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**	**2018**
A, part 2 (i)		**X**	**2018**
A, part 2 (ii)		**X**	**2018**
A, part 2 (iii)		**X**	**2018**
B		**X**	**2018**
C		**X**	**2018**
E		**X**	**2018**
F	**X**		
G		**X**	**2018**

(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: **15th April 2019**

State Party to the Convention: **Ireland**

Date of ratification/accession to the Convention: **1972**

National point of contact: **Frank Groome**

Ireland

Report by Ireland in accordance with the Final Declaration of the Third Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

2018

Measure A, Part 1:

Exchange of Information on Research Centres and Laboratories

Ireland does not currently have maximum containment Biosafety Level 4 (BL4) or P4-equivalent laboratories.

Laboratories

There are approximately 36 (BL3) laboratories distributed among the universities, State Agencies and biotechnology companies in Ireland. These predominantly handle up to Category 3 pathogens; however, some of the laboratories also conduct contained-use genetic manipulations under regulations implemented by the *Irish Environmental Protection Agency* and the *Health and Safety Authority.*

Responsibility for control of communicable diseases rests with Ireland's eight *Directors of Public Health* (Medical Officers of Health). There are over 50 clinical laboratories providing diagnostic microbiological services for humans. Seven of these are public health laboratories, which provide specialist microbiological services for food and veterinary analyses in Ireland.

Diagnostic Laboratory details:

Location	**Laboratory Details and functions**
University College Dublin, **National Viral Reference Laboratory (NVRL),** **Belfield,** **Dublin 4**	**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.
Public Health laboratory, **Cherry Orchard,** **Co. Dublin**	Both environmental and clinical specimens from suspected cases of deliberate release of *B. anthracis* are investigated in a Category 3 containment laboratory at Cherry Orchard Hospital, Dublin. This establishment can also test clinical samples for *Yersina pestis* and is currently introducing techniques to detect the *Clostridium botulinum* toxin.
National Salmonella Reference Laboratory (INSL), National University of Ireland,	National Reference Laboratory for Salmonella, Shigella, Listeria and Carbapenemase-producing Enterobacteriaceae. This facility also possesses BL3 containment laboratories.

Co. Galway	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 University Hospital, Galway, Co. Galway	Galway University Hospital has a Category 3 facility used for clinical diagnostics. This is the only CL3 facility in the Galway/Mayo/Roscommon/Sligo/Leitrim/Donegal region.
Irish Marine Institute, Oranmore, Co. Galway	Five regional fisheries laboratories - the EU-designated National Reference laboratory for the monitoring of marine biotoxins (Council Decision 1999/312/EC) and co-ordination of the analysis of shellfish samples for the presence of marine biotoxins, as set out in Directive 91/492/EEC.
Department of Agriculture, Food and The Marine (DAFM), Backweston, Celbridge, **Co. Kildare**	The primary diagnostic facility for agents causing diseases of animals in Ireland. There are 556M2 of CAT3 Laboratories. 324M2 of CAT3+ (Agriculture) Laboratories are currently being commissioned for working with viral agents exotic to Ireland that affect domestic animals. 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, Classical Swine Fever, Bluetongue, West Nile Fever, Aujeszky's disease, Equine Infectious Anaemia etc. and for bacterial diseases such as Salmonella, Campylobacter, Verotoxic *E.coli*, Bovine Tuberculosis, *M. paratuberculosis*, Bovine Brucellosis, Glanders, Dourine, Listeria, Staphylococci, Campylobacter etc. and also Transmissible Spongiform Encephalopathies.

	A diagnostic capacity for culture and molecular based techniques is maintained for a broader range of viruses and bacteria including *Bacillus anthracis*, *Clostridium botulinum* etc. Many of the protocols are accredited or undergoing accreditation procedures to the ISO 17025 Standard. There is no aerosol testing facility at DAFM laboratories. There is no room or building where aerosols or fumigants are deployed in trials for decontamination or equipment efficacy testing purposes. Ireland does not have aerosol testing facilities or biocide/pesticide spray testing facilities.
Health Research Board (HRB) Clinical Research Facility, St James' Hospital, Dublin	*The Health Research Board* funds a CL2 Sample Processing Laboratory within the Wellcome Trust-HRB Clinical Research Facility at St James' Hospital, Dublin. 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. The *Health Research Board* funds 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. Activities are regulated by *Health Products Regulatory Authority* and/or *HSE/HIQA.* **All biohazardous solid wastes (GM or pathogenic) arising from healthcare, research or industry at or above CL3 or BL3 are decontaminated and finally disposed of via licenced carriers and an industrial batch sterilisation facility SRCL, Kylemore Road Dublin. Liquid GM waste is treated chemically before disposal. This process**

	is regulated and inspected by the *Environmental Protection Agency (EPA).*

Research Centres

The *Health Protection Surveillance Centre (HPSC),* formerly known as the *National Disease Surveillance Centre*, is Ireland's specialist centre for surveillance of communicable diseases. The Director of the *HPSC* together with the National Director of 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 2018.

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) 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 undertaking research involving *"biological materials that pose a high*

individual and community risk or specialize in permitted biological activities directly related to the Convention".

Some previous work in the relevant area may have been carried out in *SFI* funded labs previously; however, *Science Foundation Ireland* is not the primary funder of these laboratories.

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.

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. 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)*

Measure A, Part 2:

Exchange of Information on National Biological Defence Research and Development Programmes

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 of time in a contaminated environment. A small number of specialists, typically with university qualifications are trained in threat identification techniques.

The *Defence Forces*, including Explosive Ordnance Disposal (EOD) teams, deploy a number of systems to detect a limited range of bacteria and toxins, including Anthrax and Ricin. The *Defence Forces Engineering Corps* also deploys a range of CBRN Decontamination equipment which include a capability to decontaminate from biological agents.

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, with the fifth iteration of the course planned for June 2019. The course is a key building block to a successful and sustainable humanitarian response in CBRN contaminated environments. It is anticipated that the DF will continue to can build on this initiative and develop the capacity and capability to deliver humanitarian assistance to those affected by CBRN events in the future.

Measure B:

Exchange of Information on Outbreaks of Infectious Diseases and Similar Occurrences caused by Toxins

No unusual outbreaks of infectious diseases or similar occurrence caused by toxins that deviate from the normal occurred in 2018.

Data regarding human diseases and zoonoses have been collected and co-ordinated methodically since 1998 under the auspices of *the Health Protection Surveillance Centre*. This is reported to the *World Health Organisation (WHO),* Geneva, via the *Department of Health and Children.*

The *State Veterinary Services/Department of Agriculture, Food and the Marine (DAFM)* reports animal diseases to the *OIE (International des Épizooties)*. Plant diseases are monitored nationally but are not systematically reported in the same way.

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 Services 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 and Children.

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 *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. 83 of 2009 - EC Control of organisms harmful to plants and Plant products (Amendment) (No. 2) Regulations 2009.

The *Food Safety Authority of Ireland* works with the *Health Protection Surveillance Centre (HPSE)* 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.

Measure C:

Encouragement of Publication of Results and Promotion of the 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 14 states:

> *14.1 The Host Institution shall, and shall ensure that the Principal Investigator shall:-*
>
> *14.1.1 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.*

14.1.2.1 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.)
14.1.2.2 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 UK PubMed Central (www.ukpmc.ac.uk) as soon as possible following the date of final publication.
14.1.2.3 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 criteria for funding at evaluation stage.*

Measure E:

Declaration of Legislation, Regulations and Other measures

Ireland has implemented national legislation, the Biological Weapons Act 2011, to ensure that Ireland's obligations under the Convention are being met. This contains provisions for appropriate and specific criminal offences to prohibit the manufacture, acquisition, possession, development, transport, transfer or use of biological weapons.

Export Control Regulations

- Control of Exports Act 2008;
- Control of Exports (Goods and Technology) Order 2012;
- Importation of Pathogenic Agents Order 1997;
- Control of Exports Act 2008;
- Control of Exports (Brokering Activities, Goods and Technology) Order 2018

The Department of Jobs, Enterprise and Innovation (DBEI) is the national licensing authority with regard to the export of chemical and biological agents on the EU Common Military List and the export of chemicals, toxins and pathogens listed by the EU as controlled dual-use products. The Control of Exports (Goods and Technology) Order 2012 controls the export of goods and technology on the EU Common Military List and the Control of Exports (Dual Use Items) Order 2009 implements Council Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual use items.

In addition, the export of pharmaceutically produced biological toxins is covered by European Community dual-use export legislation and domestic law, which controls the export of dual use goods and technology. The Control of Exports (Dual Use Items) Order 2009 implements Council Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual use items.

Infectious Diseases Regulations

Ireland collects its human infectious diseases data under the 1947 Health Act, Furthermore, this is detailed in the Infectious Disease Regulations 1981, amended 1996. The most recent amendment to the Regulations is the Infectious Diseases (Amendment) Regulations 2011 (S.I. No. 452 of 2011). Immediate preliminary notification is required for a sub-set of notifiable diseases.

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.

There have been changes in Irish human infectious disease legislation. 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 Infectious Diseases Regulations have been amended sine then in 2007 and most recently Infectious Diseases (Amendment) Regulations 2011 (S.I. No. 452 of 2011).

The key advances of the amended legislation since 2004 include:

- *A greatly expanded list of conditions and diseases (increased from 35 to 82)*
- *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 2015 Annual Report can be found here: http://www.hpsc.ie/AboutHPSC/AnnualReports/File,15956,en.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 labeling, 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

- the Safety, Health and Welfare at Work (Biological Agents) Regulations 1994, as amended 1998;

The Health and Safety Authority (HSA) is the national body in Ireland with responsibility for the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 (Statutory Instrument S.I. No. 572 of 2013). It is a state-sponsored body, established under the Safety, Health and Welfare at Work Act and it reports to the Minister for Business, Enterprise and Innovation. The *HSA*'s main function 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. This is achieved through advice, proactive workplace inspections as set out in its annual Programme of Work and workplace inspections following complaints to its Workplace Contact Unit (WCU).

The *HSA* have published a Code of Practice to support S.I. No. 572 of 2013 which provides a list of classified biological agents (Group 2 to 4), laboratory & industrial containment levels and dispensation advice from some containment measures for some Group 3 Biological Agents.

The *HSA* has also published an accompanying guidance document for both S.I. No. 572 of 2013 & its Code of Practice.
Further information and copies of the Code and guidance can be found at http://www.hsa.ie/eng/Topics/Biological_Agents/

S.I. No. 572 of 2013 can be located at the following link. http://www.irishstatutebook.ie/eli/2013/si/572/made/en/print?q=biological+agents&=& 14

Under the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013, there is a legal requirement on employers to notify the *HSA* if working with certain groups of biological agents.

Notification 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 of each subsequent use of group 4 biological agent 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 Authority unless they are working with a group 4 biological agent. However, if the laboratory is deliberately

propagating or concentrating group 2 or group 3 biological agents, then notification will be required. If a group 2 – 4 biological agent is being stored in a culture collection, this will 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.

The *HSA* received 24 notifications in 2018 from both private and public sector laboratories.

Regulations in Respect of Genetically Modified Organisms

- the Genetically Modified Organisms (Contained Use) Regulations 2001 and 2010;
- the Genetically Modified Organisms (Deliberate Release) Regulations 2003

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) 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 676 registered users on the *EPA* register of GMO users in Ireland. 97% 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 five (5) registered Class 3 GMM users and to date, the Agency has not received any Class 4 GMM notifications.

Measure 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.

Measure 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 one bulk component for a meningococcal vaccine. This bulk component is further processed at a manufacturing site outside Ireland.

(iii) The facility also holds a Manufacturer's Authorisation for investigational medicinal products (IMPs) for use in clinical trials. This includes vaccine conjugation.

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. None of these is a vaccine.

(ii) The site holds a manufacturer's authorisation for investigational medicinal products (IMPs) for use in clinical trials. This includes the PEGylation of vaccine conjugates.