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

2016

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	2015
A, part 2 (i)			
A, part 2 (ii)	x		
A, part 2 (iii)	x		
B		x	2015
C		x	2015
E			
F	x		
G			

(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:04/05/2017

State Party to the Convention: Ireland

Date of ratification/accession to the Convention: 1972

National point of contact: Rosie Keane

Measure A, Part 1:
Exchange of Information on Research Centres and Laboratories

Current Status:

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

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.

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: **http://NVRL.ie**

A training programme for staff at this laboratory in High Containment Laboratory procedures, organised by the Special Pathogens Reference Unit, UK Health Protection Agency (Porton Down), was originally completed in November 2004. There is an ongoing program of continuous training for senior staff responsible for the BL3+ laboratory in association with the UK HPA and the EU funded (European Training in Infectious Disease Emergencies) ETIDE training programme. The NVRL is also a member of the EU funded European Network for Diagnostics of "Imported" Viral Diseases (ENIVD) which provides "best practice" diagnostic assays and supply of Quality Control material.

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.

Diagnostic Laboratory details:

Location	Laboratory Details and functions
(1) University College Dublin National Virus Reference Laboratory Belfield Dublin 4	BL 3(+) Laboratory facilities (floor area of 28.3m^2 and a room volume of 85m^3) Core technology Phylogenetic analysis Molecular methodologies Serological investigations
(2) Public Health Laboratory Cherry Orchard Hospital Dublin	Cat 3 laboratory *Bacillus anthracis*; *Cl.botulinum toxin*.

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.

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. 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/

Health Protection Surveillance Centre

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The **National Salmonella Reference Laboratory** (INSL), located at the National University of Ireland, Galway, is the National Reference Laboratory for Salmonella, Shigella, Listeria and Carbapenemase-producing Enterobacteriaceae. This facility also possesses BL3 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 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.

The **Irish Marine Institute**, whose headquarters are in Oranmore, Galway and which has five regional fisheries laboratories, is the EU-designated National Reference laboratory for the monitoring of marine biotoxins (Council Decision 1999/312/EC) and co-ordinates the analysis of shellfish samples for the presence of marine biotoxins, as set out in Directive 91/492/EEC.

The **Department of Agriculture, Food and the Marine** (DAFM) Laboratories are the primary diagnostic facility for agents causing diseases of animals in Ireland. Their BL3 laboratory facilities are located at Backweston, Celbridge, Co Kildare. A Cat 3 + / MAFF Class 4 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, 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.

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

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

The Environmental Protection Agency (EPA) is the Competent Authority in Ireland for the implementation of the Genetically Modified Organism (Contained Use) Regulations (2001 – 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)

Laboratory details:

Location	**Laboratory Details and functions**
Backweston Celbridge Co Kildare	There are 556m2 of Cat 3 laboratories. 796m2 of Cat 3+ (MAFF 4) laboratories are currently being commissioned for the diagnosis of bacterial and viral agents

Science Foundation Ireland (SFI) contributes funding to support research activities in higher education institutes. Research centres funded by SFI are established within the higher education system. A link to the research centres funded by SFI can be found at the following link:
http://www.sfi.ie/assets/media/files/downloads/Investments/2015%20RC%20Leaflets/Combined.pdf
SFI mandates that all funded research bodies warrant that any funded Research Programme shall be conducted in compliance with Irish or other applicable laws; and that the Research Programme shall be 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.

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 IMB and/or HSE/HIQ.

All biohazardous solid wastes (GM or pathogenic) arising from healthcare, research or industry at or above CL3 or BL3 are decontaminated on site and finally disposed of via licenced carriers and an EPA licenced industrial scale batch sterilisation facility SRCL, Kylemore Road Dublin. Liquid GM waste is treated chemically before disposal.

Measure A, Part 2:
Exchange of Information on National Biological Defence Research and Development Programmes

Ireland does not have a national biological defence R&D programme**.**

However, there have been and continue to be many small programmes in Ireland aimed at combating infectious diseases in humans, animals and plants. These programmes include research on the mechanisms of pathogenicity, their natural incidence and the possibilities for boosting host defences against them. These programmes are mainly funded by the Health Research Board, Science Foundation Ireland, Enterprise Ireland, Teagasc (the Irish Agriculture and Food Development Authority), the Department of Agriculture, Food and the Marine, the Wellcome Trust, the EU and a range of commercial interests.

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 2016.

The Biology Department in NUI Maynooth were 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 Laboratoty, 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.

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.

The Defence Forces 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 conducted a CBRN (Chemical, Biological, Radiological and Nuclear) Survive to Function Course for the International

Committee of the Red Cross (ICRC) in September 2016. The course was a key building block to a successful and sustainable humanitarian response in CBRN contaminated environments. It is anticipated that the DF 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

Current status

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

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.

There is no R & D programme in Ireland aimed specifically at defence against biological and toxin weapons. The aim instead is to strengthen existing public health and laboratory capacity to identify possible clusters of disease that deviate from the norm or suspected deliberate release events (either in Ireland or in travellers from another jurisdiction). The intention is for early identification to minimise human health effects through effective public health controls and early clinical interventions. Thus, 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.

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 UCD NVRL or other microbiology laboratories. Research teams based at the UCD NVRL with expertise in phylogenetic analysis of viral sequences will be used to determine the source of any deliberate release agent by comparing the sequence of the agent to known sequences.

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.

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** 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, 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 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

Current status:

As no active programmes of research directly related to the Biological and Toxin Weapons Convention exist in Ireland, there is no publication in this area.

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. 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 **Publication**

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:

- 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 and end of grant reports and in detailed evaluation reports.
- 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

Current Status:

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.

A number of pieces of national legislation are also in place in Ireland, which regulate the use of biological materials. This legislation includes the following: Control of Exports Act 2008; Control of Exports (Goods and Technology) Order 2012; Importation of Pathogenic Agents Order 1997; and the Safety, Health and Welfare at Work (Biological Agents) Regulations 1994, as amended 1998; Genetically Modified Organisms (Contained Use) Regulations 2001 and 2010, and the Genetically Modified Organisms (Deliberate Release) Regulations 2003. 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.

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.

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.

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.

For biocides, 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 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. PPP and Biocides). The Health and Safety Agency is the primary Competent Authority for 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.

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 Jobs, 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 have 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&=&

Under the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013, there is a legal requirement on employers to notify the Health and Safety Authority 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 Authority as the collection will need to be maintained and this will involve viability checks of the agent and deliberate propagation.

The Health and Safety Authority received 12 notifications in 2016 from both private and public sector laboratories.

The **Department of Jobs, Enterprise and Innovation** 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.

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 641 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 notification.

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

Measure F:
Declaration of Past Activities in Offensive and/or Defensive Biological Research and Development Programmes

Current status:

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

Measure G:
Declaration of vaccine production facilities

Declaration of vaccine production facilities
Current status:
All human vaccine manufacture is subject to authorisation by the Health Products Regulatory Authority (HPRA) (formerly known as the Irish Medicines Board (name change on July 1 2014)). At present, there are three human vaccine production facilities in Ireland. These are:

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.

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