potential threats, should they appear. The intention is for early identification to minimise human health effects through effective public health controls and early clinical interventions.

Outbreak investigations are performed by public health professionals along with microbiology professionals, environmental health professionals, infection control staff and clinicians, depending on the disease, using laboratory results generated by the aforementioned laboratories in Measure A.

A single national data repository for rapid central electronic reporting of clinical and laboratory information on infectious disease (CIDR) has been established, and is used in all regions of the country.

Responsible Agencies and Bodies

The *Health Protection Surveillance Centre (HPSC)* has a close and productive interaction with the *Centres for Disease Control and Prevention (CDC),* Atlanta, and the *European Centre for Disease Control (ECDC),* Sweden.

The *Health Service Executive (HSE)* carries out surveillance and control of infectious diseases in Ireland. Notification data on infectious diseases and conditions are gathered and collated by the *HPSC.* Throughout Ireland, specified infectious diseases diagnosed by clinicians and pathogens identified in clinical laboratories and outbreaks or suspected outbreaks of infectious disease, are notified to regional *Directors of Public Health.* This information is in turn passed on to the *HPSC* on at least a weekly basis (immediately in the cases of certain serious diseases). Notification data is then published on a weekly basis by the HPSC. Subsets of this data is shared with a number of EU consortia and several other non-EU countries. Information on notifiable infectious disease is shared with the *European Centre for Disease Prevention and Control (ECDC)* in Stockholm. The *HPSC* also provides human health data to the EU Basic Surveillance Network. The main data sets are forwarded to the *WHO* in Geneva, via the Department of Health.

The *Food Safety Authority of Ireland* works with the *HPSC* in the coordination of the investigation of national, cross-border and international outbreaks of human illness where foods are implicated and is the competent authority for rapid food alerts. The *Food Safety Promotion Board* based in Co. Cork is an all-island public health body. Among its key functions is the surveillance of food-borne disease on an all-island basis.

Confidence-Building Measure "C"

Encouragement of publication of results and promotion of use of knowledge

All non-commercial research regarding biological science and infectious diseases is published in national and international journals.

In Ireland, Government policy is to promote transparency and dissemination of knowledge in the biological sciences, especially in the field of human epidemiology. Relevant data regarding epidemiology and zoonoses, as well as being available nationally, are fed into European and *WHO* networks.

Individual Agencies and Bodies

Science Foundation Ireland's (SFI) publication policy mandates that the Research Body and the Principal Investigator shall disseminate, as widely as reasonably practicable and in accordance with the Intellectual Property Guidelines, the products and results of the Research Programme in internationally peer-reviewed publications and the scientific press, and where appropriate, among the general public, except where such dissemination could undermine the Intellectual Property or other rights and entitlements of the Research Body or the Principal Investigator. In addition, SFI supports the principle of open access to publicly funded research, whereby all funded researchers are required to lodge their publications resulting in whole or in part from SFI-funded research in an open access repository as soon as possible after publication.

The Health Research Board (HRB) actively encourages the dissemination of research results that arise from the projects and programmes that it funds. This expectation is clearly stated in the Grant Conditions of the HRB where Clause 13 states:

13 Publication

13.1. In accordance with the HRB Policy on Open Access, as same as may be amended from time to time, and the National Open Research Framework, the Host Institution shall and shall ensure that the Principal Investigator shall: -

13.1.1 Work in co-operation with the HRB to publicise any research studies included in the Grant Funded Activities and the findings of them as part of the wider responsibility to promote the value of health research to the public. This shall, if required by the HRB, include: (a) Up to two agreed days during each successive twelve-month period of the Term when the Principal Investigator or a member of the Team will be available to promote and publicise its work; (b) Participation in communications/media training.

13.1.2 Disseminate any findings, results or products of the Grant Funded Activities in peer review publications through the media and among the general public as far as possible or practicable (unless this would undermine Intellectual Property or other rights/entitlements of the Host Institution, Principal Investigator or the Team).

13.1.3 Subject to any copyright entitlement of third parties, deposit electronic copies of any research papers that have been accepted for publication in a peer-review journal, which are supported in whole or in part by the Grant Funded Activities, in an Open Access repository ideally at the time of acceptance by the journal and no later than the date of formal publication.

13.1.4 Whenever possible, grant licences in respect of research papers such that they can be freely copied and re-used for, amongst other things, text and data-mining purposes, provided that such uses are fully attributed.

In addition, the HRB takes the following measures to encourage dissemination of research results:

- Launched HRB Open Research, an on-line publication platform, in January 2018 (https://hrbopenresearch.org/about) to provide all HRB-funded researchers with a place to rapidly publish. All articles benefit from immediate publication, transparent refereeing and the inclusion of all source data.
- Became a signatory to the DORA Declaration in 2018, to encourage peer review that includes not just high-impact peer reviewed journals but other forms of dissemination such as policy briefs, publication of protocols etc.
- Made registration of clinical trials study protocols mandatory in 2018, and will follow up on this requirement through annual reporting.
- Provides funding through its awards for dissemination activities (journal fees, publication of research briefs, attendance at national and international scientific conferences, public engagement events etc.)
- Gathers information on dissemination activities in both its annual progress reports, in detailed evaluation reports and through periodic bibliometric studies.
- Provides supplemental funding through a scheme, specifically targeted at innovative knowledge exchange and dissemination activities and events (KEDS).
- Requires funding applicants to provide a dissemination plan, as part of their application, and has made the quality of the dissemination plan a criterion for funding at evaluation stage.

Confidence-Building Measure "D"

(Deleted)

Confidence-Building Measure "E"

Declaration of legislation, regulations and other measure

Form E

Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures[9]	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	Yes/No	Yes/No
(b) Exports of micro-organisms[10] and toxins	Yes	Yes	Yes	Yes
(c) Imports of micro-organisms[11] and toxins	Yes	Yes/No	Yes/No	Yes/No
(d) Biosafety[11] and biosecurity[12]	Yes	Yes/No	Yes/No	Yes/No

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There are a number of pieces of national legislation which regulate the use of biological materials in place in Ireland, including the Importation of Pathogenic Agents Order 1997 for pathogens capable of causing disease in any living being (other than human). This Order prohibits the importation of pathogenic agents into the State save under and in accordance with a licence granted by the Minister for Agriculture and Food.

The **Department of Agriculture, Food and the Marine (DAFM)** is responsible for the enactment of legislation relating to zoonoses and for providing the necessary resources to ensure their monitoring and control. Under the powers of the Animal Health and Welfare Act 2013 and Regulations made under the

[9]Including guidelines.
[10]Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
[11]In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.
[12]In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

European Communities Act, veterinary inspectors inspect farms where animals and poultry are kept. As part of its zoonoses control programmes, DAFM carries out surveillance programmes to test for the presence of such pathogens on a wide range of animals and animal products.

In relation to biocidal and plant protection chemicals, there are provisions in the Biocidal Products Regulation 528/2012 (Article 56) and the Plant Protection Products Regulation 1107/2009 (Article 54), given effect in Ireland by SI 427 of 2013 and SI 159 of 2012 respectively, which allow for trial programmes/experiments for research and development purposes on biocides and plant protection products.

DAFM through the Pesticide Controls Division and the Pesticide Registration Division (PCD/PRD) is the Competent Authority for the Plant Protection Products Regulation and the Biocidal Products Regulation, Regulation (EC) 1107/2009 and Regulation (EU) 528/2012 respectively. DAFM is also responsible for the implementation in Ireland of the Sustainable Use of Pesticides Directive, enacted into Irish law by SI 155 of 2012. As the Competent Authority, **DAFM** is responsible for the regulation, implementation and enforcement of all matters concerning the registration, approval and use of plant protection products and biocidal products (including rodenticides, which are regulated as biocidal products).

For biocides, Ireland has a representative member on the Biocidal Products Committee and its Working Groups (Chemistry, Efficacy, Human Health and Environment) at the **European Chemicals Agency (ECHA).** In addition, **DAFM** provided expert assistance in 2018 to the following expert Committees and groups at ECHA: Risk Assessment Committee (RAC) for the harmonised classification and labelling of substances, PBT (Persistent, Bioaccumulative and Toxic substances) Expert Group and ED (Endocrine Disruptor) Expert Group. The Health and Safety Authority also has colleagues that sit on a number of Committees and meetings at ECHA for which they are responsible.

Under REACH (Regulation EC 1907/2006), CLP (Regulation EC 1272/2008) and PIC (Regulation EU 649/2012) Regulations, **DAFM** through PCD/PRD is the Competent Authority in respect of pesticides (i.e. plant protection and biocidal substances and products). The Health and Safety Authority is the primary Competent Authority for the REACH and CLP Regulations and joint Competent Authority under PIC (Prior Informed Consent on dangerous chemicals).

Under the poisons area **DAFM** are an enforcement body but the Department of Health hold responsibility for the regulation and administration of Poisons legislation.

Export Control Regulations

The Department of Enterprise, Trade and Employment (D/ETE) is the national competent authority with responsibility for administering and enforcing EU and national legislation regulating the export of controlled items, including biological agents and toxins, listed in the EU Common Military List and the EU 'Dual-use'[13] Regulation.

Policy in respect of Export Controls for 'Dual-use'-items is an EU competence; however, the administration of the Controls is the exclusive competence of the Member States of the EU. The 'Dual-use' Regulation gives legal effect to the controls of the multi-lateral, non-proliferation regimes, including the Australia Group and the Chemical Weapons Convention. A substantially revised 'Dual-use' Regulation, with a particular focus on strengthened enforcement was adopted by the EU in 2021.

The EU has adopted ten packages of sanctions since 24th February 2022 against Russia in response to Russia's illegal aggression against Ukraine. The trade measures are unprecedented in their breadth and sophistication and include prohibitions on the export of goods and materials relevant to the BTWC.

The relevant legislation is as follows:

National

Controls of Exports Act 2008
S.I. No. 356/2018 - Control of Exports (Brokering Activities, Goods and Technology) Order 2018
S.I. No. 454/2019 - Control of Exports (Dual Use Items) (Amendment) Order 2019
S.I. No. 443/2009 - Control of Exports (Dual Use Items) Order 2009
S.I. No. 126/2023 - European Union (Restrictive Measures Concerning Ukraine) (No.5) Regulations 2023

EU

- Regulation (EU) 2021/821 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items, as amended by Commission Delegated Regulation (EU) 2023/66.

[13] Items which have both civilian and military applications.

- Council Common Position 2008/944/CFSP of 8 December 2008 defining common rules governing control of exports of military technology and equipment, *amended by Council Decision (CFSP) 2019/1560.*
- Directive 2009/43/EC of the European Parliament and of the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community.
- Common Military List of the European Union adopted by the Council on 21 February 2022.
- Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine, as amended 25/02/2023.

Infectious Diseases Regulations

The *Department of Agriculture, Food and the Marine (DAFM)* is responsible for the enactment of legislation relating to zoonoses and for providing the necessary resources to ensure their monitoring and control. Under the powers of the Diseases of Animals Acts (1966-2001) and Regulations made under the European Communities Act, veterinary inspectors inspect farms where animals and poultry are kept. As part of its zoonoses control programmes, DAFM carries out surveillance programmes to test for the presence of such pathogens on a wide range of animals and animal products.

Ireland collects its human infectious diseases data under the 1947 Health Act (as amended), further detailed in the Infectious Disease Regulations 1981. On 1 January 2004, an amendment to the existing Infectious Diseases Regulations established a revised list of notifiable diseases. The changes introduced are consistent with a European Commission Decision on the communicable diseases to be progressively covered by the European Community network (Decision No. 2000/96/EC, under Decision No. 2119/98/EC of the European Parliament and of the Council). The most recent amendment to the Regulations is the Infectious Diseases (Amendment) Regulations 2020 (S.I. No. 53 of 2020). Immediate preliminary notification is required for a sub-set of notifiable diseases.

The key advances of the amended legislation since 2004 include:

- *A greatly expanded list of conditions and diseases*
- *A requirement for laboratory directors to report infectious diseases;*
- *Food- and water-borne illnesses are now specified (e.g. campylobacter infection, cryptosporidiosis, listeriosis), whereas previously there was merely a category of food poisoning (bacterial other than salmonella);*
- *The addition of potential biological threat agents, such as botulism and tularaemia;*
- *Hepatitis C is now specified;*
- *Several pathogens that are important in the monitoring of antimicrobial resistance became notifiable;*
- *The use of case definitions for infectious diseases has been introduced, a set of which has been drawn up, in line with standardised European case definitions; and*

- *Under the amended regulations, unusual clusters or changing patterns of illness (including outbreaks) that may be of public concern must also be reported. This was an important development, particularly in the context of any deliberate release of biological agents.*

Furthermore, under the new legislation there are a number of diseases which require immediate preliminary notification by telephone, e.g. poliomyelitis, typhus, botulism, cholera, legionellosis, smallpox, paratyphoid, typhus, viral haemorrhagic fevers, SARS, and where there is a serious outbreak of any infectious disease. The web link for HPSC's 2016 Annual Report can be found here: https://www.hpsc.ie/abouthpsc/annualreports/annualepidemiologicalreports1999-2016/HSE%20HPSC%20Annual%20Report%20ready%202016%20update%20to%20HPV%20target%20rate%2013112019.pdf

And updated statistics in relation to infectious disease notifications in Ireland, 2011-2016 can be found at the following link:
http://www.hpsc.ie/NotifiableDiseases

Plant Protection Regulations

The Department of Agriculture, Food and the Marine (DAFM) through the Pesticide Controls and Registration Divisions (PCD/PRD) is the Competent Authority for the Plant Protection Products (PPP) and Biocide Regulations, Regulation (EC) 1107/2009 and Regulation (EU) 528/2012, respectively. As the competent authority, *DAFM* is responsible for the regulation, implementation and enforcement of these areas. For biocidal products and plant protection products this also includes rodenticides.

In relation to biocidal and plant protection chemicals provisions which exist in the Biocidal Products Regulation 528/2012 (Article 56) and the Plant Protection Products Regulation 1107/2009 (Article 54), and as transposed in Ireland by SI 427 of 2013 and SI 159 of 2012, respectively, that allows for trial programmes/experiments for research and development purposes on biocides and plant protection products.

Ireland has a representative member on the Biocidal Products Committee and it's Working Groups (Chemistry, Efficacy, Human Health and Environment) at the *European Chemicals Agency (ECHA).* In addition, *DAFM* provides experts to the following expert Committees and Working Groups (WG) at ECHA: Risk Assessment Committee (RAC) for the harmonised classification and labelling, PBT WG (Persistence, Bioaccumulation and Toxic substances) and ED (Endocrine Disruption) WG. The *Health and Safety Agency (HSA)* also sits on a number of Committees and meetings at *ECHA* for which they are responsible.

Under REACH (Regulation EC 1907/2006), CLP (Regulation EC 1272/2008) and PIC (Regulation EU 649/2012) Regulations DAFM through PCD/PRD is the Competent Authority in respect of pesticides (i.e. PPP and Biocides). The *Health and Safety Authority (HSA)* is the central Competent Authority in Ireland for the REACH and CLP Regulations and a joint Designated National Authority with under PIC (Prior Informed Consent on the export and import of dangerous chemicals).

Under the poisons area *DAFM* are an enforcement bod, with the *Department of Health* holding responsibility for the regulation and administration of Poisons.

Safety at Work Regulations

- Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020, to give effect to EU Directives EU 2019/1833 and EU 2020/739) – commonly known as the Biological Agents Regulations.
- European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 to 2021 (S.I. No. 349 of 2011 as amended) – commonly known as the ADR Regulations.

The Health and Safety Authority (HSA) is the national body in Ireland with responsibility for occupational health and safety. It is a state-sponsored body, established under the Safety, Health and Welfare at Work Act and reports to the Minister of State for Business, Employment and Retail at the Department of Enterprise, Trade and Employment. The HSA enforces the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 and is the Competent Authority for all ADR Classes (with the exception of Class 9) under the European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 to 2021. Class 6.2 of ADR relates to infectious substances.

One of the *HSA*'s functions is to ensure that workers are not at risk from exposure or potential exposure to biological agents while at work and/or performing their work activities and that Class 6.2 infectious substances are safely transported on public roads. This is achieved through advice, proactive workplace inspections as set out in the *HSA's* annual Programme of Work and reactive workplace inspections following complaints to the *HSA's* contact centre.

A Code of Practice, which was updated in 2020, accompanies the Biological Agents Regulations. This Code provides a list of classified biological agents (Risk Groups 2 to 4) and specifies containment measures (and where applicable dispensations) for laboratories, isolation facilities (humans/animals), animal rooms and industrial processes. The *HSA* previously published an accompanying guidance document for the Biological Agents Regulations and work is still currently ongoing in updating and expanding this guidance.

Under the Biological Agents Regulations, there is a legal requirement for employers to notify the *HSA* if working with certain biological agent risk groups.

Notification to the *HSA* is required 30 days prior to commencement of work with respect to the following:

- First time use of group 2 biological agents
- First time use of group 3 biological agents
- First time use of a group 4 biological agent and first time use of any subsequent group 4 biological agents and;
- First time of a new group 3 biological agent, where the employer provisionally classifies that biological agent.

Laboratories carrying out a purely diagnostic service are not required to notify the *HSA* unless they are working with a group 4 biological agent. However, if the laboratory is deliberately propagating or concentrating risk group 2 or 3 biological agents, then notification will be required. If a risk group 2 – 4 biological agent is being stored in a culture collection, this will in general need to be notified to the *HSA* as the collection will need to be maintained and this will involve viability checks of the agent and deliberate propagation.

During 2022, the *HSA* received 11 notifications from private industry and the public sector. Of the 11 notifications, 1 related to a risk group 3 biological agent and the remainder related to risk group 2 biological agents.

Further information can be found at http://www.hsa.ie/eng/Topics/Biological_Agents/

Regulations in Respect of Genetically Modified Organisms

- the Genetically Modified Organisms (Contained Use) Regulations (2001 – 2010);
- the Genetically Modified Organisms (Deliberate Release) Regulations 2003
- the Genetically Modified Organisms (Transboundary Movement) Regulations, 2004

The *Environmental Protection Agency (EPA)* is the "regulator" or Competent Authority in Ireland for the implementation of the Genetically Modified Organism (GMO) Regulations on the contained use and the deliberate release of GMOs into the environment. In practice this means that anyone planning to use a GMO in a laboratory (contained use) or as part of a field/clinical trial (deliberate release into the environment) or for any purpose other than placing on the market, must first obtain consent from the *EPA.* The *EPA* also has remit for the transboundary movement of GMOs. Genetically Modified Organisms are defined as bacteria, viruses, fungi, plant and animal cells, plants and animals capable of replication or of transferring genetic material in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination.

There are a total of 523 registered users on the *EPA* register of GMO users in Ireland. 99% of these users work with Class 1/2 GMMs and GMOs (GM plants and GM animals). 86% of the contained use activities take place in academia while 14% take place in manufacturing facilities or state-owned research facilities. There are eight (8) registered Class 3 GMM users and to date, the Agency has not received any Class 4 GMM notifications.

Confidence-Building Measure "F"

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

Form F

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

No offensive or defensive biological R & D programmes have been undertaken in Ireland since 1 January 1946.

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

   Ratified: 27 October 1972

   Entry into force: 26 March 1975

2. Past offensive biological research and development programmes:

- No

- Period(s) of activities

  N/A

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

N/A

3. Past defensive biological research and development programmes:

- No

- Period(s) of activities

  N/A

- Summary of the research and development 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.

N/A

Form G

Declaration of vaccine production facilities

All human vaccine manufacture is subject to authorisation by the *Health Products Regulatory Authority (HPRA).* At present, there are three human vaccine production facilities in Ireland.

A. Pfizer Ireland Pharmaceuticals

1. Name of facility: Pfizer Ireland Pharmaceuticals
2. Location (mailing address): Grange Castle Business Park, Clondalkin, Dublin 22
3. General description of the types of diseases covered:

(i) Preparation of bulk components for a pneumococcal vaccine. These bulk components are further processed at a manufacturing site outside Ireland. In addition, bulk final pneumococcal vaccine is brought to the site from outside Ireland and filled into syringes.

(ii) Preparation of bulk components for Covid-19 and influenza vaccines. These bulk components are mRNA based Drug Substances synthesised from linearised plasmid-DNA via in vitro transcription and further processed at a manufacturing site outside Ireland.

(iii) Preparation of one bulk component for a meningococcal vaccine. This bulk component is further processed at a manufacturing site outside Ireland.

(iv) The facility also holds a Manufacturer's Authorisation for investigational medicinal products (IMPs) for use in clinical trials. This includes vaccine conjugation, formulated bulk and final dosage form (pre-filled syringe).

B. MSD International GmbH, trading as MSD Ireland (Carlow),

1. Name of facility: MSD Ireland (Carlow)
2. Location (mailing address): Dublin Road, Carlow, Co. Carlow
3. General description of the types of diseases covered:

(i) Formulation and filling of a pneumococcal vaccine

(ii) The facility also holds a Manufacturer's Authorisation for investigational medicinal products (IMPs) for use in clinical trials. This includes formulation and filling of vaccines.

C. MSD International GmbH, trading as MSD Ireland (Brinny)

1. Name of facility: MSD Ireland (Brinny)
2. Location (mailing address): Brinny, Inishannon, Co. Cork

3. General description of the types of diseases covered:

(i) The site holds a manufacturer's authorisation for medicinal products for human use for the manufacture of monovalent bulk conjugate drug substance.
(ii) The site holds a manufacturer's authorisation for investigational medicinal products (IMPs) for use in clinical trials. This includes monovalent bulk conjugate drug substance.

Manufacture of veterinary vaccines is subject to authorisation by the *Health Products Regulatory Authority (HPRA).* At present, there is one veterinary vaccine production facility in Ireland.

A. Phibro Animal Health Limited

1. Name of facility: Phibro Animal Health Limited
2. Location (mailing address): Finisklin Business Park, Sligo
3. General description of the types of diseases covered:

(i) Manufacture of non-sterile oral viral vaccines in the form of effervescent tablets for use in poultry for Newcastle disease, infectious bronchitis and infectious bursal disease.