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

18 April 2011

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 and biotechnology companies in Ireland. These predominantly handle up to Category 3 pathogens. The laboratories also conduct contained use genetic manipulations under regulations implemented by the Environmental Protection Agency

A high containment Class 3 (+) laboratory has been commissioned at the University College Dublin National Virus Reference Laboratory (UCD NVRL). The NVRL BL3 is viewable on the web at:

http://NVRL.ie

Training in High Containment Laboratory procedures organised by the Special Pathogens Reference Unit, HPA (Porton Down) was originally completed in November 2004. There is a program of continuous training for senior staff responsible for the BL3 laboratory in association with the HPA and the EU funded training ETIDE (European Training in Infectious Disease Emergencies).The NVRL is also a member of the EU funded ENIVD (European Network for Diagnostics of "Imported" Viral Diseases). This interactive laboratory network is a valuable source of "best practice" diagnostic assays and the supply of Quality Control material.

Molecular assays have been validated at the UCD 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 such as Influenza A (H5N1) or Swine lineage Influenza A (H1N1) in clinical samples. In addition, the testing protocol to investigate suspected smallpox infection utilises an electron microscope which is situated at the Belfield campus of UCD adjacent to the UCD NVRL. 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.

Both environmental and clinical specimens from suspected cases of deliberate release of *B. anthracis* are investigated in a Class 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.

Laboratory details:

Location	Laboratory Details and functions
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
Public Health Laboratory Cherry Orchard Hospital Dublin	Cat 3 laboratory *Bacillus anthracis*; *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, of which 7 are public health laboratories, which provide specialist microbiological services in foods and veterinary isolates in Ireland.

The Health Protection Surveillance Centre (HPSC), formerly known as the National Disease Surveillance Centre, is Ireland's leading specialist centre for surveillance of communicable diseases. Along with the National Director of Health Protection in HSE, the Director of the HPSC is the National Focal Point for Ireland in respect of the International Health Regulations and is the National Contact Point for The European Commission's Early Warning and response System for Communicable Diseases. 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. It is also published on the HPSC website. Reports are also published in the monthly bulletin of HPSC Epi-insight. In addition a report of all outbreaks of infectious diseases are produced on the HPSC website at
http://www.hpsc.ie/hpsc/NotifiableDiseases/WeeklyOutbreakReport/

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The National Salmonella Reference Laboratory (INSL), located at the National University of Ireland, Galway, collects isolates of salmonella and data from all positive human faecal and blood samples, food samples and veterinary isolates in Ireland.

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.

Department of Agriculture, Fisheries and Food (DAFF) Laboratories are the primary diagnostic facility for agents causing diseases of animals in Ireland. There are BL3 laboratory facilities in DAFF Laboratories at Backweston, Celbridge, Co Kildare and a Cat 3 Plus / MAFF Class 4 facility is currently being commissioned.

DAFF Laboratories are the National Reference Laboratory for viruses 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.

DAFF Laboratories also act as National Reference Laboratories for Bacterial Diseases such as Salmonella, Campylobacter, Vero Toxic E Coli, Bovine Tuberculosis, *M. paratuberculosis*, Bovine Brucellosis, Glanders, Dourine, Listeria, Staphlococci, Campylobacter etc. and also Transmissible Spongiform Encephalopathys.

A diagnostic capacity is maintained for a broader range of Viruses and Bacteria such as *Bacilus antracis*, *Clostridium botulinum* etc.

A range of tests for the agents ranging from culture to molecular based techniques is maintained in the laboratory and many are accredited or undergoing accreditation procedures to ISO 17025.

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

Destruction of the above mentioned pathogens is carried out by internationally accepted norms.

Laboratory details:

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

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 received a notification on the 23 August 2010 from the Veterinary Sciences Centre in University College Dublin to work with Class 3 Genetically Modified Micro-organisms (GMMs). The purpose of the contained use activity is to understand the virulence or pathogenicity of *Mycobacterium tuberculosis* complex organisms *(M. bovis* and in *M. tuberculosis)* by assessing the function of genes. The contained use activity will be carried out in the Containment level 3 (CL3) facility, 3rd floor, Veterinary Sciences Centre, School of Agriculture, Food Science and Veterinary Medicine, University College Dublin, Dublin 4. The EPA granted consent for this work to be carried out on 22nd December 2010.

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

There are no organisations or institutions in Ireland currently directly involved in research and development into agents associated with biological and toxin weapons or the development of diagnostics to detect these agents and no national programme to conduct biological defence R & D in Ireland.

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, Enterprise Ireland, Teagasc (the Irish Agriculture and Food Development Authority), Bioresearch Ireland, the Department of Agriculture, Fisheries and Food, the Wellcome Trust, the EU and a range of commercial interests.

The Irish 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 identification techniques.

The Defence Forces deploy a number of detectors to detect a limited number of bacteria and toxins, including Anthrax and Ricin.

In addition, Explosive Ordnance Disposal (EOD) teams deploy field test equipment permitting microbial screening and testing for a limited number of bacteria and toxins, including Anthrax and Ricin.

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

Current status

Ireland has had no outbreaks of infectious diseases or similar occurrence caused by toxins of which we are aware, 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, Fisheries and Food 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 heath 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 a 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, but has not yet been fully rolled out nationally

The Health Protection Surveillance Centre (HPSC) has a close and productive interaction with the Health Protection Agency (CDSC), Colindale, London, UK and the Centres for Disease Control and Prevention (CDC), Atlanta.

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 are then published on a weekly basis by the HPSC. Subsets of the data are 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.

The Department of Agriculture, Fisheries and Food (DAFF) and the Food Safety Authority of Ireland collect and collate zoonotic disease data. This information is collected under the EU Zoonoses Directive 2003/99/EEC and Regulation 2160/2003, and is fed into the European Food Safety Authority. These data are available on the Internet. 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 is involved in the coordination of the investigation of national, cross-border and international outbreaks 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 the 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.

Measure D:
Promotion of Professional Contacts

Current Status

While no active programmes of research directly related to the BTWC Convention exist in Ireland, Ireland believes that international cooperation in the field of peaceful bacteriological (biological) activities is important.

Most Irish microbiologists are members of international microbiology and immunology societies, which are in turn affiliated to the International Union of Microbiology Societies (IUMS). There is a National Committee for Microbiology that is part of the Royal Irish Academy, which arranges and facilitates international contacts. There are also many medical and general scientific exchanges between microbiology institutions in Ireland and abroad.

The UCD NVRL has a close collaboration with the Special Pathogens Reference Unit, HPA Porton Down and also the Centre for Infection, Colindale in the UK. Samples, either environmental or clinical, for which there are no diagnostic investigations currently available in Ireland, will be referred to one of the appropriate centres detailed above. The UCD NVRL is a member of the European Network for Diagnostics of "Imported" Viral Diseases (ENIVD) and this facilitates collaboration with member laboratories throughout Europe.

Ireland participates in a number of European organisations and programmes such as HELICS and HARMONY, which closely track infectious diseases and drug resistance patterns.

Zoonoses Committees have been established at regional and national level to provide formal contact points for professionals in the animal, human, food and environmental health areas.

The Defence Forces is associated with Bio defence networks in NATO/PfP and the European Defence Agency. Representatives attend meetings and use information/data gathered to inform risk assessment measures and to structure appropriate response measures in suspected bio attacks.

Measure E:
Declaration of Legislation, Regulations and Other measures

Current Status:

- Ireland is currently preparing new national legislation to ensure that all of Ireland's obligations under the Convention are being met. The proposed Biological Weapons Bill will create appropriate and specific criminal offences to prohibit the manufacture, acquisition, possession, development, transport, transfer or use of biological weapons.

There are also a number of pieces of national legislation already 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 2009; 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 biological toxins is covered by European Community dual-use export legislation and domestic law, which controls the export of military goods.

Ireland collects its human infectious diseases data under the 1947 Health Act, amended by the 1983 Act. Furthermore, this is detailed in the Infectious Disease Regulations 1981, amended 1996.

The Department of Agriculture, Fisheries and Food (DAFF) 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 DAFF carries out surveillance programmes to test for the presence of such pathogens on a wide range of animals and animal products.

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, 1994 (Statutory Instrument No. 146 of 1994), as amended in 1998 by S.I. 248 of 1998. It is a state-sponsored body, established under the Safety, Health and Welfare at Work Act and it reports to the Minister for Enterprise, Trade 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). Where there is intentional work with biological agents, e.g. research, teaching and diagnostic purposes and thus a potential for exposure to biological agents (in particular Group 3 or 4 organisms), those employers are obliged to notify the HSA 30 days in

advance of work commencing. The HSA are currently revising and updating the Safety, Health and Welfare at Work (Biological Agents) Regulations 1994 (as amended).

The Environmental Protection Agency 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. The Agency also has the remit for the Transboundary movement of GMOs. In practice what this means is that anyone planning to use a GMO in a laboratory (contained use) or in a field trial (deliberate release into the environment) must first obtain consent from the Agency. 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 427 registered users on the EPA register of GMO users in Ireland. This is broken down into 218 Class 1 GMM users, 106 Class 2 GMM users, one Class 3 GMM user, 93 GM animals/GM plants users and 9 deliberate users. It should be noted that not all of these registered users are active at present.

There have been recent 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 key advances of the new legislation include:

- A greatly expanded list of conditions and diseases (increased from 35 to 68)
- 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 2009 Annual Report can be found here:
http://www.hpsc.ie/hpsc/AboutHPSC/AnnualReports/
and updated statistics at:
http://www.hpsc.ie/hpsc/NotifiableDiseases/AnnualIDStatistics/

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

Current status:

All human vaccine production is subject to licence by the Irish Medicines Board. At present, there is one human vaccine production facility in Ireland. Pfizer began operation of a vaccine manufacturing plant located at Grange Castle in Co. Dublin within the last year

There are also a number of veterinary vaccine production companies in the biotechnology sector in Ireland. Elanco Laboratories in Co. Sligo have the capability to manufacture live vaccines.

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