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TITLE: WP2 Study & Analysis

SUBTITLE: D2.6 Report on Intentionally Caused Outbreaks

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ASSET

Action plan on SiS related issues in Epidemics and Total Pandemics

7th RTD framework programme

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D2.6 Report on Intentionally Caused Outbreaks

Task: 2.6

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V3	Draft	04 Dec 2014	FFI/Kjersti Brattekas	V3 distributed for CoP input
V4	Final	19 Dec 2014	FFI/Kjersti Brattekas	Final draft submitted for WP/SC review
Vf	Final	17 Feb 2015	ISS/Alberto Perra FFI/Kjersti Brattekas	Comments from Scientific Coordinator worked into document. Final version submitted

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EXECUTIVE SUMMARY

Background

The possibility of intentionally caused outbreaks represents a concern for law enforcement, governments and public health officials around the world due to its possible high consequences.

The problems posed by intentionally caused outbreaks have been addressed with three approaches in this report:

- Analyses of history, terrorism and science progress and its potential consequences (sections 2-4)
- Countermeasures to respond to any biological threat (section 5)
- Overview of international and national policies (Sections 5-6)

D2.6 includes an analysis of the current knowledge and main policy documents concerning intentionally caused outbreaks and a taxonomy of the main governance problems posed by the risk of intentionally caused outbreaks in democratic societies, chiefly the tension between secrecy and transparency, freedom of research and security, citizen involvement and experts' decisions.

Objectives

The objectives of this report are to collect and analyse relevant policy documents and create a taxonomy of the main governance problems posed by the risk of intentionally caused outbreaks in democratic societies.

The main objective is to create the taxonomy, or classify, the main governance problems posed by intentionally caused outbreaks based on the analysis made in the document. Therefore, it has been important to research a vast background of materials, including science and academic reports, policy documents and historical reviews.

Methods

In order to reach the objectives for this report, we have used the method of document analysis and created a taxonomy based on the results from the analysis. The focus for the document analysis has been divided into a historical overview of intentionally caused outbreaks, a review of state-of-the-art literature with aspects relevant for this report, and a review of main policy documents focusing on the issues included in the taxonomy.

The taxonomy has been developed in collaboration with the ASSET partners involved in Task 2.6. Firstly, the main problem areas are qualitatively described and analysed based on state of the art and the main policy documents. Thereafter, the taxonomy has been developed and populated as a table cross-categorising the problems.

In order to include the governance problems highlighted in the DOW, these have been included as main focus areas in the taxonomy. To classify different problems, we have developed different features divided by involved societal entities or specific issue areas for governance bodies. The features are then categorised under each specific problem area as: The tension between secrecy and transparency; Freedom of research and security; Citizen Involvement and Experts' decisions.

Based on the methodological approach, we fulfil the objectives by describing and analysing the history, state of the art and main policy documents, and categorising the defined governance problems in the taxonomy based on this background. This report thus constitutes a comprehensive description of intentionally caused outbreaks and main governance problems posed by the risk of Intentionally Caused Outbreaks in democratic societies.

Findings

The main findings from the taxonomy concerning "the tension between secrecy and transparency" are problems related to state BW programmes, international agreements with vague repercussions and loose implementation, dual-use research, stockpiles, biological agents' reservoirs and public communication. In "freedom of research and security", problems mainly relate to dual-use issues, movements of agents and equipment, laboratory safety and security and the security of the public. "Citizen involvement" problems are mainly within the areas of protection of citizens, their say in decision-making processes, involvement in prevention, preparedness, response and recovery as well as public communication aspects. As for "experts' decisions" the main governance problem areas lie within expert involvement in policy, expert involvement that is required for decisions and complex problem areas not possible to solve without expert advice and communicating complex areas to policy-makers and the public.

Conclusions

The report identifies governance *problems*, but this does not mean there are no solutions to the identified problems. They should be kept in mind while developing policies and good governance, but some potential solutions and important focus areas already exist and are progressing. Policy-makers do not necessarily have to come up with new solutions for all governance problems. It is important to address the problems identified, but equally important to keep working with solutions that can be furthered and broadened such as international regimes and agreements.

In order to include the issues identified in the report further in the ASSET project, the taxonomy may be used as a "checklist" for policy analysis in the field. It should also be noted that the taxonomy can be consulted before making the MMLAP in order to better define which areas to focus on in this field and to investigate which aspects from the taxonomy are most important to include. Policy makers dealing with intentionally caused outbreaks, CBRNe, bioterrorism and related subjects may also take interest in the results from this report.

Abbreviations

AG	Australia Group
ASSET	Action plan on SiS related issues in Epidemics and Total pandemics
B	Biological
BTWC/BWC	Biological and Toxin Weapons Convention
BW	Biological weapon
CABRI	Common Access to Biological Resources and Information
CBM	Confidence-building measures
CBW	Chemical and biological weapons
CDC	Centers for Disease Control and Prevention
CoP	Community of Practice
D	Deliverable
DOW	Description of work
ECDC	European Centre for Disease Prevention and Control
ERCC	Emergency Response Coordination Centre
EU	European Union
EWRS	Early Warning and Response System
GLP	Good Laboratory Practices
HFA	Hyogo Framework for Action
HSC	Health Security Committee
IHR	International Health Regulations
IMS	Integrated Management System
MMLAP	Mobilisation and Mutual Learning Action Plan
OIE	World Organisation for Animal Health
RRI	Responsible research and innovation

RTD	Research and technology development
R&D	Research and development
SiS	Science in Society
T	Task
TRC	South Africa's Truth and Reconciliation Commission
UNSCOM	United Nations Special Commission
WHO	World Health Organisation
WP	Work Package

1. Introduction

This deliverable is report D2.6 of the ASSET Project WP2, Report on Intentionally Caused Outbreaks. The report is based on the work done in Task 2.6 of the description of work (DOW).

The possibility of intentionally caused outbreaks represents a growing concern for law enforcement, governments and public health officials around the world. Biological materials – such as bacteria, viruses and toxins – are significantly cheaper and easier to produce, handle and transport than radiological or chemical materials. They are difficult to detect and symptoms from exposure may not appear for days, possibly weeks. Moreover, advances in laboratory technology brought the science for building a bioweapon within reach of terrorists and non-state actors. Although it has been very rare to see biological materials being used as weapons, such incidents are of importance due to their potentially high consequences. Even a hoax event can be an effective way of instilling widespread fear among the public.

To address these issues, three approaches are needed:

- Analysis of terrorism and of science progress and its potential consequences (sections 2-4)
- Countermeasures to respond to any biological threat (section 5)
- Overview of international and national policies (Sections 5-6)

1.1. Scope of the Project:

ASSET (Action plan in Science in Society in Epidemics and Total pandemics) is a 48 month Mobilisation and Mutual Learning Action Plan (MMLAP), which aims to

1) forge a partnership with complementary perspectives, knowledge and experiences to address affectively scientific and societal challenges raised by pandemics and associated crisis management;
2) explore and map SiS-related issues in global pandemics;
3) define and test a participatory and inclusive strategy to succeed;
4) identify necessary resources to make sustainable the action after the project completion. ASSET combines public health, vaccine and epidemiological research, social and political sciences, law and ethics, gender studies, science communication and media, in order to develop an integrated, transdisciplinary, strategy, which will take place at different stages of the research cycle, combining local, regional and national levels.

1.2. Scope of the Work Package:

WP2 is about the state of the art research and existing studies on pandemics, and their wider societal implications, research and innovation in this area, and the operational and regulatory environment. Its main objectives are to establish baseline knowledge about:

1) governance of flu pandemics and other similar crises;
2) unsolved scientific questions regarding influenza and pandemic situations;

3) past experiences of participatory governance, bringing research about influenza and pandemics closer to democratic institutions at all levels;
4) targeted ethical, legal and societal implications of pandemics;
5) gender issues in pandemics;
6) the research and innovation context;
7) the risk of intentionally caused outbreaks

1.3. Scope of the Task:

Task 2.6 Intentionally Caused Outbreaks is led by FFI with contributions from LYON and HU.

T2.6 includes a collection and analysis of the main policy documents concerning Intentionally Caused Outbreaks and a taxonomy of the main governance problems posed by the risk of Intentionally Caused Outbreaks in democratic societies, chiefly the tension between secrecy and transparency, freedom of research and security, citizen involvement and experts' decisions.

1.4. Document

D2.6 Report on Intentionally Caused Outbreaks is a comprehensive report of concerned activities. FFI has led the work on developing the report with contributions from LYON and HU.

The document is structured as follows:

Chapter 1: "Introduction" describes the scope of the project, work package and task as well as the structure of the document.

Chapter 2: "Objectives, Methods and Definitions" includes a thorough description of objectives, work methods and relevant definitions as well as a biological threat agents list.

Chapter 3: "History of Intentionally Caused Outbreaks" gives a summary of historically described incidents.

Chapter 4: "Current Knowledge" is a state-of-the-art overview of research status relevant for the field, as well as sections on dual-use research and laboratory policies.

Chapter 5: "Main Policy Documents" is an overview of the relevant existing policies in the area relating to the creation of the taxonomy.

Chapter 6: "Taxonomy of the Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies" presents categorisation of the issues identified in the previous sections.

Chapter 7: "Conclusion" is a summary of the main findings in this document, and recommendations for further work with identified issues in the ASSET project.

Chapter 8: "References" includes a full reference list of all the sources used for this document.

2. Objectives, Methods and Definitions

2.1. Objectives

The objectives of this report are to collect and analyse relevant policy documents and create a taxonomy of the main governance problems posed by the risk of intentionally caused outbreaks in democratic societies. The result is a comprehensive report on the concerned activities. Furthermore, a state of the art review creates an approach to the taxonomy based on research and policy.

The aim of the document is to address the issues defined in Task 2.6 and recommend the way forward for including these issues in the MMLAP and the overall ASSET project. The document is of importance in order to be aware of issues concerning intentionally caused outbreaks throughout the project lifetime and beyond.

2.2. Methods

In order to reach the objectives for this report, we have used the method of document analysis and created a taxonomy based on the results from the analysis. The focus for the document analysis has been divided into a historical overview of intentionally caused outbreaks, a state of the art review of academic literature with relevant aspects for this report, and a review of main policy documents focusing on the issues included in the taxonomy.

The taxonomy has been developed in collaboration between the involved ASSET partners working on Task 2.6. First, the main problem areas are qualitatively described and analysed based on state of the art and the main policy documents. Thereafter, the taxonomy has been developed and populated as a table cross-categorising the problems.

In order to include the main governance problems as stated in the DOW, these have been included as main focus areas in the taxonomy. To classify different problems, we have divided after international and national problems. The features are then categorised under each specific problem area; The tension between secrecy and transparency, Freedom of research and security, Citizen involvement and Experts' decisions. Furthermore different features divided after involved societal entities or specific issue areas for governance bodies are crossed off after relevance for each identified problem. The collection and categorisation of potential governance problems has been done based on the theory that the problems identified in the literature may have consequences for the identified entities if not addressed.

Based on the methodological approach, we fulfil the objectives for this task by describing and analysing the history, state of the art and main policy documents, and categorising the defined governance problems in the taxonomy based on this background. This report thus constitutes a comprehensive description of intentionally caused outbreaks and main governance problems posed by the risk of Intentionally Caused Outbreaks in democratic societies.

2.3. Definitions

Intentionally caused outbreaks: Deliberate spread of infectious disease[1].

Biological weapon, biotechnological weapon or bioweapon: "Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict "[2].

Biological weapons are complex systems that disseminate disease-causing organisms or toxins to harm or kill humans, animals or plants. They generally consist of two parts – a weaponised agent and a delivery mechanism. In addition to strategic or tactical military applications, biological weapons can be used for political assassinations, the infection of livestock or agricultural produce to cause food shortages and economic loss, the creation of environmental catastrophes, and the introduction of widespread illness, fear and mistrust among the public[3].

"**Biological agents** are not biological weapons. Merely possessing biological agents with the theoretical potential to cause harm is insufficient; the toxins or microorganisms need to be "weaponized", i.e. prepared and disseminated effectively to their target."[4]

"Biological threat agents are microorganisms such as bacteria, rickettsia, fungi, viruses and toxins, that cause infections leading to incapacitation or death of people, domestic animals and/or destruction of crop plants."[5]

Biological attack is the intentional release of a pathogen (disease causing agent) or biotoxin (poisonous substance produced by a living organism) against humans, plants, or animals. An attack against people could be used to cause illness, death, fear, societal disruption, and economic damage. An attack on agricultural plants and animals would primarily cause economic damage, loss of confidence in the food supply, and possible loss of life. It is useful to distinguish between two kinds of biological agents:

- Transmissible agents that spread from person to person (e.g., smallpox, Ebola) or animal to animal (e.g., foot and mouth disease).
- Agents that may cause adverse effects in exposed individuals but that do not make those individuals contagious to others (e.g., anthrax, botulinum toxin)[6].

Bioterrorism or biological terrorism: "A bioterrorism attack is the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants"[7].

[1] ASSET Glossary
[2] Biological Weapons Convention, Article I
[3] The United Nations Office at Geneva
[4] Ackerman, G.A. and Moran, K.S. (2006), p.3
[5] FFI FACTS
[6] Fact sheet from the National Academies and the U.S. Department of Homeland Security 2004

Biological warfare or germ warfare: is the use of biological toxins or infectious agents such as bacteria, viruses, parasites and fungi with intent to kill or incapacitate humans, animals or plants as an act of war.

Toxin: A Toxin is any toxic substance that can be produced by an animal, plant or microbe. Some toxins can also be produced by molecular biological techniques (protein toxins) or by chemical synthesis (low molecular weight toxins)[8].

Mass Casualty Biological (toxin) Weapon (MCBW) is any toxin weapon capable of causing death or disease on a large scale, such that the military or civilian infrastructure of the state or organization being attacked is overwhelmed[9].

Biosafety: Biosafety refers to the development and implementation of administrative policies, microbiological practices, facility safeguards, and safety equipment to prevent the transmission of potentially harmful biologic agents to workers, other persons, and the environment. Containment is used to describe safe methods, facilities, and equipment for managing infectious materials in the laboratory where they are being handled or maintained. Risk assessment of the work to be done with a specific agent determines the appropriate biosafety practices[10].

Biosecurity (Laboratory): The term biosecurity refers to the protection, control of, and accountability for high-consequence biological agents and toxins, and critical relevant biological materials and information within laboratories to prevent unauthorized possession, loss, theft, misuse, diversion, or intentional release[11].

Biodefense: The measures taken to prevent, detect, respond to, and/or recover from harm or damage caused by microorganisms and/or biological toxins to humans, animals, or the food supply[12].

Medical Countermeasures: Medical countermeasures include both biological and pharmaceutical medical countermeasures (e.g. vaccines, antimicrobials, and antibody preparations), non-pharmaceutical medical countermeasures (e.g. ventilators, devices, personal protective equipment such as face masks and gloves), and public health interventions (e.g. contact and transmission interventions, social distancing, and community shielding) to prevent and mitigate the health effects of biological agents[13].

Dual use research of concern: research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health, agriculture, plants, animals, the environment, or material[14].

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[7] CDC Bioterrorism overview
[8] Defense against toxin weapons - U.S. Army Medical Research and Materiel Command (1997)
[9] Defense against toxin weapons - U.S. Army Medical Research and Materiel Command (1997)
[10] The white house Office of science and technology policy
[11] ibid
[12] ibid
[13] ibid
[14] ibid

Resilience: A community's or region's ability to effectively prepare for, respond to, and successfully recover from a manmade or natural disaster, by having the ability to quickly: return citizens to work, minimize disruption to life and economies, reopen schools and businesses, and prevent and mitigate cascading failures, often characteristic of critical infrastructure impacts[15]

Biorisk: the combination of the likelihood of the occurrence of an adverse event involving exposure to biological agents and toxins and the consequence of such an exposure[16]. As a result, biorisk can result from both accidental and deliberate release of such agents and toxins (as well as events with a natural origin).

These are the definitions the partners in ASSET Task 2.6 have agreed on for the purpose of this document. However, a plethora of definitions are made by - and available to - the public, researchers, experts and policy-makers, and the set of definitions should be harmonised for the purpose of consistency in governance.

2.4. Agents

"Biological threat agents may be disseminated by food, water, insect vectors, direct contact or as aerosols"[17]. The US Centers for Disease Control and Protection have classified likely bioterrorism agents in three categories:

Category A consists of agents or diseases that can be easily disseminated, are transmissible from person-to-person, may result in high mortality rates or may require special health preparedness. Such agents are Anthrax, Botulism, Plague, Smallpox, Tularaemia and viral haemorrhagic fevers such as Ebola and Marburg.

Category B consists of moderately disseminated agents with lower mortality rates. Category B includes Brucellosis, Epsilon toxins, food safety threats (such as *Salmonella*, *E. coli* and Shigella), Glanders, Melioidosis, Psittacosis, Q fever, Ricin toxin, Staphylococcal enterotoxin B, Typhus fever, viral encephalitis and water safety threats (such as *Vibrio cholera*).

Category C consists of emerging infectious diseases[18]. These agents are of emerging pathogens possible to engineer for mass dissemination due to their availability, ease of production and dissemination, as well as high mortality and morbidity rates.

Classifications of biological agents and diseases*:

Group, causative agent	Disease
Bacteria	

[15] ibid
[16] Specifications for an international occupational health and safety management system from the Occupation Health and Safety Assessment Series (OHSAS 18001).
[17] FFI FACTS
[18] CDC agent list

Bacillus anthracis	Anthrax
Yersinia pestis	Plague
Francisella tularensis	Tularemia
Brucella spp.	Brucellosis
Malleomyces pseudomallei	Melioidosis
Rickettsiae	
Coxiella burnetii	Q fever
Viruses	
Variola virus	Smallpox
VEE Virus	Venezuelan equine encephalitis
Marburg virus, Ebola virus [filoviruses]	Haemorrhagic fever
Toxins	
Botulinal toxins	Botulism
Ricin	Ricin poisoning
Staphylococcal enterotoxin B (SEB)	SEB poisoning

*The table has been modified from Szinicz' original table[19]

Additional agents and diseases*:

Biological agent	**Disease caused by the agent**
Arenaviruses (for example, Lassa, Machupo)	Viral haemorrhagic fevers
Epsilon toxin of *Clostridium perfringens*	Food poisoning
Salmonella species, *Escherichia*	Food poisoning

[19] Szinikz (2005), p.168

coli O157:H7, Shigella	
Burkholderia mallei	Glanders
Chlamydia psittaci	Psittacosis
Rickettsia prowazekii	Epidemic typhus
Vibrio cholerae	Cholera
Cryptosporidium parvum	Cryptosporidiosis
Alphaviruses (for example, Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis) and flaviviruses (for example, West Nile encephalitis, Saint Louis encephalitis, dengue fever)	Viral encephalitis
Influenza virus	Influenza
Mycobacterium tuberculosis	MDR TB and XDR TB

*The table is modified from Medicine Net[20]

A currently relevant example of a Category A agent is the consideration of Ebola as a bioterrorism agent. Ebola is classified as a Category A disease which may pose a risk to security due to its dissemination possibilities (transmission from person to person), its high mortality rates, possibility of survival outside the human body, difficulty to diagnose, possibility for fear and social disruption and the fact that it requires special action for public health preparedness. Both Ebola and Marburg viruses are considered potential bioterrorist weapons if aerosolised, and it is believed that the Aum Shinrikyo attempted to obtain Ebola for bioterrorist use in 1992[21].

Biological threat agents may enable malevolent actors to commit clandestine attacks because the delayed impact can be confused with natural disease outbreaks. Attention also needs to be given to how natural disease outbreaks may be exploited for malicious purposes[22] as described above.

Early and rapid identification of biological threat agents is crucial for medical diagnostics and treatment, and several identification techniques are needed in order to verify the biological agent[23].

[20] Medicine Net, Bioterrorism agents
[21] Berger, S. (2014), p.10
[22] Parachini (2001), pp.10-11
[23] FFI FACTS

Medical health care providers should be familiar with the symptoms caused by the defined bioterrorism agents, and need reporting systems to identify correlations and competence to determine whether the outbreak is intentional.

3. History of Intentionally Caused Outbreaks

Using infectious biological agents intentionally for hostile purposes has been described several times through history. Although the historical data set of state or non-state actors' use of biological weapons is very limited[24], the records leave no doubt that intentionally caused outbreaks are not a new occurrence.

The history of biological warfare is described by Poupard and Miller in six historic periods from 300 B.C. to the 1990s[25]:

300 B.C.-1763 A.D.: No specific starting point is described, but the main biological warfare occurred in a crude form, e.g. when the Greeks polluted enemies' water supplies with animal corpses, a tactic later used by Persians and Romans. In a battle in Tortona, Italy, in 1155 Barbarossa's use of dead soldiers and animals to pollute wells was described. Well poisoning has been frequently recorded, and was also used in the U.S. Civil War in 1863. In 1422, catapults were used to "…project diseased bodies into walled fortifications…" at the siege of Carolstein, a tactic frequently described in literature and works of art.

1763-1925: In 1763 smallpox blankets were used to spread disease to Native Americans in the North American Indian Wars. This particular use of the tactic can be documented, but there were most probably several occurrences other than the specific incident in 1763. In the American Revolutionary War, British troops were vaccinated against smallpox whereas American rebels were not. In the nineteenth and early twentieth centuries the science of bacteriology widened the scope of biological warfare agents. Germany was accused of using cholera and plague in 1915, as well as anthrax and glanders in 1916 and 1917. Biological agents were included in the Geneva Convention in 1925, as the Geneva Protocol.

1925-1940: Many industrialised states scaled up their research activities on biological warfare in this period, creating increasingly sophisticated biological weapons. Despite the Geneva Protocol, many states saw the threat of biological warfare as a well-founded reason to create their own programmes.

1940-1969: An intense period of programmes and technology developments took place in this politically unstable period, and many states had active biological warfare programs by the 1960s. Allegations of use were made in World War II and the Korean War, but none were confirmed. By the end of the period, a turning point came with the U.S. renouncing biological weapon systems.

1969-1990: In 1972 the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BWC) came into place. However, there were problems with verification of the treaty, and the Cold War era was tense when an outbreak of anthrax occurred in Sverdlovsk, U.S.S.R. in 1979. Also, in the 1980s, possible use of biological agents in terrorism came on the agenda.

[24] Parachini (2001), p.2
[25] Poupard, J.A.; Miller, L.A. (1992), pp.9-20

1990s: Biological warfare was still considered as a threat in the 1990s, particularly in the first Gulf War and the threat of possible terrorist use[26].

The terrorist threat and rogue states continue to be in focus after 1992, and they are considered to be a necessary focus area for military strategic planning.

Bioweapons timeline from FFI FOCUS[27]	
1346	During the Middle Ages, the Tartars are said to have catapulted bodies of plague victims over the walls of Kaffa in an attempt to initiate an epidemic upon the residents.
1763	Blankets from smallpox patients were given to the Native American tribes in order to transfer the disease and influence the outcome of the ongoing conflict.
1914-1918	The Germans used biological agents for sabotage such as infecting animal feed and horses intended for export with Anthrax and Glanders during World War I.
1925	The Geneva protocol bans the use of bioweapons.
1937-1945	In response to suspected bioweapon (BW) development in Nazi Germany, the US, UK, and Canada initiated a BW development program in 1941 resulting in the weaponisation of anthrax, brucellosis, and botulism toxin. Japan also had a comprehensive program, mainly on plague (unit 731 in Japanese-occupied Manchuria dropped plague-infected fleas in China resulting in more than 50 000 deaths).
1942-1969	Centre for U.S. military BW research developed and tested biological and chemical weapons at the Dugway Proving Grounds in Utah. Research carried out in the U.K. during World War II left Gruinard Island in Scotland contaminated with anthrax for the next 48 years. In the USSR, a biological weapons program continued until the dissolution of the union.
1972	The Biological and Toxin Weapon Convention (BTW) banned the use, possession and development of chemical and biological weapons.
1978	KGB-agents allegedly killed the Bulgarian dissident Georgi Markov by stabbing and injecting him with ricin. In the Soviet Union, toxin from Ricinus communis, was redefined as an assassination tool at the time.
1979	An Anthrax epidemic broke out in humans in the city of Sverdlovsk in the former USSR. The reason was an accidental release from the BW-research facility in Sverdlovsk, resulting in ca. 66 human deaths.
1984	The Rajneesh Cult deliberately released *Salmonella typhimurium* at salad bars and supermarkets in Oregon, USA, to keep people from voting, causing an outbreak of salmonellosis where 751 people fell ill.
1985	The inception of Iraq's biological weapons program, which embraced a comprehensive range of agents and munitions. Agents under Iraq's biological weapons program included lethal agents, e.g. anthrax, botulinum toxin, aflatoxin and ricin, and incapacitating agents, for example some mycotoxins, haemorrhagic conjunctivitis virus and rotavirus.
1995	Members of the Aum Shinrikyo sect failed in attempts to release Anthrax and Botulinum toxin but succeeded in a chemical attack with sarin which was released

[26] ibid.
[27] Blatny, J.M.; Lausund, P.L. (2012)

	on several lines of the Tokyo Metro, killing thirteen people, severely injuring fifty and causing temporary vision problems for nearly a thousand others.
1996	On 28 August, in Dallas, Texas, USA, 12 laboratory workers at St Paul's Medical Centre became ill after eating muffins and doughnuts in their cafeteria. Apparently, the food had been intentionally contaminated with Shigella dysenteriae type 2 by a disaffected worker.
2001	In the aftermath of 9/11, the dissemination of anthrax spores by letters and the postal processing and distribution centres in the United States resulted in 22 cases of anthrax, of which five of the inhalation cases were fatal, and necessitated the treatment of more than 2000 with antibiotics in one of the postal facilities alone.
2011	North Georgia men arrested, charged in plots to purchase explosives, silencer and to manufacture a biological toxin for use in attacks against U.S. citizens and government personnel and officials.

In addition to this extensive overview, it should be added that in 1495 Spanish soldiers tried to contaminate the French's wine with blood from leprosy patients near Naples, in 1650 a Polish general put rabies infected dog saliva in hollow spheres fired on the enemies, and in 1710 the Russians deposited plague-infected cadavers in the Estonian town of Revel which was then held by the Swedes[28].

The historical overview shows that the use of biological threat agents for hostile purposes has occurred in several countries and by different actors. Spanning from military use in conflicts, to politically motivated acts by non-state actors and individual assassinations, it is difficult to discern typical trends or patterns in the history of intentionally caused outbreaks that may be of concern in contemporary society. This can make further assessments and governance of the issues particularly complex.

[28] Szinicz (2005), pp.169-170

4. Current Knowledge

4.1. Literature review

In order to analyse main policy documents and populate the taxonomy of main governance problems posed by the risk of intentionally caused outbreaks, it is necessary to take into account a basic state of the art analysis about research on the subjects. In the review, some relevant governance problems also become visible without explicitly being parts of official policies and should also be taken into account for the purposes of the taxonomy.

In order to address all intentionally caused outbreaks, we have included both state and non-state actors as possible origins of the agent causing the outbreak. However, due to regimes and some strict regulations in the international environment, as well as deteriorating state military control of biological weapons and agents, the review mainly focuses on non-state actors including terrorists.

4.1.1. Non-state actors

A large part of the literature focuses on assessing the threat, risk and use of bioweapons and agents by non-state actors; aspects that are important to consider in policymaking.

The threat level and risk of bioterrorism is disputed between academics; it is perceived high and imminent by some and low and unlikely by others. However, it is largely agreed that assessments of threat and risks must be made before creating and implementing policies.

In order for policymakers to assess the threat of bioterrorism, Ackerman and Moran created a model for this purpose in 2006:

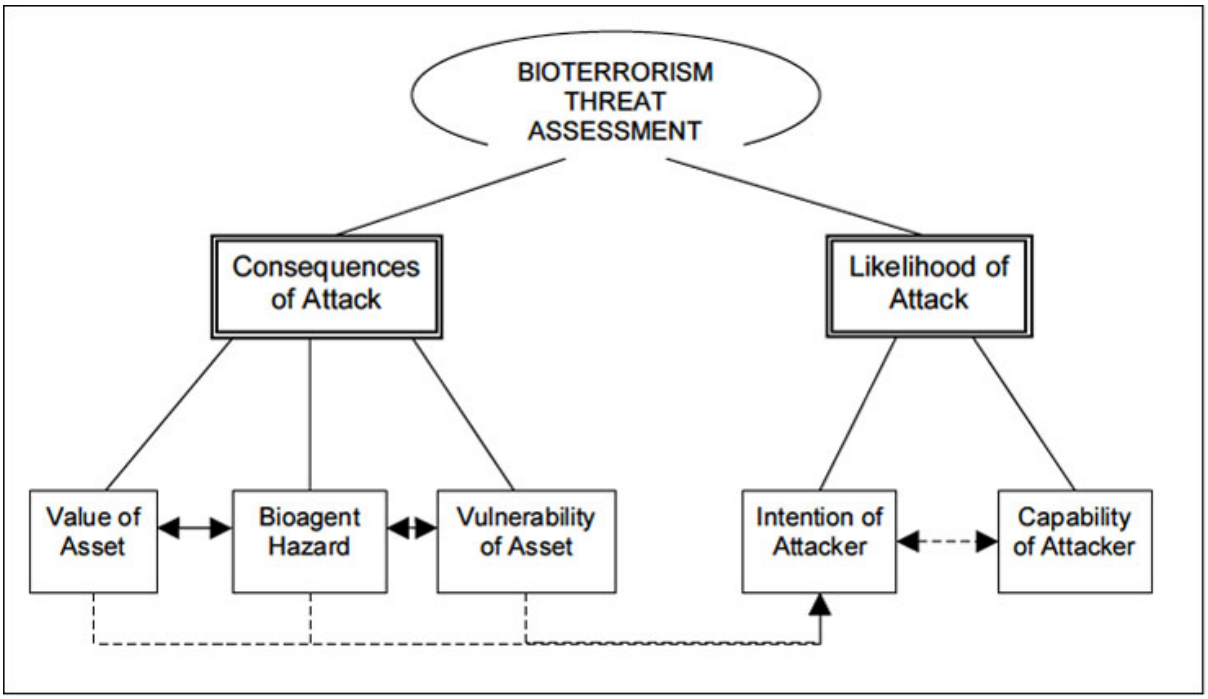

Figure 4.1 Bioterrorism threat assessment[29]

According to Ackerman and Moran "…the threat of bioterrorism is a function of the interaction between the value and vulnerability of the asset being defended, the harm potential of the biological agent, and the capabilities and intentions of potential attackers."[30]

Furthermore, it is argued in the paper that "…an accurate and comprehensive assessment of the threat posed by bioterrorism is essential for policymakers working to identify and prioritize opportunities for reducing the global risk of such attacks."[31] In order to do so, several issues are identified and highlighted, starting with definitions and issues with policy relevance. A model for threat assessment, as presented above, is elaborated with descriptions of how to determine the value of asset to defender, harm potential of biological agents, vulnerability to biological weapons and capabilities of non-state actors to conduct a bioterrorist attack. The recommendations to policymakers following from the analysis are:

1. Foster a common, accurate understanding of bioterrorism, including an understanding of bioterrorism as a distinct issue that should be understood "comprehensively" and "flexibly", as well as presented "realistically".
2. Strengthen global norms against biological weapons in order to focus international efforts on rejecting these tactics and discourage attacks.
3. Enhance and standardise international biosecurity efforts through creating an agreed upon "high-priority agents" list and establish an international biosecurity convention.

[29] Ackerman and Moran (2006), p.5
[30] ibid.
[31] ibid., p.2

4. Support multilateral non-proliferation initiatives like the Geneva Protocol, the BWC and the Australia Group.
5. Improve relationships between science and law enforcement communities to increase the expertise behind decision-making processes.
6. Enhance global preparedness and response capabilities including identifying public health as a key component of international security, encourage realistic, "dual-use" national bioterrorism response strategies, emphasize the importance of crisis communication and promote cooperative bio-preparedness research and disseminate lessons learnt.[32]

To analyse the risk of bioterrorism and base countermeasures on the analyses can be difficult, as there is also a need to foresee potential terrorist response to countermeasures. If a simple direct relationship between regulatory measures and the change in risk is assumed, without taking into account responsive behaviour, the analyses can be faulty[33]. Hence, another governance problem would be to also assess potential responsive behaviour when implementing countermeasures.

It is argued by Stern and Weiner that risk being a combination of probability and severity, low probability cannot be considered sufficient reason to neglect a potentially severe consequence risk. Even if the probability of a bioterrorism event is low, the "dread risk" is high as such events cause larger distress in the population than e.g. individual deaths occurring from car accidents[34]. Policies must address this issue and weigh the risk of bioterrorism depending on severity assessments especially.

Policy-makers should also maintain a perspective of relative dangers. History shows that biological warfare, terrorism and crime have caused fewer casualties than conventional weapons. Small-scale biological attacks are considered more likely, and a challenge for governments is to "…put relative dangers in proper perspective and yet still hedge against future eventualities that are unlikely, but possible."[35] Governments have a responsibility to also prevent, protect and respond to unlikely incidents, which proves challenging in terms of weighing efforts against more probable events to less likely (and possibly more complex) ones[36].

It is also argued that "…every protective intervention—military, regulatory or medical— also runs the risk of causing new harms. Precautionary regulation can transfer risks to new populations, substitute new risks for old ones in the same population, or both…"[37] This aspect should be taken into consideration for governance and policies.

Based on twelve case studies, Tucker argues that the use of biological (or chemical) weapons by non-state actors is a diverse phenomenon and it is difficult to identify trends and conclusions from the few cases that have occurred. Through summarising and comparing various parameters across the case studies, namely case,

[32] ibid
[33] Stern, J. and Weiner, J.B (2006), p.416
[34] ibid
[35] Parachini (2001), pp.10-11
[36] ibid p.12
[37] Stern, J. and Weiner, J.B (2006), p. 427

motivation/objective, ideology, target(s), agent(s), delivery and outcome[38] Tucker identifies some broad trends and characteristics of terrorists' acquisition or use of CBWs.

Tucker concludes that:

Since policymakers cannot count on prevention alone, they must deploy a multi-layered approach to counterterrorism in which efforts to profile and monitor those terrorists deemed most likely to acquire and use CBW agents are backed up with mitigation measures in the event of an unexpected attack.[39]

Furthermore, public health and consequence-management activities can be informed by historical analyses of elements like the choice of agent and delivery systems[40].

In a review based on the terrorist actions of Aum Shinrikyo in Japan in the 1990s, Tu recommends lessons learnt after the incidents for preparing for biological and chemical terrorism: he states that active prevention should be done in the form of implementing export controls of precursors, and that sale, possession and manufacture of biological and chemical weapons should be forbidden. He also suggests post incident measures in the form of identifying the agent, decontamination, neutralisation and prevention of further damage. For biological agents it is crucial to determine which sort of agent it is. Furthermore rescue of victims, training of rescue workers, counter terrorist action and stockpiling of drugs and equipment is recommended[41].

Researchers also conclude that

An efficient biological preparedness and response requires close collaboration between the human and veterinary medical fields, practitioners, public health, first responders, police and researchers as well as policy- and decision makers within ministries and directorates[42].

Furthermore, it is claimed that efficient medical alert systems are required as well as emergency support systems, detection and identification capabilities and multi-disciplinary training with involved actors[43]. It is also recommended to support non-proliferation initiatives, reinforce normative prohibition, enhance global health monitoring, establish registries of dangerous pathogen locations and strengthen international legal regimes to also include non-state actors[44]. This shows the complexity of handling intentionally caused outbreaks.

From the section above we see that non-state actors' use of biological agents and weapons is considered as a threat to societies. Assessing this threat and implementing knowledge-based policies for prevention,

[38] See Tucker, J.B. (ed.) (2000), pp.250-251
[39] Tucker (2000) pp.268-269
[40] ibid
[41] Tu, A.A. (2002), pp. 227-235
[42] Blatny, J.M.; Lausund, P.L. (2012), p.6
[43] ibid
[44] Parachini (2001), pp.13-16

preparedness and recovery is considered wise, but there are several complex areas to consider before a solution should be selected.

4.1.2. State actors

Modern bioweapons were originally developed by state military research projects as seen in the historical overview. It is widely believed that several states still possess bioweapons or have bioweapon programmes.

According to an overview of countries involved in bioweapons development, the USA, Russia, Iraq, Iran, Syria, Egypt, Libya, Israel, North Korea, China and South-Africa are discussed. However, few of these countries currently have confirmed stocks or programmes. In the USA, all anti-personnel biological weapons agent stocks and munitions were destroyed, and all offensive research was terminated by 1972. This unilateral disarmament process set the stage for the 1972 Biological and Toxins Weapons convention (BWC)[45] which is discussed later in this report.

In Russia and the former Soviet Union, it was assessed that they had BW R&D programmes quite parallel to the USA. After the fall of the Soviet Union, Russia made commitments to implement the BWC and disarm its BW programme. However, there are several uncertainties surrounding BW facilities and actual implementation in Russia[46].

Furthermore, when Vladimir Putin resumed the presidency in 2012, he had developed 28 tasks to be undertaken by his new administration, whereof number 4 on the list called for "…the development of weapons based on new physical principles: radiation, geophysical, wave, genetic, psychophysical etc." The task was removed after release of the list, but due to Russia's history with BW, it was recommended that the other parties in BWC take action to consult Russia about clarifying the task. There are no signs that Russia intends to scale back on biological institutes once involved in the Soviet BW programme or destroy culture collections and recipes[47].

Iraq signed the BWC in 1972 and ratified it in 1991. UN inspections after the Gulf War revealed work on BW facilities, where Iraq mass-produced several agents and had created an arsenal of BWs. In 1995 Iraq claimed to have destroyed all its stockpiles, but this was not confirmed by the United Nations Special Commission (UNSCOM). In Iran, there is no direct evidence of BW programmes or arsenals, but strong allegations that due to the technology and infrastructure possessed by Iran, the probability is high. However, this has not been verified by unclassified sources. Syria is also suspected to have developed BW stockpiles given their substantial CW arsenal. Although the US Department of Defence listed Syria as having an active BW programme in 2001, the evidence is ambiguous.

[45] Croddy, E. et al (2002), pp.30-31
[46] Croddy et al (2002) pp.34-35
[47] Zilinskas, R.A. (2012), p.850

It has been strongly alleged that Egypt had a BW programme with specific agents in the 1960s and 70s. Furthermore, Egypt's contact with Iraqi CBW experts in the 1980s and 90s led to suspicions of BW collaboration. Egypt has signed the BWC, and it was stated in 1980 that Egypt had never developed or produced BWs, but that they will not ratify the agreement before a wider regime covering all WMDs is created.

Libya is believed to be in the R&D phase of developing BWs, although it is seen as unlikely that they could develop a military capacity in the near future [this is the 2002 assessment which may be inaccurate at the time of writing due to the current political situation]. Israel is believed to have BWs, but little is known about the nature of their biological weaponry. Israel has not signed the BWC and is by some believed to have modelled their arsenals on those of the US and the former Soviet Union.

North Korea has signed and ratified BWC, but is believed to have a BW arsenal. Due to its closed nature, sources may be unreliable, but it is estimated that they do indeed have the technical capacity to develop BWs, including weaponry to spread biological agents, and that a BW programme has existed since the 1970s. For South Korea, no BW information is known. China signed the BWC in 1984, but it is uncertain if they still possess the programme they had before this. The Chinese deny any offensive BW programmes, and claim that the only research is defence-related.

After the apartheid regime was abolished in South Africa, testimonies before South Africa's Truth and Reconciliation Commission (TRC) revealed that BWs had been used by the government to murder political opponents, and that attempts had been made to develop a serum that would render black women infertile and a bacteria that would only kill or injure black people. These attempts failed, and there is no proof of ongoing BW programmes in South Africa[48].

It is stated that indiscriminate biological attacks have only been conducted by states in wartime, and in those instances the attacked state could not respond the attacks. States have historically been reluctant to use biological weapons, aside from assassinating regime opponents. There are considerable disincentives for states to use biological weapons, such as the risk of a clandestine attack being traced back with fear of devastating retaliation[49]. In addition, states will probably be conscious of the non-discriminatory effects of biological weapons which pose a risk to their own population or troops, such as in the 1979 Sverdlovsk incident. Attempts have been made to develop BWs that only affect target populations, such as in South Africa, or by vaccinating troops against known threats as in the American Revolutionary War, but such measures cannot be seen as completely secure and may also be even less accepted than general BW development.

In conclusion, no states have pronounced and transparent offensive biological weapons programmes, but it is assumed that certain capability, arsenals, research or stockpiles are held by several states. The BWC could

[48] Croddy, E. et al (2002), pp.36-58
[49] Parachini (2001), pp.4-5

largely prevent use of BW between states and in warfare, but a pronounced fear is sponsorship by states to non-state actors who are likely to use such weapons for their purposes. In addition, downscaling or termination of many state BW programmes since the 1970s has led to a significant amount of BW researchers being cut loose and possibly made available for non-state actors' BW capacity building. If strict control of culture collections and stockpiles still possessed by states is not upheld, these may too be available for acquisition by non-state actors wanting possession of such materials.

4.1.3. Mitigating dread effects of intentionally caused outbreaks

Another part of the literature to be taken into consideration is the psychological impacts of intentionally caused outbreaks, as the "dread risk" is one of the features distinguishing this from other risks.

Reasons for using biological agents as weapons can be manifold, such as covert assassinations or attacks, uninhibited spread of disease, targeting groups or populations vulnerable for a specific agent, breaking down public health systems or discredit a specific company or government. In addition, what could be spectacular and different about the spread of disease compared to conventional weapons is the fear and public outrage such an act would create. This is particularly an important feature for bioterrorism, as terrorists are not only interested in as many casualties as possible, but also in creating public fear and distrust in the target populations.

Governments should plan for addressing the public in the case of an intentionally caused outbreak. Information about the nature of the threat and recommendations for treatment, detection and transmission should be effectively disseminated. Such information can help people reduce health risks, limit adverse social and psychological effects and maintain trust and confidence in the official services. It can also help people take protective actions as well as reducing the level of disorder, morbidity and mortality[50].

It is recommended that experts' assessments and advice be taken into account for the public communication, and that addressing the issues openly and honestly will aid the continued trust in governmental and public institutions, keep people from making rash decisions and ease the handling of the people who may or may not be affected by the outbreak. If the fear and dread of the outbreak remains unaddressed, people will lose faith in the government and be prone to counteract government advice.

After the H1N1 pandemic, it was concluded that

> *Developments during the H1N1 threat seem to have shown that (a) democratic 'rules and routines' were bypassed, and (b) together with insufficient preplanning and concrete precautionary actions, the stress, and low transparency of democratic rules and routines, made civic society vulnerable to several types of attacks.*[51]

Indeed, this underpins the importance of communication before, during and after an event.

[50] Wray and Jupka (2004) p.214, Fischhoff et al (1993) pp.198-199, Becker (2004) p.205
[51] HEG Expert Group (2011)

4.2. Dual-use issues

It is stated by experts that "It is generally believed that biological threat agents can easily be acquired and produced due to "dual-use" technology"[52]. Dual-use research and technology refers to research and technology development (RTD) for civilian purposes that may also be relevant for military RTD or used by groups or individuals for malicious purposes.

The European Commission defines dual-use as follows:

> *Dual-use items are goods, software and technology normally used for civilian purposes but which may have military applications, or may contribute to the proliferation of Weapons of Mass Destruction (WMD)[53].*

Advances in biological sciences and large amounts of information about biological weapons being made publicly available over the past few years has made it possible for other state or non-state actors than those known to have BW programmes to develop bioweapons[54].

It is stated that "Today, technology needed for genetic engineering is available for purchase, also second-hand. This allows for the construction of synthetic genes and genetically modified cells in a hobbyist's basement or garage; so-called "do it yourself"-biology"[55]. This entails that designing biological threat agents is no longer reserved for highly skilled scientists, but also available for "grass-roots biohackers"[56]. These developments could mean that biological threat agents are more easily attainable for non-state malicious actors, and may further cause the threat and risk assessments for bioterrorism to rise to a higher level.

Dual-use technologies, other than dual-use precursors, can also obstruct investigation efforts as technology used for BW production could quickly be converted back to its original and inconspicuous form of use. "Much of the equipment, knowledge, technology and infrastructure required in agriculture and medicine can be put to peaceful uses as well as non-peaceful ones."[57] In other words, it could be difficult for investigators to prove the origins of agents causing intentionally caused outbreaks should there be a suspicion against actors and their whereabouts are known.

Dual-use technology and education may be impossible to avoid, and academics and researchers are encouraged to consider carefully which results should be published, e.g. about re-creation and genetic modification of known viruses[58].

An example of dual-use issues occurred in 2012 when virologists from the USA and the Netherlands published two articles about how the H5N1 virus could be mutated to be transmissible to – and between – mammals.

[52] FFI FACTS – Biological threat agents
[53] European Commission: dual-use controls
[54] Parachini (2001), p.3
[55] Blatny, J.M.; Lausund, P.L. (2012)
[56] ibid
[57] Croddy et al (2002), p.12
[58] FFI FOCUS (2012), The threat of bioterrorism: Identifying the unknown.

The development of the strain created fears that it might escape the laboratory and be used to cause an intentional outbreak, or that terrorists could start mutating viruses on their own with the knowledge. Before the publishing of the articles, the issues were debated amongst several stakeholders for eight months. However, the articles were published and all contents made freely available in the end. It is claimed that the articles could be beneficial for protectors of the world from an influenza pandemic, or for bioterrorists[59].

Whether or not to consider some research as restricted information if not relevant on a need-to-know basis for developing cures or for defence-related purposes is a very difficult tradeoff. The central tenants of transparency, discussion and debate upon which civilian scientific research is based do not support a restrictive view. Several researchers are told to prioritise publishing in open access journals for the research to be available not just to a limited audience, and to enable further advancement of the field worldwide based on their results. This is also the decision that was precedential in the decision to publish the H5N1 articles in 2012.

4.3. Assessing biological risks within and outside laboratories

This section presents an analysis of the local level of policies for laboratory security. The aim is to address prevention of the dispersal of biological materials in any form (non-proliferation of bioweapons and control of "dual-use" biological materials and technologies).

If a release from a laboratory were to occur, the significance of the leak and its consequences would depend upon the type of environment outside the laboratory and the national preparedness and response measures. It is necessary to take into account the health situation of the country, which can also impact upon the significance and consequences of a release, including: whether a population has been vaccinated against a specific type of risk; whether capacity exists for an effective government response; and the local population density, which will determine person to person transmissibility ratios.

4.3.1. Implementing an effective biorisk management system

Biorisk management systems, understood as a global approach, often involve a number of interconnected and complementary responses, taking advantage of different types of measures and requirements coming from international standards, international best practices and recommendations (such as WHO/OIE manuals), as well as laws and regulations (European or national), which deal with specific aspects of the risk both within and outside of laboratories, such as during the exchanges of pathogens between laboratories. For this reason it is mandatory to adopt a global approach, such as an integrated management system (IMS). This takes into account the different types of measures and requirements that have to be applied at the laboratory scale, considering not only the types of activities but also the strategic policy defined by the directorate, as well as for the activities that occur between laboratories.

[59] Tu, Michael (2012)

The first requirements of these quality management systems are:

Exhaustive traceability of the “resources” (that is to say personnel, premises, operations—which have to be conducted in compliance with validated methods—equipment and biological materials) are quite useful in sourcing accidental mistakes. These indicators could also be a powerful tool to identify as soon as possible a “deliberate” mistake—that is to say a malevolent act.
The competence of the staff. standards—such as **ISO/IEC 17025:2005**, with general requirements and **ISO 15189:2007**,dedicated to medical laboratories— take into account the traceability but also the competence of the staff (which is a real key point regarding biosafety and biosecurity.)
Good laboratory practices (GLP) outline the best practice for carrying out scientific studies. It describes how such studies should be organized and managed, taking into account test facilities, the study director and personnel aspects. They also deal with how studies are planned, controlled and recorded as well as how their results are disseminated and archived. There are two key themes in GLP: the importance of the reproducibility and reliability of scientific studies; and their traceability.
Testing and calibration laboratories. In an attempt to ensure the competence of such facilities, a series of international standards were developed. Accreditation under ISO/IEC 17025:2005 allows a laboratory to demonstrate that they have an effective quality management system, are technically qualified and competent and are able to generate technically valid results. Compliance with this standard also necessitates meeting relevant requirements of general quality management standards under **ISO 9001:2008** and **ISO 9002:1994.15**
Standard for biological resource centres: Biological resource centres (BRCs) are service providers and repositories of the living cells, genomes of organisms, and information relating to heredity and the functions of biological systems. BRCs contain collections of culturable organisms (e.g. micro-organisms, plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses cDNAs), viable but not yet culturable organisms cells and tissues, as well as data bases containing molecular, physiological and structural information relevant to these collections and related bioinformatics. According to the model developed under the **OECD Best Practice Guidelines for Biological Resource Centres**, BRCs should be accredited nationally to certify their competence. This also means that their activities are the responsibility of governments and that transfers of relevant biological materials are ultimately under government control. At a practical level the quality management system chosen by the OECD is ISO/IEC 17025:2005, which could be usefully complemented by the **Common Access to Biological Resources and Information (CABRI) guidelines**.

The complementarities of responses facing biorisks which are different in nature could be measures within laboratories regarding the five interconnected aspects of the operation of a BRC: personnel, premises, operations, equipment used and biological materials.

See also European committee for standardization workshop agreement (LWA)15793 "laboratory biorisk management standard)

4.3.2. Surveillance and assessment (early detection or awareness) by epidemiological methods

Well before any event, public health authorities must implement surveillance systems so that they can recognise patterns of non-specific symptoms that could indicate the early manifestations of a biological warfare attack. The system must be timely, sensitive, specific, and practical. Primarily, the surveillance activity will be around the following key elements.

Components include:

1. Harnessing data, which are considered to be epidemiologic clues of a possible biological warfare
    - Epidemiologic clues of a biologic warfare or terrorist attack
    - The occurrence of an epidemic with a similar disease or syndrome, especially in a discrete population
    - Many cases of unexplained diseases or deaths
    - More severe disease than is usually expected for a specific pathogen or failure to respond to standard therapy
    - Unusual routes of exposure to a pathogen, such as the inhalational route for diseases that normally occur through other exposures
    - A disease that is unusual for a given geographic area or transmission season
    - Disease normally transmitted by a vector that is not present in the local area
    - Multiple simultaneous or serial epidemics of different diseases in the same population
    - A single case of disease by an uncommon agent (smallpox, some viral hemorrhagic fevers)
    - A disease that is unusual for an age group
    - Unusual strains or variants of organisms, or antimicrobial resistance patterns different from those circulating
    - Similar genetic type among agents isolated from distinct sources at different times or locations
    - Higher attack rates in those exposed in certain areas, such as inside a building if released indoors, or
    - lower rates in those inside a sealed building if released outside
    - Disease outbreaks of the same illness occurring in non-contiguous areas
    - A disease outbreak with zoonotic impact (animal health)
    - Intelligence of a potential attack, claims by a terrorist or aggressor of a release, and discovery of munitions or tampering
    - Multiple disease entities in one patient, indicating that mixed agents have been used in the event

2. Verification, immunization, and confirmation
3. Initiation of appropriate prevention and control measures
4. Laboratory investigation for diagnosis and characterization/sensitivity of the biological organism.

The main role of the hospital-based clinical microbiology laboratory in support of a bio-threat, bio-crime, or act of bioterrorism is to “raise suspicion” when a targeted agent is suspected in a human specimen. It should be prepared to recognise and respond to a covert event involving the collection, preservation, transport, and testing of human specimens. Consequently, emergency medicine physicians and other primary healthcare providers, including the clinical microbiology laboratory staff, are the sentinels or medical first responders and will most likely identify the initial cases.

To be successful in this role, laboratory personnel, including the laboratory director, in conjunction with infection control and administrative personnel should develop both laboratory- and institution-wide response plans. These plans must include the following:

(i) Criteria for distinguishing the type of bioterrorism event;
(ii) Information regarding access to and utilization of the Laboratory Response Network, including diagnostic testing protocols;
(iii) Safety guidelines;
(iv) Communication and notification protocols; (v) criteria for the safe packaging and transport of infectious substances; and (vi) measures to increase laboratory security

Medical management (preventive, promotional, and curative services):

Administering chemo-prophylactic drugs to prevent the spread of the disease is essential. For undertaking such exercise, the following things will be required:

- Medicines and vaccine to be provided;
- the category of population to be given chemoprophylaxis/immune-prophylaxis identified;
- availability of the requisite quantity of drugs or vaccine; and outline of the mechanism of administration with health infrastructure

Dissemination (public safety and law enforcing agencies):

Training and education: Management of biological attacks has two critical elements:

- Warning networks such as hospitals and public health agencies
- Individual clinical expertise of medical personnel

Proper training of medical personnel, laboratory technicians, public health officials, epidemiologists, veterinary public health and emergency personnel is essential to a comprehensive detection, assessment, and response framework.

General public sensitisation: Preparedness and response capability, therefore, will rely heavily on effective information, dissemination, and communication. So, information should try to address issues to reduce public distress and simultaneously give the factual details to enable people to take appropriate decisions.

Additionaly, it was recommended by the HEG Expert Group after the H1N1 outbreak for democratic societies to "…enter into some kind of democratic, ethical, transparent and traceable process."[60] This entails also involving the citizens in communication (not only by conducting successful risk communication), to identify and operate new communication channels, to promote stable connections between citizens and specialised institutions and advocate for these connections.

[60] HEG Expert Group (2011)

5. Main Policy Documents

The main aim of this section is to identify and analyse the main policy documents regarding intentionally caused outbreaks. Chapter five is divided into different sections addressing the main policy documents, reflecting both international and national policies.

5.1. International agreements on Bioweapons

This section describes the most important international agreements relating to bioweapons and intentionally caused outbreaks. Many national and local policy documents are based on these agreements.

In the Hague Conventions of 1899 and 1907, the use of dangerous chemical agents was outlawed. In spite of this, the First World War saw large-scale chemical warfare and the start of the chemical arms race. Around 1.3 million casualties of the conflict were attributed to the use of gas and the psychological impact on troops may have had a much greater effect[61].

The Treaty of Versailles included some provisions that banned Germany from either manufacturing or importing chemical weapons. Similar treaties banned the other countries on the losing side from manufacturing or importing chemical weapons.

At the 1925 Geneva Conference for the Supervision of the International Traffic in Arms the French suggested a protocol for non-use of poisonous gases. The Second Polish Republic suggested the addition of bacteriological weapons. It was signed on 17 June[62].

5.1.1. The 1925 Geneva Protocol

The Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare, usually called the **1925 Geneva Protocol**, is a treaty prohibiting the use of chemical and biological weapons in international armed conflicts. It was signed in Geneva on 17 June 1925 and entered into force on 8 February 1928. The French government is the depository of this treaty. Thirty eight states originally signed the Protocol of which France was the first on 10 May 1926. Today, 138 states have ratified, acceded to, or succeeded to the Protocol[63].

It prohibits the use of "asphyxiating, poisonous or other gases, and of all analogous liquids, materials or devices" and "bacteriological methods of warfare". This is now understood to be a general prohibition on chemical weapons and biological weapons, but does not apply to their production, storage or transfer, nor to their use in situations other than war. Later treaties did cover some of these aspects: the 1972 Biological Weapons Convention (BWC) and the 1993 Chemical Weapons Convention (CWC).

[61] D. Hank Ellison (2007), pp. 567–570
[62] E. A. Croddy, J.J. Wirtz (2005), pp. 140–142
[63] Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (2014)

A number of countries submitted reservations when becoming parties to the Geneva Protocol, declaring that they only regarded the non-use obligations as applying to other parties and that these obligations would cease to apply if the prohibited weapons were used against them.

Moreover, several countries have deployed or prepared chemical weapons in spite of the treaty. Eric Croddy, assessing the Protocol in 2005[64], took the view that the historic record showed it had been largely ineffectual. Specifically it did not prohibit:

- Use against not-ratifying parties
- Retaliation using such weapons, so effectively making it a no-first-use agreement
- Use within a state's own borders in a civil conflict (in recent times, the protocol has been interpreted to cover internal conflicts as well international ones)
- Research and development of such weapons, or stockpiling them

Finally, The Geneva Protocol does not include an international verification mechanism. However, a number of resolutions taken by the General Assembly of the United Nations give the General Secretary the possibility to commit enquiries in cases of the non-respect suspicion[65].

5.1.2. The 1972 Biological Weapons Convention (BWC)

The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, commonly known as "the Biological Weapons Convention (BWC)" or "Biological and Toxin Weapons Convention (BTWC)"[66], opened for signature in 1972 and entered into force in 1975. The Convention prohibits the development, production, acquisition, transfer, retention, stockpiling and use of:

1. *Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;*
2. *Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.*

110 signatory states and 168 state parties are currently committed to the BWC[67].

The absence of any formal verification regime to monitor compliance has limited the effectiveness of the Convention. A long process of negotiation to add a verification mechanism began with the Second Review Conference in 1986. It agreed that the States Parties were to implement a number of confidence-building measures (CBM) in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions and in

[64] Eric A. Croddy, James J. Wirtz (2005), pp. 140–142
[65] United Nations, Disarmament office, Geneva Protocol
[66] The United Nations Office at Geneva- The biological weapons convention
[67] United Nations, Disarmament office (ONUDA)- The biological weapons convention

order to improve international co-operation in the field of peaceful biological activities. The CBMs were expanded by the Third Review Conference in 1991.

Under these agreements, the States Parties undertook to provide annual reports using agreed forms on specific activities related to the BWC including: data on research centres and laboratories; information on vaccine production facilities; information on national biological defence research and development programmes; declaration of past activities in offensive and/or defensive biological research and development programmes; information on outbreaks of infectious diseases and similar occurrences caused by toxins; publication of results and promotion of use of knowledge and contacts; information on legislation, regulations and other measures. The Sixth Review Conference in 2006 succeeded in comprehensively reviewing the Convention, adopting a final document by consensus[68].

In December 2013 France drafted a report on the pilot exercise illustrating the concept of a peer review mechanism in the framework of the BWC[69].

In order to fully implement the BWC, States Parties are obliged to translate the commitments found in the Convention into effective national action. The Seventh Review Conference called upon States Parties "to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation" to enhance domestic implementation and ensure the safety and security of microbial or other biological agents or toxins. Article IV of the Convention requires each State Party to

> *…take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere*[70].

To strengthen the implementation of Article IV, States Parties agreed upon the value of:

- Implementing voluntary management standards on biosafety and biosecurity
- Encouraging the promotion of awareness of obligations to the Convention as well as relevant national legislation amongst those working in the biological sciences and related professionals in the private and public sectors
- Encouraging the development of education programmes and voluntary codes of conduct to promote a culture of responsibility for those with access to biological agents and toxins relevant to the Convention
- Strengthening methods and capacities for surveillance and detection of outbreaks of disease at the national, regional and international levels[71]

[68] United Nations Office for disarmament affaires (UNODA) - The biological weapons convention
[69] Non paper proposed by France - Peer review pilot Exercise Paris, December 4-5-2013
[70] United Nations Office for disarmament affaires (UNODA) - The biological weapons convention - Implementation
[71] ibid

5.2. Countermeasures to respond to a biological threat

In this section, several policy documents from WHO, the United Nations, the EU, the Australia Group and ISO standards have been analysed with the aim to identify planned countermeasures to prevent, prepare for and address intentionally caused outbreaks.

5.2.1. WHO: World Health Organization

The approaches and methods used to prepare for, detect and respond to biological and chemical weapons use are very similar to those used for ordinary disease outbreaks.

This is why WHO has been closely involved in preparedness for any biological or chemical event: advising Member States, maintaining its reserve stock of vaccines for use as an emergency supply in the case of an outbreak, and working with countries to advocate investment in public health preparedness and response for disease outbreaks and public health emergencies.

Moreover in the 2002 Resolution at the World Health Assembly, countries have agreed to treat any deliberate use as a global public health threat, and to respond to such a threat by sharing expertise, supplies and resources in order rapidly to contain the event and mitigate its effects.

In addition to its documents on “preparedness and risk management in health emergency” and on “Pandemic influenza” WHO reissued and updated **a guidance manual** in 2004for countries on how to build up preparedness and respond to a possible biological or chemical attack : **Public health response to biological and chemical weapons**[72]**.**

WHO "*preparedness and risk management in health emergency*" actions help countries improve the management of health risks from all types of hazards and protect the health of their communities before, during and after emergencies. WHO also works on a process of strengthening preparedness and response capacities and capabilities at all levels – local, national, regional, and global.

The World Health Assembly adopted **a resolution on "Strengthening national health emergency and disaster management capacities and resilience of health systems"** in 2011[73]**.**

5.2.1.1. International Health Regulations IHR (2005)

The IHR is binding for 196 countries across the globe, including all the Member States of WHO[74]. States became Parties to the IHR with the purpose of preventing and controlling the international spread of adverse public health events, including epidemics. One of the key obligations of States Parties to the IHR is to develop

[72] WHO, deliberate epidemics
[73] WHO, 128th session
[74] From http://www.who.int/topics/international_health_regulations/en/

and maintain national core capacities for the detection, investigation, response and reporting of public health events within their territories[75].

Secondly, the work of WHO on *Pandemic influenza* provides guidance documents to inform and harmonise national and international preparedness and response to influenza pandemics, and supports countries in developing national pandemic preparedness plans though capacity building activities and simulation exercises.

5.2.1.2. WHO checklist for influenza pandemic preparedness planning (2005)

The aim of the pandemic preparedness checklist is primarily to provide an outline of the essential minimum elements of preparedness, as well as elements of preparedness that are considered desirable. Responsible authorities or institutes in countries that are in the process of planning should consider the specific aspects of the checklist for which they are responsible. Countries that already have a national pandemic preparedness plan in place may use the checklist to evaluate the completeness of the current plan[76].

5.2.1.3. WHO Pandemic influenza preparedness and response guidance document (2009)

WHO previously published pandemic preparedness guidance in 1999 and a revision of that guidance in 2005. Since 2005, there have been advances in many areas of preparedness and response planning. For example, stockpiles of antiviral drugs are now a reality and a WHO guideline has been developed to attempt to stop or delay pandemic influenza at its initial emergence. There is increased understanding of past pandemics, strengthened outbreak communications, greater insight on disease spread and approaches to control, and increasingly sophisticated statistical modelling of various aspects of influenza.

Extensive practical experience has been gained from responding to outbreaks of highly pathogenic avian influenza A (H5N1) virus infection in poultry and humans, and from conducting pandemic preparedness and response exercises in many countries. There is greater understanding that pandemic preparedness requires the involvement of not only the health sector, but the whole of society. In 2007, the International Health Regulations (IHR, 2005) entered into force providing the international community with a framework to address international public health concerns[77].

5.2.1.4. WHO Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (2011)

The aim of this document is to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system ("WHO GISRS"), with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing:

[75] WHO IHR emergency committee
[76] ibid
[77] WHO checklist

- The sharing of H5N1 and other influenza viruses with human pandemic potential; and
- Access to vaccines and sharing of other benefits[78].

WHO also published practical documents for governments such as:

- Whole of society pandemic readiness
- Considerations on exercises to validate pandemic preparedness plans
- Maintaining a Safe and Adequate Blood Supply during Pandemic Influenza
- Options for the design and financing of an H5N1 vaccine stockpile: key findings and study methodology
- WHO guidelines on the use of vaccines and antivirals during influenza pandemics[79]

5.2.1.5. WHO Pandemic Influenza Risk Management Interim guidance document (2013)

This WHO guidance document updates and replaces the *Pandemic Influenza Preparedness and Response guidance document* published in 2009. This revision of the guidance takes account of lessons learnt from the influenza A (H1N1) 2009 pandemic and of other relevant developments.

The experience of Member States during the pandemic varied, yet several common factors emerged. Member States had prepared for a pandemic of high severity and appeared unable to adapt their national and subnational responses adequately to a more moderate event. Communications were also demonstrated to be of immense importance: the need to provide clear risk assessments to decision-makers placed significant strain on ministries of health; and effective communication with the public was challenging. These, and other areas with improvement potential, were identified by the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009.

The approach taken in this 2013 guidance applies the principles of all-hazards emergency risk management for health (ERMH) to pandemic influenza risk management. The objectives of emergency risk management for health are to:

- Strengthen capacities to manage the health risks from all hazards;
- Embed comprehensive emergency risk management in the health sector;
- Enable and promote multi-sectorial linkage and integration across the whole-of-government and the whole-of-society[80].

[78] WHO Influenza framework
[79] WHO pandemic preparedness
[80] WHO, influenza risk management

5.2.2. The United Nations

5.2.2.1. The United Nations plan of action on disaster risk reduction for resilience

This plan of action presents a strategy for integrating disaster risk reduction into UN country level operations. It is intended to all partners committed to reducing the risks that disasters pose and making our societies more resilient. It aims to position the work of the UN in the context of:

(i) The remaining term of the Hyogo Framework for Action (HFA);
(ii) the development of a successor or post-2015 framework for disaster risk reduction (HFA2);
(iii) the post-2015 development agenda; and
(iv) the UN Secretary-General's second mandate and Five-Year Action Agenda.

The plan of action outlines the purpose, a set of core commitments and actions, a shared approach to measure impact and progress, and steps for implementation. It also embraces the international momentum to use "resilience" as a common outcome that integrates poverty reduction, disaster risk reduction, sustainable livelihoods and climate change adaptation, as integral to sustainable development[81]. This plan is not specific for disease outbreaks, but is relevant for the overall international management of disasters including intentionally caused outbreaks.

5.2.2.2. Hyogo Framework for action 2005-2015

The Hyogo Framework for Action (HFA) is a 10 year plan which was endorsed by the UN General Assembly in the Resolution A/RES/60/195 following the 2005 World Disaster Reduction Conference. The HFA is the first plan to explain, describe and detail the work that is required from all different sectors and actors to reduce disaster losses. It was developed and agreed on with the many partners needed to reduce disaster risk; governments, international agencies, disaster experts and many others, bringing them into a common system of coordination. The HFA outlines five priorities for action, and offers guiding principles and practical means for achieving disaster resilience. Its goal is to substantially reduce disaster losses by 2015 by building the resilience of nations and communities to disasters. This means reducing loss of lives and social, economic, and environmental assets when hazards strike[82]. This is also an overarching plan spanning multiple areas, but also relevant for intentionally caused outbreaks related disasters.

5.2.3. Europe

Several initiatives for health surveillance, non-proliferation, secure research and common policies are ongoing in the European Union (EU). In 2001, the European Council established the Health Security Committee (HSC) to focus on preparedness and response for influenza, CBRN and public health emergencies. In addition, the

[81] Preventionweb actionplan
[82] UNISDR

Early Warning and Response System (EWRS) connect the EC to public health authorities in member states, including the ECC states, and the European Centre for Disease Prevention and Control (ECDC)[83].

In 2004, the European Council released Resolution 1367 "Bioterrorism: A serious threat for citizen's health", in which the threat was acknowledged and initiatives started. The resolution calls for member states to inform the public about bioterrorism, make national threat assessments, devise emergency plans and test them, provide responders with appropriate training, promote disease studies, frame a vaccination policy, introduce strict procedures for purchase and movement of dangerous substances and strict control of activities based on modern biotechnologies. It also invites states to accede to international counterterrorism initiatives and to implement the CWC and BWC[84].

Furthermore, the resolution welcomed the establishment of the ECDC. The ECDC is an EU agency established in 2005 with the aim to strengthen Europe's defences against infectious diseases. The mission of ECDC is to "…identify, assess and communicate current and emerging threats to human health posed by infectious diseases"[85]. The mission is achieved by working partnerships with national public health systems in Europe to develop and strengthen disease surveillance and early-warning systems. This way it also gathers a network of experts to develop scientific opinions about the risk posed by infectious diseases.

The ECDC publishes a scientific journal, Eurosurveillance, which covers epidemiology, surveillance, prevention and control of communicable diseases of relevance to Europe. The journal is published weekly, with several different features, and also covers short papers on ongoing health events or outbreaks when occurring[86]. The journal has a broad reading group, and can be considered an arena for disease communication.

The EC has also established the Emergency Response Coordination Centre (ERCC) [previously the Monitoring and Information Centre (MIC)] to support and coordinate swift responses to disasters, including surveillance, monitoring, planning, deployment and mapping. The ERCC is also active in supporting prevention and preparedness activities, and has resources in 31 countries in the Civil Protection Mechanism[87].

The EC has released a series of communications to establish its strategy against bioterrorism, whereof the most important is the Green Paper on Bio-Preparedness released in 2007. The Green Paper established a discussion between relevant stakeholders, and brought forward the relevance of close collaboration internationally, nationally and between research, public health and industry and an all-hazards approach[88]. The green paper is not legally binding, but has been relevant for policymaking and legal work since 2007.

[83] European Commission (2009), memo/09/363
[84] Council of Europe (2004), Resolution 1367
[85] European Centre for Disease Prevention and Control
[86] Eurosurveillance
[87] European Commission, Humanitarian aid and civil protection, Emergency Response Coordination Centre (ERCC)
[88] Commission of the European Communities (2007)

5.2.4. The Australia Group

The Australia Group (AG) is an international forum discussing harmonisation of export controls to ensure that exports do not contribute to the development of biological (or chemical) weapons. The AG coordinates national export control measures to assist participants in fulfilling their obligations under the CWC and BWC[89].

The informal forum consists of 42 member states, all of which are parties to the CWC and BWC. The forum does not create legally binding obligations, but helps the member states reduce the risk of chemical and biological exports being used in - or as - weapons.

5.2.5. Standards

Relevant standards for setting up quality management systems do exist: standards to coordinate activities to direct and control an organisation with regards to quality (**IS0 9001:2008**), standards for environmental management systems (**ISO 14001:2004**), and standards for health and safety management systems (**OHSAS 18001).** Those standards which are used to control safety of drugs, food and water from biological agents and toxins constitute useful tools to reduce the opportunity of an intentionally caused outbreak, find the contamination source and limit its propagation.

5.3. Examples of national policies

5.3.1. France

In France, programmes were set up from 1980 by the general secretary of National Defence[90]. However, the Anthrax episode in USA in 2001 marked a decisive step towards the real consideration of the bioterrorism risk worldwide[91]. The following years numerous national plans for rescue were set up in order to coordinate the different institutions and organisms which could intervene on the national territory.

National plans: The 2010 National Resources Defence Council (NRDC) Governmental Plan aims to deliver decision making assistance to the Prime Minister in case of an attack using NRBC (nuclear, radiological, biological or chemical) materials. This plan offers an adapted answer to each of the six generic situations identified in internal security, civil security, human sanitary security, vegetal and animal sanitary security, all ending up directly or indirectly to threats concerning human health. The regional Prefects[92] are in charge of implementing this plan on a regional level[93]. A methodological guide has been annexed to this memorandum and offers an inter-ministerial territorial plan integrating the Vigipirate plan, ORSEC, PRBC plans and animal and vegetal health departmental emergency plans.

[89] Australia Group
[90] Binder P, Brucker G, Berche P.(2007), pp.1005-1018
[91] Buisson Y, Cavallo JD, Kowalski JJ, Renaudeau C, Treguier JY.(2004) p.300
[92] State representatives in a department/region in France
[93] Circulaire du ministère de l'intérieur no NOR/IOC/A/11/04281/C, 2011

The Vigipirate plan is a governmental plan under the Prime Minister, involving all the ministries. It is a central tool for the French measures to fight terrorism. This vigilance prevention and protection measure is applied in France and abroad and involves all the actors of the country: State, local authorities and citizens. It is supported by permanent measures which apply to all fields of activities (transport, health, energy networks, information systems security and the like)[94].

ORSEC (Organisation de la réponse de sécurité civile) plan: The plan is designed to mobilise and coordinate, under the authority of the regional Prefects, the actors of the civil security in order to set up a permanent and unique operational organisation to manage events critically affecting the population. This operational measure plans general steps for the management of all kinds of events, and specific steps to take for identified risks and threats[95].

The "suspects parcel and letters" plan was set up in 2001 and is applied to all letters, parcels and other material, when a radioactive, biological or chemical danger is suspected. It is a support to operational decisions, adapted to the type of alert signalled, preventing disproportionate use of means. The central point of this measure is the "National advising cell" (CNC), placed under the responsibility of the civil security and defence director, within the COGIC (Centre Operational de gestion interministériel des crises). Its mission is to help and advise the Prefect of the concerned department on the best conduct to adopt after discovery of a suspect parcel or letter.

Several inter-ministerial memorandums, for example the n°747 of 2009 on prevention and answer to bioterrorism risk, exist for these purposes.

The *General Secretary of defence and national security* (SGDSN) is in charge of ensuring coherence and complementarity of different ministries' contributions. Therefore, it is defining the general strategy and organising intervention principles in case of an attack

Surveillance: Alongside traditional surveillance systems used in public health, France has set up real-time syndrome surveillance systems. However, these systems proved that they were not working soon enough, because they needed a large scale event. Cases of West Nile or SARS coronaviruses were reported by biologists and clinicians, as it is compulsory in the French 2004 law on public health[96], without being detected by the syndrome surveillance system[97]. It appears that a specific surveillance of disease involving pathogens which could be used for bioterrorism, and better knowledge of the symptoms are a better way of detection, as these diseases are rare in France.

In France the death and emergencies sanitary surveillance system (SurSaUD) developed by the Sanitary Watch Institute (InVS) covers 50 % of the activity in emergency services participating in the network of emergencies

[94] Vigipirate plan
[95] Le-Plan-ORSEC
[96] Loi d'Orientation de Santé Publique, 9 août 2004.
[97] Kman NE, Bachmann MJ. (2012).

coordinated surveillance organisation (OSCOUR), 90 % of the "SOS medicine" activity and 80 % of daily public death.

New surveillance systems are being developed using the Internet, taking into account data like scholar absenteeism, emergency calls, drug consumption and the number of ambulance emergency responses.

Laboratory networks (réseau national des laboratoires Biotox-Piratox): Laboratories competent in the NRBC field and environmental toxicology were mapped, resulting in the cartography of technical capacities within the 12 defence zones of France. An organisation was set up in 2009[98] in order to coordinate biological and human toxicology laboratories on one part and chemical, toxicological and environmental biology on the other part. Those two laboratory groups rank in three levels of expertise and have been inspired from the American organisation Center for disease control and prevention (CDC).

5.3.2. The United States of America (USA)

In the USA, legislation concerning bioterrorism constitutes main parts of the basis for policy. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) consists of five titles; I. National Preparedness for Bioterrorism and Other Public Health Emergencies, II. Enhancing Controls on Dangerous Biological Agents and Toxins, III. Protecting Safety and Security of Food and Drug Supply, IV. Drinking Water Security and Safety and V. Additional Provisions[99]. The Bioterrorism Act is an act "To improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies"[100].

The Act includes a vast framework for all involved sectors regarding prevention, preparedness and response to intentionally caused outbreaks.

As previously mentioned, the White House Office of Science and Technology Policy administers a website to "…inform the public and the academic and private sector research communities about government policies related to the safe and secure conduct of biological research and the technologies arising out of the application of the life sciences."[101] This site summarises the main areas of concern to the US and briefly explains areas surrounding biosecurity. All of the USAs main strategies are also summarised on this website, namely[102]:

- HSPD - 4/NSPD-17: National Strategy to Combat Weapons of Mass Destruction (2002): Calls for a strategy to comprehensively counter the WMD threat based on strengthening counter-proliferation, non-proliferation, and consequence management. Also included are enabling functions that need be pursued on a priority basis: intelligence collection and analysis on WMD, delivery system technology,

[98] Note n°153/SGDSN/PSE/PPS, 24 fevrier 2009.
[99] FDA, Bioterrorism Act of 2002
[100] Bioterrorism act, Title I
[101] The White House Office of Science and Technology Policy, Biosecurity
[102] All strategy descriptions are collected from The White House Office of Science and Technology Policy

research and development on response to evolving threats; bilateral and multilateral cooperation; and targeted strategies against hostile states and terrorists.

- National Defence Strategy of the United States of America (2005): Employs an active, layered approach to the defence of the nation and seeks to create conditions conducive to respect of sovereignty and a secure international order. This strategy promotes close cooperation with others entities around the world committed to these goals while addressing old and emerging threats.
- National Strategy for Combating Terrorism (2006): This comprehensive approach addresses WMD terrorism and focuses on: determining terrorist intentions, denying access to materials and expertise, deterrence, disrupting attempted movement of WMD-related materials, prevention, response, and attribution.
- National Strategy for Countering Biological Threats (2009): Presidential Policy Directive 2 highlights the beneficial nature of advances in the life sciences and their importance in combating infectious diseases of natural, accidental, and deliberate origin. It also outlines how the risks associated with misuse and potential consequences of a biological attack require tailored actions to prevent biological threats. The strategy puts emphasis on promoting global health security, reinforcing norms of responsible conduct, reducing potential for exploitation, strengthening attribution, and utilizing communication and education domestically and abroad[103].

5.3.3. The United Kingdom (UK)

Since 2010, the UK has had a national strategy for countering CBRN terrorism. This strategy focuses on terrorism only, with the principles of the UK counterterrorism strategy CONTEST: Prevent, pursue, protect and prepare. The strategy is based on the CBRN threat to the UK, and the strategic objectives are mainly related to "pursue, protect and prepare". The main objectives are to stop terrorists from carrying out an attack, deny access to CBRN materials, reduce vulnerability to a CBRN attack and respond promptly and effectively to a CBRN attack as well as recovering as quickly as possible. The strategy is carried out in a collaborative manner between governance bodies, science and technology, academia, industry and international collaboration[104]. The strategy is currently under revision based on findings and lessons learnt in the time between 2010 and 2014.

The UK also has a strategy for non-proliferation, and also – more specifically – a programme for biological non-proliferation aimed at addressing proliferation risks in the biological sciences[105]. This programme additionally aims to promote and adopt the BWC, secure and account for biological materials, protect facilities that contain biological material and make efforts to minimise holdings of threat agents.

The UK Government organises biological and CBRN work under different ministries; Public Health England (PHE) is under the Ministry of Health and is responsible for protecting the nation's health and preparing for

[103] More information on http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf
[104] HM Government (2010)
[105] Department of Energy & Climate Change

public health emergencies[106]. PHE releases weekly reports about notifiable diseases and causative agents, which is a part of health surveillance[107]. In the UK strategy, the National Network of Laboratories (NNL) is mentioned as a cross-sectional approach that can be activated in different locations when needed. For other scientific or response support, the Defence Science & Technology Laboratory (DSTL)[108], the Government Decontamination Service (GDS)[109] and the Police National CBRN Centre[110] can be involved in suspected intentionally caused outbreaks.

The UK is a party to the BWC, and rid themselves of all stockpiles in the 1970s. The UK is also involved in European policy collaborations about bioterrorism and intentionally caused outbreaks (see section about Europe), as well as NATO, G8 and UN initiatives[111].

5.4 Final remarks on main policy documents

When looking at the main existing policy documents, very few of them take into account the effect or use of social networks. It has been admitted that a bioterrorism threat can do much harm to a country whilst costing nothing to its perpetrator, as a bioterrorism act.

> *The radius of fear generated by a terrorist attack far exceeds the zone of injury and death. It is a form of psychological warfare whose goal is to bolster the morale of its supporters, and demoralize and frighten its target audience—victims and their sympathizers.*[112]

Social networks would often be the first mean used for this. Moreover, when managing biorisk, the influence of social networks can determine the outcome in terms of population cooperation.

[106] PHE
[107] PHE, NOID reports
[108] DSTL CBRN research
[109] GDS
[110] PNCBRN
[111] Foreign & Commonwealth Office, Countering Weapons Proliferation
[112] Stern, J. and Weiner, J.B (2006), p. 414

6. Taxonomy of the Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies

The Oxford Dictionary describes a taxonomy as "The branch of science concerned with classification, especially of organisms; systematics."[113] A taxonomy is usually hierarchically structured with top-down relationships and classification under main thematic branches. For this purpose it is suggested to organise the taxonomy more associative, as a categorisation of main governance problems.

Based on the theory that the problems identified in the literature may have consequences for the identified entities if not addressed, we have collected and categorised potential governance problems into main categories and affected areas of society. The taxonomy has been deductively divided into the main categories "International" and "National" to reflect the different levels of governance problems. Furthermore, the two categories are divided into the governance problems stated in the main task of the report.

The classification of issue areas has been divided into inductive categories for involved societal entities or specific issue areas for governance bodies. This division was done to indicate which areas the problem in question would affect and has the most relevance for. The reason for the inclusion of the columns containing societal entities or issue areas was based on our overall approach trying to categorise the main governance problems as much as possible. The theory that a problem will affect one or more areas has been applied to the problems identified and thus may help to get the structure of the taxonomy more oversightly. The taxonomy is associative, and could also include more or less categories depending on specific interest areas. For this purpose we have included the inductive categories seen most relevant after the literature review and the context of the ASSET Project.

In order to include as many aspects in the classification as possible, some problems in different categories may be similar or partly overlapping. The complexity of intentionally caused outbreaks makes this an inherent feature, and similar problems may occur for different categories. Particularly, international and national problems may be interdependent and not mutually exclusive.

First we describe the main governance problems with a qualitative approach based on the documents analysed above. These analyses will be used as a base for the classification of issues in the taxonomic presentation of governance problems in the table below.

6.1. Main governance problems posed by the risk of Intentionally Caused Outbreaks in democratic societies

In this section, the background for the final taxonomy is established on the basis of the previous sections. The analysis of the history, state of the art and policy documents concerning intentionally caused outbreaks is here briefly summarised under the related governance problems.

[113] Oxford Dictionary

6.1.1. The tension between secrecy and transparency

This category consists of problems related to state BW programmes, international agreements with vague repercussions and loose implementation, dual-use research, stockpiles, biological agents' reservoirs and public communication.

Several countries do not have policy documents regarding intentionally caused outbreaks. It is most probably assumed that such outbreaks will be handled under regular frameworks for outbreaks in the health sector, and that law enforcement will be involved on an ad-hoc basis if necessary. This is a major issue in order to determine the nature of – and response to – an intentionally caused outbreak. Many medical health care providers are not familiar with the symptoms caused by bioterrorism agents, and may have problems identifying an intentionally caused outbreak and report this.

Many of the states assumed to have biological weapons programmes deny these allegations disregarding strong evidence. This may be due to strict regimes and fear of intervention, but the issue of states not complying –or refusing to sign – the BWC and other initiatives is a significant one. Another problem is that international legal regimes rarely include non-state actors, which is not in line with the threat assessments of recent years. However, another problem is to do threat assessments on the basis of empirical evidence, as it is difficult to identify trends and conclusions from past incidences.

When countermeasures are implemented, it is not always taken into consideration which potential behaviours can occur. Some actors may react responsively with adjusting or changing their focus to other target groups or methods, which can be difficult to predict, but fatal to ignore. The risks of bioterrorism are often calculated on likelihood and consequences, and both areas may be reduced with certain measures, but the measures should not increase other risk factors. In addition, the expertise in decision-making processes is often not satisfactory due to e.g. the relationship between sciences and law enforcement.

If an intentional outbreak is suspected, governments may hold information back from the public, which is also a major problem area. Communication is essential in order to handle the outbreak and keep the public's trust. Governments' plans for addressing the public in case of an intentionally caused outbreak are not standardised.

The issue of communication and transparency is recurring both under this point and under the next point dealing with freedom of research and security. In the context of tension between secrecy and transparency, it is relevant to consider this in the context of responsible research and innovation (RRI), which aims to align research and innovation to the values, needs and expectations of the society. A compromise between secrecy and transparency is necessary to fulfil the process of RRI and to avoid making society more vulnerable to attacks in the context of intentionally caused outbreaks. The considerations of the HEG Expert Group (point 4.1.3) would indicate that communication is of great importance in both the preparedness and the response phase of an incident, and that transparency without compromising i.e. weaknesses that should be held confidential is needed. A balanced compromise between secrecy and transparency is strongly adviced in order

not to make society even more vulnerable to threats of intentionally caused outbreaks. This discussion is also related to the following points about main governance problems.

6.1.2. Freedom of research and security

This category involves dual-use issues, movements of agents and equipment, laboratory safety and security and the security of the public.

As seen from the above analysis, the freedom of research can be a two-edged sword. Research contributing to the publications and release of material that can aid malicious actors to obtain or produce agents suitable for intentionally caused outbreaks can be a threat to societies. It is claimed that advances in laboratory technology has made BW development within reach for non-state actors. Large amounts of research about biological sciences are being published openly and may also aid actors in reaching their BW ambitions. The trade-off between public access to research and benefits for the community must be weighed before publishing.

The international norms against biological weapons are weak, and international efforts for biosecurity are not standardised. Global health monitoring is not seen as sufficient, and neither are global preparedness and response capabilities. It should also be taken into consideration that unaddressed natural outbreaks may also be exploited for malicious purposes.

Another problem area is what happens to BW researchers that are cut loose from their previous positions in developing BWs when such programmes are discontinued. These individuals constitute an asset for actors pursuing BW development, and are in a similar category as poor protection of culture collections and stockpiles. There are also few export controls of precursors, and sale, manufacture and possession of BWs are not explicitly forbidden in all states.

The major issue in this category is the lack of collaboration between relevant fields: human and veterinary medical fields, practitioners, public health, first responders, researchers, and policy- and decision makers. Without sufficient communication and collaboration between the fields, it is difficult to create well founded and multidisciplinary policies covering all problem areas for intentionally caused outbreaks.

6.1.3. Citizen involvement

This category relates to the protection of citizens, their say in decision-making processes, involvement in prevention, preparedness, response and recovery as well as public communication aspects.

Policy-makers often decide on which level they will protect citizens, with only basic knowledge of what the citizens actually require. It is a problem for governance taking into account experts' advice that the experts' opinion may differ from the public opinion in many cases.

Within the citizen realm, it may be that malevolent actors can commit clandestine attacks that are confused with natural outbreaks due to the delayed impact of certain agents. Hence, it is important that citizens are

alert and aware of the risks and signs of bioterrorism. However, communicating the risks must be done in a balanced way in order not to create unnecessary fear. Even a hoax could instil widespread fear among the public, and suspected hoaxes should be addresses swiftly. Addressing bioterrorism needs a factual basis, and sometimes experts may explain complex matters too complicated for the general public understanding. Citizens' understanding of risk and threat may also differ significantly from opinions held by experts, which necessitates mutual understanding and dialogue about the issues as a preparatory action.

For addressing the public as soon as possible in a suspected or proven attack, efficient alert systems are required. This is also a requirement for being able to detect an attack, namely medical alert systems. However, as discussed, it is also necessary to communicate with a preparedness perspective in order to prepare the public for possible incidents and countermeasures, and also tak into account the citizens' view of the situation.

ASSET is a Mobilisation and Mutual Learning Action Plan (MMLAP) where one of the aims is to define and test a participatory and inclusive strategy to succeed. In this regard, it is natural to consider the aspects of the MMLAP in the context of intentionally caused outbreaks. Participatory and inclusive approaches may be disputed when a sensitive topic like biological attacks arise. However, there is general agreement that miscommunication should be avoided, and that to address the citizens one must know what they need. This cannot be done without consulting citizens, and address their perceptions about intentionally caused outbreaks. The MMLAP approach can be useful in order to include citizen perspectives and establish connections between citizens and specialised institutions to create a dialogue about intentionally caused outbreaks.

6.1.4. Experts' decisions

This category includes issues relating to expert involvement in policy, expert involvement that is required for decisions and complex problem areas not possible to solve without expert advice.

Experts in specific fields are often not included in policy-making. However, for a complex governance area like intentionally caused outbreaks, it is essential to take into account expert advice. As mentioned in the previous category, expert advice may not always be consistent with public opinion or citizen involvement. Clear and brief, but thorough, scientific advice is needed for the public to understand decisions and aid themselves and others in case of an intentional outbreak. However, experts do not necessarily share the understanding of bioterrorism, risks and threats, and definitions are not generally agreed upon or standardised.

An important matter for expert involvement is within detection, and it is widely agreed that detection and identification capabilities are lacking. Furthermore, many countries do not stockpile medication and equipment to handle an outbreak. Experts' decisions are necessary, and should preferably be aligned - and in consistence - with governance and citizens' needs.

6.2. Taxonomy

The columns in the taxonomy describe several issues within the below categories:

- International
  - The tension between secrecy and transparency
  - Freedom of research and security
  - Citizen involvement
  - Experts' decisions
- National
  - The tension between secrecy and transparency
  - Freedom of research and security
  - Citizen involvement
  - Experts' decisions

In the rows after the description of the specific governance problems, different features specifically important to consider for the particular problem are checked in boxes, namely:

- Medical services
- Infrastructure
- Public
- Law enforcement
- Industrial
- Communication
- Media
- Research
- Pharmaceutical

These features mainly consist of societal entities or issue areas that could be affected by the problem in question and should be included in any mitigation. Governance bodies are intrinsic in the "governance problems" approach and hence relevant for all problems.

Based on the analysis in this report, we found that areas mainly affected or very relevant in some problems are medical services (care for the affected, testing, treatment etc.), infrastructure (vulnerabilities, importance for response etc.), public (information, collaboration, cooperation etc.), law enforcement (investigation, forensics, prevention etc.), industrial (dual-use, safety, security etc.), communication (threat-, risk- and crisis communication etc.), media (transparency, communication/miscommunication channel etc.), research (secrecy/transparency, dual-use, laboratory etc.) and pharmaceutical (treatment needs, vulnerabilities, laboratory etc.). The categories may be guiding when using the document results, and take into consideration which areas are affected based on the theory that one or more societal features are particularly important when addressing the problem.

The main governance problems posed by the risk of intentionally caused outbreaks in democratic societies are listed in the taxonomy below:

Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies										
Scope of problem	**Problem area**	**Description**	**Medical services**	**Infrastructure**	**Public**	**Law enforcement**	**Industrial**	**Communication**	**Media**	**Research**	**Pharmaceutical**
International	**Tension between secrecy and transparency**	International legal regimes do not include non-state actors.			X	X		X		X	
International	**Tension between secrecy and transparency**	Several uncertainties surrounding BW facilities and implementation of the BWC in many countries.		X		X	X	X		X	
International	**Tension between secrecy and transparency**	Medical health care providers are not familiar with the symptoms caused by the defined bioterrorism agents, and do not have reporting systems to identify correlations and competence to determine whether the outbreak is intentional.	X	X				X			
International	**Tension between secrecy and transparency**	It is difficult to identify trends and conclusions from the few proven cases of intentional outbreaks that have occurred. This can make assessments and governance of the issues particularly complex.			X	X				X	
International	**Freedom of research and security**	Weak global norms againts biological weapons			X	X				X	
International	**Freedom of research and security**	International biosecurity efforts are not standardised, and there is need for an agreed upon “high-priority agents” list and establishing an international biosecurity convention.			X	X	X	X	X	X	

Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies											
Scope of problem	**Problem area**	**Description**	**Medical services**	**Infrastructure**	**Public**	**Law enforcement**	**Industrial**	**Communication**	**Media**	**Research**	**Pharmaceutical**
International	**Freedom of research and security**	Global health monitoring is not sufficient.	X	X	X			X		X	X
International	**Freedom of research and security**	Global preparedness and response capabilities need to be enhanced, including identifying public health as a key component of international security.	X	X	X	X				X	X
International	**Freedom of research and security**	Significant amount of BW researchers being cut loose and possibly made available for non-state actors' BW capacity building. If strict control of culture collections and stockpiles still possessed by states is not upheld, these may too be available for acquisition by non-state actors wanting possession of such materials.				X	X			X	
International	**Freedom of research and security**	Advances in biological sciences and large amounts of information about biological weapons being made publicly available over the past few years has made it possible for other state or non-state actors than those known to have BW programmes to develop bioweapons.		X		X	X		X	X	X
International	**Freedom of research and security**	Early and rapid identification of biological threat agents for medical diagnostics and treatment is lacking, and several identification techniques are needed in order to verify the biological agent.	X				X			X	

Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies											
Scope of problem	**Problem area**	**Description**	**Medical services**	**Infrastructure**	**Public**	**Law enforcement**	**Industrial**	**Communication**	**Media**	**Research**	**Pharmaceutical**
International	**Freedom of research and security**	Biological research information being made publicly available is a dual-use issue. The benefit for public health and reserach must be weighed against potential terrorist use, which is a difficult tradeoff.						X	X	X	X
International	**Freedom of research and security**	Natural disease outbreaks may be exploited for malicious purposes.	X	X	X	X				X	
International	**Freedom of research and security**	Biological materials – such as bacteria, viruses and toxins – are significantly cheaper and easier to produce, handle and transport than nuclear or chemical materials.		X		X	X				X
International	**Freedom of research and security**	Advances in laboratory technology brought the science for building a bioweapon within reach of terrorists and non-state actors.			X	X	X			X	
International	**Citizen involvement**	Biological threat agents may enable malevolent actors to commit clandestine attacks because the delayed impact can be confused with natural disease outbreaks.	X			X				X	
International	**Citizen involvement**	Even a hoax event can be an effective way of instilling widespread fear among the public.	X		X			X	X		
International	**Experts' decisions**	A common, accurate understanding of bioterrorism in not agreed upon.						X	X	X	

Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies										
Scope of problem	**Problem area**	**Description**	**Medical services**	**Infrastructure**	**Public**	**Law enforcement**	**Industrial**	**Communication**	**Media**	**Research**	**Pharmaceutical**
International	**Experts' decisions**	Worldwide detection and identification capabilities are lacking.		X		X	X			X	
International	**Experts' decisions**	Stockpiling of drugs and equipment for response is not done in all countries.	X	X							X
International	**Experts' decisions**	Definitions are not harmonised.						X	X	X	
International	**Experts' decisions**	An assessment of the historic record of the Geneva Protocol showed it had been largely ineffectual. Specifically it did not prohibit use against not-ratifying parties, retaliation using such weapons, use within a state's own borders in a civil conflict, research and development of such weapons, or stockpiling them. The Geneva Protocol also does not include an international verification mechanism.			X	X					
National	**Tension between secrecy and transparency**	Multilateral non-proliferation initiatives like the Geneva Protocol, the BWC and the Australia Group are not supported by all states.			X	X		X	X		
National	**Tension between secrecy and transparency**	Potential responsive behaviour is not always assessed when implementing countermeasures.			X					X	
National	**Tension between secrecy and transparency**	Weighing the risk of bioterrorism depending on severity assessments may be difficult to quantify.			X					X	

Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies											
Scope of problem	**Problem area**	**Description**	**Medical services**	**Infrastructure**	**Public**	**Law enforcement**	**Industrial**	**Communication**	**Media**	**Research**	**Pharmaceutical**
National	**Tension between secrecy and transparency**	The relationships between science and law enforcement communities to increase the expertise behind decision-making processes is not satisfactory.				X		X		X	
National	**Tension between secrecy and transparency**	Knowledge-based policies for prevention, preparedness, protection and recovery may be complicated and require much effort.			X					X	
National	**Tension between secrecy and transparency**	Governments' plans for addressing the public in the case of an intentionally caused outbreak are not standardised or clear. Information about the nature of the threat and recommendations for treatment, detection and transmission should be effectively disseminated, and thought of ahead of an incident.	X		X			X	X		
National	**Freedom of research and security**	Missing export controls of precursors. Sale, manufacture and possession of biological weapons is not forbidden.		X		X					X
National	**Freedom of research and security**	Lacking close collaboration between the human and veterinary medical fields, practitioners, public health, first responders, police and researchers as well as policy- and decision makers within ministries and directorates.	X		X	X	X	X		X	X

Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies										
Scope of problem	**Problem area**	**Description**	**Medical services**	**Infrastructure**	**Public**	**Law enforcement**	**Industrial**	**Communication**	**Media**	**Research**	**Pharmaceutical**
National	**Freedom of research and security**	If release from laboratory, the significance and consequences depend on environment outside the laboratory and national preparedness and response measures. An account must be given about the health situation of the country (vaccines, capacities for effective government response and local population density).	X	X							X
National	**Freedom of research and security**	Well before any event, public health authorities must implement surveillance systems so that they can recognize patterns of non-specific syndromes that could indicate the early manifestations of a biological warfare attack. The system must be timely, sensitive, specific, and practical. No such system exists today.	X	X	X	X	X	X		X	
National	**Citizen involvement**	Realistic, “dual-use” national bioterrorism response strategies are lacking.	X		X	X	X	X	X	X	
National	**Citizen involvement**	Danger of transfering risk to other population segments or change risks with protective interventions.		X	X						
National	**Citizen involvement**	Efficient medical alert systems.	X		X			x			
National	**Citizen involvement**	The importance of crisis communication is underestimated.		X	X			X	X		

Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies											
Scope of problem	**Problem area**	**Description**	**Medical services**	**Infrastructure**	**Public**	**Law enforcement**	**Industrial**	**Communication**	**Media**	**Research**	**Pharmaceutical**
National	**Citizen involvement**	Proper training of medical personnel, laboratory technicians, public health officials, epidemiologists, veterinary public health and emergency personnel is essential to a comprehensive detection, assessment, and response framework. This is currently not sufficient.	X		X			X		X	X
National	**Experts' decisions**	Taking into account experts' assessments and advice for public communication. Addressing the issues openly and honestly will aid the continued trust in governmental and public institutions, keep people from making rash decisions and ease the handling of the people who may or may not be affected by the outbreak. If the fear and dread of the outbreak remains unaddressed, people will lose faith in the government and be prone to counteract government advice.			X			X	X	X	
National	**Experts' decisions**	Difficult to keep perspective of relative dangers: Weigh efforts against more probable events to less likely events.			X						
National	**Experts' decisions**	A multi-layered approach to counterterrorism is lacking in most states.				X				X	
National	**Experts' decisions**	Using threat - and risk assessment models to determine the likelihood and consequences of								X	

Main Governance Problems Posed by the Risk of Intentionally Caused Outbreaks in Democratic Societies											
Scope of problem	**Problem area**	**Description**	**Medical services**	**Infrastructure**	**Public**	**Law enforcement**	**Industrial**	**Communication**	**Media**	**Research**	**Pharmaceutical**
		an attack.									
National	**Experts' decisions**	Public health and consequence-management activities can be informed by historical analyses of elements like the choice of agent and delivery systems, but this rarely taken into account.	X	X	X	X	X	X		X	
National	**Experts' decisions**	Low probability cannot be considered sufficient reason to neglect a potentially severe consequence risk.			X	X	X			X	

7. Conclusion

This report has given an overview of intentionally caused outbreaks by presenting a review and analysis of the history, current knowledge and main policy documents concerning intentionally caused outbreaks in democratic societies. Based on this analysis, a taxonomy classifying the main governance problems posed by the risk of intentionally caused outbreaks in democratic societies has been created and presented.

The taxonomy categorises governance problems under the categories “international” and “national”, as well as the main problem areas outlined in the DOW; tension between secrecy and transparency, freedom of research and security, citizen involvement and experts’ decisions. Furthermore, the categories “Medical services, Infrastructure, Public, Law enforcement, Industrial, Communication, Media, Research and Pharmaceutical” were added to make the taxonomy more readily understood. We have analysed the background material on the basis of the theory that the problems identified in the literature may have consequences for the identified entities if not addressed.

The main findings from the taxonomy concerning “the tension between secrecy and transparency” are problems related to state BW programmes, international agreements with vague repercussions and loose implementation, dual-use research, stockpiles, biological agents’ reservoirs and public communication. In “freedom of research and security”, problems mainly relate to dual-use issues, movements of agents and equipment, laboratory safety and security and the security of the public. “Citizen involvement” problems are mainly within the areas of protection of citizens, their say in decision-making processes, involvement in prevention, preparedness, response and recovery as well as public communication aspects. As for “experts’ decisions” the main governance problem areas lie within expert involvement in policy, expert involvement that is required for decisions and complex problem areas not possible to solve without expert advice and communicating complex areas to policy-makers and the public.

The taxonomy for governance problems for intentional and unintentional outbreaks contains some overlapping elements. These elements will be of importance for several levels of problem areas and involved societal entities, but in different ways and for different aspects of the somewhat same problem. Therefore, problems that may look quite identical in the taxonomy are important to mention, regardless, for more than one problem area due to different perspectives, roles and repercussions.

In this report, the focus has been on governance *problems*. An approach based on identifying problems may in fact be less complicated than a solution-oriented approach; however, identifying problems does not mean there are no solutions to these. These are problems that should be kept in mind while developing policies and good governance, but the overview of main policy documents does give some pointers to viable solutions and important focus areas that are already progressing. Governance problems may be more easily identified in current literature and research rather than existing policy documents that aim to address the problems. In other words, policy-makers do not necessarily have to come up with new solutions for all governance problems. It is important to address the problems identified, but equally important to keep working with solutions that can be furthered and broadened such as international regimes and agreements.

In order to include the issues identified in the report further in the ASSET project, the taxonomy may be used as a “checklist” for policy analysis in the field. It should also be noted that the taxonomy can be consulted before making the MMLAP in order to better define which areas to focus on in this field and to investigate which aspects from the taxonomy are most important to include. Policy makers dealing with intentionally caused outbreaks, CBRNe, bioterrorism and related subjects may also take interest in the results from this report.

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