"SYNTHETIC BIOLOGY AS A NEW THREAT TO BIOSECURITY. IS THERE A ROAD TO SUITABLE GOVERNANCE?"

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ABSTRACT: Synthetic biology, which is a new emerging technology aiming at re-writing existing biological systems and designing completely new parts and devices, brings several potential benefits, but at the same time it constitutes a new threat to biosecurity: for such "double Janus face", it can be considered as a "dual use research". Indeed, the risk that its theoretical discoveries and applications are handled by bioterrorists and used for malevolent purposes is not a mere hypothesis. Therefore, it is necessary to look for possible solutions for the governance of this type of risk. In order to try to achieve such purpose, the analysis focuses, first of all, on the overview of the existing regulations against bioterrorism. Then, these regulations are evaluated in the light of the constitutional frame of fundamental rights at stake (in the belief that any policy/regulation should take into account and be based on the respect of fundamental rights). Thirdly, the applicability of the existing regulatory framework to synthetic biology is checked. Fourthly, the different positions that have been proposed so far for addressing biosecurity risks in the area of synthetic biology are shown and put into comparison. Finally, the proposal of a model of governance, called of "prudent vigilance", is described.

KEY WORDS: Synthetic biology – biosecurity – bioterrorism – regulation -
Biología sintética – bioseguridad – bioterrorismo – regulación -

1. SYNTHETIC BIOLOGY: A TYPE OF "DUAL USE RESEARCH".

Biosecurity, meant as the whole set of measures and efforts that are to be taken and needed to prevent the creation of deadly pathogens for the purposes of bioterrorism[1], has become a central and challenging part of any global policy-making agenda in the 21st Century, due to the rapid advancement of science and technology. Among the threats to biosecurity, there is «*a game changing scientific development that transcends all in human history. It is already underway and it even has a name: synthetic biology*»[2]. With Watson's and Crick's discovery of double-helix structure of DNA, together with the studies of genetic engineering (focused on isolating a single gene and manipulating it), and the analysis of short and long pieces of DNA of many organisms (object of attention by molecular biology), the field of science has entered into a new era. It starts from the idea of looking at the whole genome of organisms and takes it a step further, going beyond the trying to understand and know the genome to the idea of manipulating it by the writing and re-writing the genome. Such a new "revolution" is known as synthetic biology, a discipline that - to put it provocatively - seems to be capable of realizing the ancient human dream of being able to create life and finding the answer to the mystery that is life. Briefly, it can be defined as a converging science and technology that aims at «*a) the design and construction of new biological parts (called "building blocks"),*

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[1] For this definition, see WORLD HEALTH ORGANIZATION (W.H.O.), *Biorisk Management: Laboratory Biosecurity Guidance,* Geneva, 2006, pp. 1-41; and ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (O.E.C.D.), "Best Practice Guidelines on Biosecurity for Biological Research Centers", *http://www.oecd.org/science/biotechnologypolicies/38778261.pdf,* 2007.

[2] SASSELOV, Dimitar D., "What will change everything?", *http://www.edge.org/response-detail/11143,* 2009.

scratched and put together in novel circuits, networks and systems (that are synthetic because they do not exist in the natural world), and b) the re-design of existing, natural biological systems for useful purposes»[3]. Beyond the potential applications, synthetic biology arises several risks, such as the biosecurity one[4]. Indeed, the possibility of creating synthetic viruses having harmful purposes for environment, human and animal health is not a mere hypothesis, but a concrete reality, especially following the events of the 11th September 2001[5]. This is demonstrated, for example, by the *de novo* synthesis of poliovirus[6] and of the 1918 Spanish flu[7]. These viruses could be handled by bioterrorists or by "lone operators", i.e. highly trained synthetic biologists with a grudge against someone or an organisation. Such individuals could be professional researchers that have access to lab equipments or "garage biologists"[8], belonging to the Do-It-Yourself movement (D.I.Y.)[9]. There is also the figure of "biohacker", who aims at creating virus «*out of curiosity or to show his technical prowess*»[10]. Indeed, the worry that synthetic biology could be used for creating new pathogens and viruses is amplified by information technology (IT), which provides open access to such information on the Internet, and by the lowering of prices for obtaining technological equipment. In addition, beside the risk of malevolent use of biological knowledge by bioterrorists, there is «*the concern that the knowledge output of synthetic biological research and development could be incorporated into the offensive bioweapons programs of Developed States*»[11]. Both these aspects give origin to the so-called "dual use dilemma"[12], i.e. the dilemma which arises when scientific knowledge could be used in both good and harmful ways, such as for civil purposes (e.g., drugs development, in medical treatment) and military purposes (e.g., in the production of bioweapons).The same dilemma occurred within nuclear fission

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[3] For this definition, see *http://www.syntheticbiology.org*. This website welcomes the activities of the synthetic biology community, set up by researchers from the Synthetic Biology Department and individuals from research laboratories at other institutions in the U.S.A., among which the Massachusetts Institute of Technology (M.I.T.) and Harvard University. The definition given by the mentioned community reflects the one given in 2003 by the Physical Biosciences Division at Lawrence Berkeley National Laboratory (L.B.N.L. or the Berkeley Lab), which established a Synthetic Biology Department with the claim that this was the world's first research facility in synthetic biology (*http://www.lbl.gov/pbd/synthbio/default.htm,* 2006). For a similar definition, see also the High-level Expert Group of European Commission, that labels synthetic biology as «*the engineering of biological components and systems that do not exist in nature and the re-engineering of existing biological elements*» (HIGH-LEVEL EXPERT GROUP OF EUROPEAN COMMISSION, "SYNBIOLOGY. An Analysis of Synthetic Biology Research in Europe and North America Final Report on Analysis of Synthetic Biology Sector", *http://www2.spi.pt/synbiology/documents/news/D11%20-%20Final%20Report.pdf*, 2006).

[4] As McLeish and Nightingale specify, biosecurity is a broad umbrella, that covers different areas: bio-terrorism (the threat or use of disease by non-state actors for political ends); bio-defence (the development of responses to biological warfare attack, including bioterrorism); dual-use controls (controls on technologies with legitimate and prohibited applications) and non-proliferation (controls on the diffusion of technologies to prevent their illegal hostile use). See MCLEISH, Caitríona / NIGHTINGALE, Paul, "Biosecurity, bioterrorism and the governance of science: The increasing convergence of science and security policy", *Res. Pol.,* Vol. 36, 2007, pp. 1635–1654.

[5] An early Central Intelligence Agency (CIA) report (2001) warned that synthetic biology could produce engineered agents worse than any disease known to man and proposed that a qualitatively different working relationship was now required between the intelligence and biological sciences communities (see https://www.cia.gov/index.html). Schmidt and Giersch underline what experiments are actually generating the most worrying concerns (see SCHMIDT, Markus / GIERSCH, Gregor, "DNA Synthesis And Security", *DNA Microarrays, Synthesis and Synthetic DNA*, CAMPBELL, Melissa J. (ed.), Nova Publishers, New York, U.S.A., 2011, pp. 285-300).

[6] See CELLO, Jeronimo / PAUL, Aniko V. / WIMMER, Eckard, "Chemical synthesis of poliovirus cDNA: generation of infectious virus in the absence of natural template", *Science*, Vol. 297, 2002, p. 1016 ff. In the poliovirus case, some researchers obtained from a scientific mail-order house the chemical basis used to create a laboratory-synthesized virus, which was virtually identical to the naturally occurring one causing polio. The scientists modelled it on the genetic sequence for the poliovirus, which could be obtained from a public database on the Internet. They ordered short stretches of DNA in the proper chemical order from a commercial company, stitched those chunks together and transformed them into a poliovirus that could reproduce itself and paralyze mice.

[7] TUMPEY, Terrence et al., "Characterization of the reconstructed 1918 Spanish influenza pandemic virus", *Science*, No. 5745, Vol. 310, 2005, pp. 77–80.

[8] See WHITTALL, Simon, "The Ethics of Synthetic Biology", *Ethical Aspects of Synthetic Biology*, EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (EDS.), Proceedings of the Round Table, *http://ec.europa.eu/bepa/european-group-ethics/docs/publications/round_table_ethical_aspects_of_synthetic_biology.pdf*, 2009, p. 27.

[9] See ALPER, Joe, "Biotech in the basement", *Nature Biotechnology*, No. 12, Vol. 27, 2009, pp. 1077-1078.

[10] The matter of "*biohacker*" was deeply discussed at the 2004 International Meeting on Synthetic Biology in Boston, referring to those who create computer viruses.

[11] BUCHANAN, Allen / POWELL, Russel, *The Ethics of Synthetic Biology: Suggestions for a Comprehensive Approach* (to the U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES), *http://bioethics.gov/sites/default/files/The-Ethics-of-Synthetic-Biology-Suggestions-for-a-Comprehensive-Approach.pdf,* 2011.

[12] See, for example, U.K. PARLIAMENTARY OFFICE OF SCIENCE AND TECHNOLOGY, *The dual-use dilemma*, London, U.K., 2009. About the multiple meanings of "dual use", see ATLAS, Ronald M. / DANDO, Malcolm R., "The Dual-use Dilemma for the Life Sciences: Perspectives, Conundrums, and Global Solutions", *Biosecurity Bioterrorism,* No. 3, Vol. 4, 2006, pp. 276–286.

technology regarding the ethics in usage of that technology. Certainly, "dual use" is an aspect that pertains not only to research, but also to the technological application of a research[13]. According to Michael Selgelid[14], though, the threat posed by the misuse of knowledge from synthetic biology will ultimately be greater than that posed by nuclear technology: firstly, nuclear technology was and is too expensive for common people, while the technologies required to produce bioweapons may become quite portable and cheap; secondly, in contrast to nuclear technology, which was kept confidential, the biological field has a long tradition of openness in its access to knowledge and sharing of resources.
As seen, the abuse of synthetic biology in order to create biological weapons could occur by side of governments and by single terrorists. Therefore, it is urgent to consider how this new threat could be faced with and managed, and what the role of the law in the governance of such risks might be.

2. WHERE ARE WE NOW? AN OVERVIEW OF THE EXISTING REGULATIONS AGAINST BIOTERRORISM.

Since synthetic biology generates a potential threat to biosecurity, it is of utmost importance to check whether the existing regulations in the field of bioterrorism could be applied to cover synthetic biology too, or whether a modification of the norms should be boosted. Therefore, an overview of the main regulations at stake at the international and European level, and within some national experience is offered hereafter.
As a premise, it can be observed that the regulations about bioterrorism that have been enacted so far pertain to the following fields[15]:
(1) Criminal law: bioterrorism as a crime and the formulation of sanctions against bioterrorists for possession, manufacture, or distribution of bioweapons; the "goods" that are protected by this type of norms are physical integrity, life, health, public security, constitutional (national and international) order and economic goods as well[16];
(2) Public health (and medical) law: norms for preparedness in case of bioterrorist act and response, addressed to public health community such as hospitals, laboratory network, medical doctors, health professionals, forensic scientists (norms concerning data collection, control of people, such as for quarantines, and control of property, such as for decontamination of facilities);
(3) Emergency management law: norms for preparedness and response to emergency situations;
(4) National security law: rules for law enforcement communities, such as police, customs agents, governments, and so on, with regards to the controlling of transfer and movements of dangerous biological agents and toxins, the prevention and the response to bioterrorist attacks.

2.1. AT THE INTERNATIONAL LEVEL.

At the international level, the starting point for biosecurity rules can be found in 1925 Geneva Protocol[17], which prohibited the deployment of chemical and biological weapons following the horrible impact of

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[13] See the reference of "dual use" to research, technology and artifacts (i.e., the products of technology), by FORGE, Joe, "A Note on the Definition of "Dual Use", *Science of Engineering Ethics,* No. 1, Vol. 16, 2010, pp. 111–118. An example of the dual-use as intrinsic to research could be the experiments conducted by Nazis doctors during the World War II (i.e., the sadly known Nazi programs in extermination camps, such as "Aktion T4" and "Neue Aktion 14F13"), or the "Tuskegee Study of Untreated Syphilis in the Negro Male" pursued in the U.S.A., and concerning 616 African American males, who were given blood tests in 1932. More than half of them were diagnosed with syphilis. The test subjects were not told they had syphilis and were not treated for it, despite the fact that after 1943 penicillin was available as a cure. The purpose of the research was to study the long term effects of untreated syphilis. An example of the dual-use with reference to the purposes of research and to applications of research could be the dynamite, which could be used for digging water wells in Poor countries or for killing people.
[14] SELGELID, Michael J., "A Tale of Two Studies. Ethics, Bioterrorism, and the Censorship of Science", *Hastings Center Report*, No. 3, Vol. 37, 2007, pp. 35-43.
[15] See FIDLER, David P., "Legal Issues Surrounding Public Health Emergencies", *Public Health Reports,* Suppl. No. 2, Vol. 116, 2001, pp. 79-86.
[16] For instance, Spanish criminal code is very meaningful in this regard, presenting, beyond crimes about genetic sphere, specific crimes against the production of biological weapons through genetic engineering (see art. 160.1, which refers only to biological elements that have genetically manipulated material, and are used as bioweapons). See also art. 566 and 567 about fabrication, commercialization and traffic of biological and chemical weapons. For further details, see DE LA CUESTA ARZAMENDI,José Luis, "Armas biológicas o exterminadoras e ingeniería genética: perspectiva juridico-penal", *Genética e Derecho Penal. Previsiones en el Código Penal Español de 1995*, ROMEO CASABONA, Carlo María (ed.), Ed. Cátedra Interuniversitaria de Derecho y Genoma Humano - Comares, Bilbao-Granada, Spain, 2001, pp. 239-265.
[17] 1925 Geneva Protocol, Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare. The Protocol was drawn up and signed at a conference which was held in

chemical warfare during the World War I. However, this Protocol mentioned only the ban of developing biological weapons, and no reference was made with regards to their production, storage, and transfer[18].
With the birth of the first biological weapons programs, the need for more specific rules was perceived as a urgency, and this led to the enactment of the 1972 Biological and Toxins Weapons Convention (B.W.C.)[19], which is still the main instrument in this field, despite it lacking relevant elements.
Considered as a complement of Geneva Protocol, it contains a lot of provisions, starting with a list of specific biological agents (art. 1), and showing the States' obligations, such as the forbade to "develop, reproduce, stockpile, acquire or retain microbial or biological agents or toxins or weapons, equipment or the means of disseminating such agents for non-peaceful purposes" (art. 1), "transfer biological weapons to third party states or international organisations or assist them, encourage them or induce them to manufacture or acquire such weapons" (art. 3), and to allow "these activities in their territory" (art. 4). The Convention requires the destruction of existing inventories and delivery devices, and it fosters mutual assistance in case a State is attacked by biological weapons. It should be noted that there are no references to specific agents or pathogens. This leaves the freedom to the States to decide which ones are the addressed agents. Furthermore, there is no ban for the use of those biological agents for therapeutic and civil purposes. The States are called upon to implement the issues about (1) the definitions (of toxins, agents, etc.), (2) the prohibitions and the penalties (pertaining to the preparation, development, production, acquisition, stockpiling, retention, direct or indirect transfers, and use of biological weapons), (3) the jurisdiction, (4) the enforcement (through national authorities, laboratories, surveillance bodies, international cooperation), (5) the export control, and (6) the biosafety and biosecurity measures.
This Convention has an unlimited duration, but a series of review conferences were conducted and have been held in order to establish (a) compliance procedures (through an organisation or implementing body or any other effective means), (b) measures for monitoring national implementation, and (c) mechanisms for investigating the alleged violations, since all these aspects were not indicated in the original treaty and the provisions of the B.W.C. are so general that they do not provide specific guidance. Yet, these conferences (the last one, the 7th, occurred in 2011[20]) have failed in resolving the accountability and enforcement procedures. In fact, there is a strong resistance (especially within the U.S.A.) against the intrusion of an international convention upon national activities. So, a system of verification of B.W.C. and of control of application is still lacking, along with excessive vagueness of some dispositions. Other weaknesses of the Convention are represented by the fact that its focus does not cover the role of private (non-state) actors, such as bioterrorists, and the States' obligation to take all the necessary measures to prevent any of the prohibited activities within their territories does not explicitly state what these measures actually would be.
In general, the international regulation, as Bassiouni says[21], has followed two roads, namely:
(1) the way of international humanitarian law (Geneva Conventions), stating a ban for the use of belligerency methods producing high damages to environment and people, and
(2) the way of multilateral agreements about the control of weapons. In the second category, three types of instruments can be found:
(a) agreements that have a general character, namely the banning of the use of weapons of mass destruction weapons (1968 Treaty of non proliferation of nuclear weapons[22]; 1972 B.W.C; 1980 Geneva Convention on conventional weapons having indiscriminate effects[23], and 1993 Chemical Weapons Convention, C.W.C., about the prohibition of chemical weapons[24]);

Geneva under the auspices of the League of Nations from 4th May to 17th June 1925, and it entered into force on 8th February 1928.

[18] In reality, the Protocol was anticipated by some Declarations and conventions, such as the Paris Declaration (1856), followed by some conventions and other declarations, such as the Convention of Red Cross (Geneva 1864), Saint Petersburg Declaration (1868), Bruxelles Declaration (1874), Le Hague Conventions (1899 and 1907).

[19] U.N., *International Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, 10th April 1972, entered into effect in 1975. Currently, there are 165 States Parties, 12 signatories, 19 states that neither signed nor ratified.

[20] In the last review conference, States were called to adopt measures designed to "ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins", in particular through implementing voluntary management standards on biosafety and biosecurity, promoting the development of training and education programmes for scientists, encouraging a culture of responsibility amongst relevant national professionals and the voluntary promulgation of codes of conduct. The 8th Review Conference will be taken in 2016. For more information, see *http://www.unog.ch/bwc*.

[21] BASSIOUNI, M. Cherif, *International Humanitarian Law and Arms Control Agreements*, Transnational Publishers, Ardsley, New York, U.S.A., 2000, p. 17 ff.

[22] The Treaty on the Non-Proliferation of Nuclear Weapons, commonly known as the Non-Proliferation Treaty or N.P.T. was adopted on 1st July 1968 and entered into force on 5th March 1970.

[23] The Convention on Prohibitions or Restrictions on the Use of Certain Conventional Weapons Which May be Deemed to be Excessively Injurious or to Have Indiscriminate Effects was adopted in 1980 and entered into force in 1983.

[24] The Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction was adopted on 13th January 1993 and entered into force on 29th April 1997.

(b) treaties which ban the weapons of mass destruction in certain areas: the Antarctic Treaty (Washington 1959)[25], the treaty on the prohibition of proofs of nuclear weapons in the atmosphere and submarine territories (Moscow 1963)[26], the Treaty on the activities of States about the exploration of space (Washington, London, Moscow 1967)[27], the treaty on the use of nuclear weapons in the depth of sea and ocean (Washington, London, Moscow 1971)[28], and the agreement on the activities of States on the Moon (New York 1979)[29];
(c) the agreements which establish the zones of atomic exclusion (1968 Tlatelolco Treaty[30]; 1985 Raratonga Treaty[31]; 1995 South-Eastern Asia Treaty[32], and the 1996 Pelindaba Treaty[33]).
The main principles underlying these conventions are that the weapons that generate indiscriminate and useless suffering, which are not proportional and not necessary, must be prohibited. These principles usually contain a list of prohibited behaviours, and ask the State to develop policies of prevention and to sanction the violations.
In the U.N. system, since 2001, the Security Council focuses its attention on terrorism, as its role is central in cases «*overwhelming outbreak of infectious disease that threatens international peace and security*»[34]. With the Resolution 1453/2003[35], the U.N. makes reference to the possibility that terrorists could have access and to detain biological materials having lethal functions. The main resolution is the n. 1540/2004[36], where it is stated that all the States of the International Community should introduce national controls in order to prevent the proliferation of nuclear, chemical and biological weapons and of connected materials, thus intensifying international cooperation against fabrication, construction, transport and diffusion of those weapons. The focus is posed particularly on non State use of bioweapons. The Resolution also establishes the creation of the Committee 1540, which is voted to control the effective application of the Resolution[37].
At the international level the initiative of G7 members is relevant as well. In 2001, in Ottawa, the G7 Ministries of Health (together with the Mexican Secretary of Health and one Member of the European Commission, responsible for health and protection of the consumers) created the Global Group of Sanitary Action and Security[38], which aims to organize a coordinate response in cases of bioterrorism.
Interpol (International Police) also plays a meaningful role here. In 2006, Interpol established a specific programme about bioterrorism detailing the implementation of security education, and the legislative norms about cooperation. The programme was called "Bio-criminalization" and, through the support of Sloan Foundation and the Government of Canada, a Guide on the anticipatory measures and response to bioterrorist incidents was published[39].
Furthermore, "Australia Group" (A.G.) is «*an informal forum of countries which, through the harmonisation of export controls, seeks to ensure that exports do not contribute to the development of chemical or biological weapons*»[40]. The A.G. maintains Common Control Lists that require controls on the export of certain

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[25] The Antarctic Treaty and related agreements, collectively called the Antarctic Treaty System or A.T.S., was adopted on 1st December 1959 and entered into force on 23rd June 1961.
[26] The Limited Test Ban Treaty was adopted on 5th August 1963 and entered into force on 10th October 1963.
[27] The Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies (Outer Space Treaty) was adopted on 27th January 1967 and entered into force on 10th October 1967.
[28] The Treaty on the Prohibition of the Emplacement of Nuclear Weapons and Other Weapons of Mass Destruction on the Seabed and Ocean Floor and in the Subsoil Thereof (Seabed Treaty) was adopted on 11th February 19711 and entered into force on 18th May 1972.
[29] The Agreement Governing the Activities of States on the Moon and Other Celestial Bodies was adopted on 18th December 1979 and entered in to force on 11th July 1984.
[30] The Treaty of Tlatelolco is the conventional name given to the Treaty for the Prohibition of Nuclear Weapons in Latin America and the Caribbean. It was adopted on 14th February 1967 and entered into force on 22nd April 1968.
[31] The Treaty of Rarotonga is the common name for the South Pacific Nuclear Free Zone Treaty. It was adopted on 6th August 1985.
[32] The Treaty of Bankok is the common name for the Treaty on the Southeast Asia Nuclear-Weapon-Free Zone. It was adopted on 15th December 1995 and entered into force on 27th March 1997.
[33] The Treaty of Pelindaba is the common name for the African Nuclear-Weapon-Free Zone Treaty. It was adopted on 11th April 1996, but is not entered into force yet.
[34] See Kofi Annan, about U.N. Reform Project, U.N.G.A., *In Larger Freedom: Toward Development, Security and Human Rights for All,* Report of the Secretary-General, U.N. Doc. A/59/2005, 21st March 2005, p. 29.
[35] The U.N. Security Council resolution 1453 was adopted unanimously on 24th December 2002.
[36] The U.N. Security Council resolution 1540 was adopted unanimously on 28th April 2004.
[37] The Committee has been extended in its role through Resolution 1673/2006 and Resolution 1840/2008.
[38] The 7th G7 Summit was called the Ottawa Summit, and was held in Montebello, Quebec, Canada and nearby Ottawa between 20th and 21st July 2001.
[39] See at *https://secure.interpol.int/public/BioTerrorism/bioC/default.asp.*
[40] See *http://www.australiagroup.net.* Chaired by Australia, the "Australia Group" was formed as an informal arrangement, found in 1984 as a result of C.W. use in the Iran-Iraq War. The members of the Group are presently: Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Czech Republic, Croatia, Cyprus, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Netherlands, New Zealand,

biological agents or parts[41]. The list is being implemented through national laws and regulations, but it clearly requires the States within the A.G. to regulate exports of such material, and not domestic transfers. The additional biosecurity screening of domestic orders and customers by DNA synthesis companies is *de facto* done on a voluntary basis.

In 2005, the World Health Assembly, the highest decision-making body of W.H.O., adopted a revised set of International Health Regulations[42], which is in force from 2007, and it binds the W.H.O. Member States on an opt-out basis. It adopts an "all risk" approach, which includes any emergency with repercussions for international health security (outbreaks of epidemic diseases, outbreaks of food, natural disasters, accidental or deliberate release of pathogens). It has the purposes of protecting against public health threats, controlling and providing adequate response in cases of spread of diseases. The States have to notify W.H.O. of events within their territories that may constitute a "public health emergency of international concern" and they have to intervene without being invasive or intrusive to people's lives.

In the Council of Europe, bioterrorism has been contemplated in Resolution 1367/2004[43], in which the Parliamentary Assembly[44] asks the States to inform and educate the public about the inherent dangers of bioterrorism, to draw up an objective assessment of the potential sources of bioterrorist danger, and elaborate on an efficient and effective surveillance and warning systems, to devise emergency intervention and public-health relief plans, to frame a suitable public vaccination policy, to control the purchase and movement of dangerous substances, and to establish strict control over activities based on the use of modern biotechnologies in order to avoid their misuse for bioterrorism.

The Organisation for Economic Co-operation and Development (O.E.C.D.) has, over the years, had a relevant role in the development of a culture of biosecurity both on the governmental and scientific community level. Indeed, it has indicated the importance of common standards of safety in labs[45] and established a Group of Experts on Biosecurity to the Task Force on Biological Resource Centres (2002). Moreover, in 2004, the O.E.C.D. International Futures Programme (I.F.P.)[46], which has been working on risk management issues since 2000, conducted a workshop on "*Promoting Responsible Stewardship in the Biosciences: Avoiding Potential Abuse of Research and Resources*" in Frascati, Italy[47].

2.2. AT THE EUROPEAN LEVEL.

The first list of biological agents enacted by the E.U. is contained in the Directive 90/679[48].

Regarding the export of technological material of "double use", the Regulation n. 1334/2000 establishes a regime of control of exports and transfer[49], and it contains a list of biological and chemical agents that are to be subjected to strict measures of check and authorization by Member States before export (as indicated in Annex I).

Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, United States of America, and the European Community Commission (Observer).

[41] Australia Group, List of Biological Agents for Export Control, *http://www.australia group.net/en/biologicalagents.html*, 2006. The control list refers to: genetic elements that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in the list; genetic elements that contain nucleic acid sequences coding for any of the toxins in the list, or for their sub-units; genetically-modified organisms that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in the list; and genetically-modified organisms that contain nucleic acid sequences coding for any of the toxins in the list or for their sub-units.

[42] International Health Regulations (2005), W.H.A. Res. 58.3, 23rd May 2005.

[43] Resolution 1367 (2004), adopted by the Standing Committee, acting on behalf of the Assembly, on 2nd March 2004.

[44] See also the Doc. 10095, 17th February 2004, *Bio-terrorism: a serious threat for citizens' health*, Opinion by the Committee on the Environment, Agriculture and Local and Regional Affairs, where the possibility of terrorist use, not only of known natural pathogens but also of synthetic biological agents produced for peaceful purposes, is mentioned. Moreover, see the Report by Social, Health and Family Affairs Committee (9th February 2004).

[45] See the publication of the reports: *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology,* 2001, and *Best Practices for Biosecurity in Biological Resource Centres,* 2007.

[46] See at *http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/33855561.pdf.*

[47] For deepening the role of O.E.C.D. in biosecurity, see SAWAYA, David B., "Biosecurity at the OECD", *Biosecurity Origins, Transformations and Practices*, RAPPERT, Brian / GOULD, Chandr (eds.), Palgrave Macmillan, England, 2009, p. 79 ff.

[48] Council Directive 90/679/EEC of 26th November 1990 on the protection of workers from risks related to exposure to biological agents at work, in *O.J.* L 374/1990.

[49] See Regulation 1334/2000 of 22nd June 2000 setting up a Community regime for the control of exports of dual-use items and technology in *O.J.* L 159/2000, modified by Regulation 2432/2001 of 20th November 2001 in *O.J.* L 338/2001, and by Regulation 428/2009 of 5th May 2009 in *O.J.* L 134/2009.

Since 2001, the European Union has started worrying about anthrax cases after the events that occurred in the United States in the aftermath of 9/11[50]. Such events generated the necessity of adopting preventative measures in the sanitary field, in order to protect the people from the risks to their health and security. The E.U. also instituted a network of information for a rapid response to threats, a policy of vaccination and cooperation in the management of risks[51].

Following a chronological order analysis, in 2001, the Committee of Sanitary Security was established (formed of the highest members of health coming from different E.U. States), with the duty to ensure the adequate coordination between security and health agencies within the E.U., to share knowledge and information through the establishment of an alert mechanism, to cooperate and approve a programme of preparedness and response in case of attacks with chemical and biological agents (programme BICHAT)[52]. This programme fostered (a) the creation of a database including medical, sanitary and pharmaceutical data that could be useful in case of attack, a list of national reservation of antibiotics and vaccines (currently not yet in existence), and a list of medical experts in the hypothesis of an attack, and (b) the elaboration of norms and codes of conduct to be adopted in case of threat.

A system of rapid alarm for signalling cases of propagation of harmful biological agents became operative since 2002 (called RAS-BICHAT, Rapid Alert System for Biological and Chemical Attacks and Threats). It connected the members of the Committee of Sanitary Security and the contact points at national level, and it was aimed at ensuring controls and emergency responses.

Interventions in the sector of civil protection were also designed as a means for ensuring sanitary security, in a cooperative way among the States[53].

Moreover, a "*Guidance document on use of medicinal products for treatment and prophylaxis of biological agents that might be used as weapons of bioterrorism*"[54] was enacted by the European Medical Agency and its Committee for Proprietary Medicinal Products (C.P.M.P.), on the E.U. Commission's request, to describe the most used agents of bioterrorism and list the possible drugs that might be useful in the case of an attack.

A Working Group on Bioterrorism and some Task Forces were established, such as (a) a Task Force with Commission and States members about C.B.R.N. (Chemical, Biological, Radiological, Nuclear) protection, (b) a Task Force Commission-Pharmaceutical Industries, (c) a Task Force Commission-Research chiefs, and (d) a Research and Development Expert Group on Countering the Effects of Biological and Chemical Terrorism. Again in 2002, the Council and the Commission, jointly, elaborated on a C.B.R.N. Terrorism Programme[55], in order to improve the cooperation in the E.U. for the prevention and limitation of the consequences of terrorist threats.

In 2003, the Commission drafted a Communication to the Council and Parliament about the cooperation within the E.U. regarding the preparation and response in case of attacks with chemical and biological agents[56], including all the measures to be adopted (in pharmaceutical, public health, surveillance areas).

In the same year, the E.U. Strategy against proliferation of weapons of mass destruction and their means of delivery, known as the E.U. W.M.D. strategy, was adopted by the European Council[57]. The European Council reviewed it through the adoption of "*New lines for action by the European Union in combating the proliferation of weapons of mass destruction and their delivery systems*" (December 2008)[58]. In addition, since 2003, W.M.D. clauses were inserted in all new or renewed mixed agreements with third countries.

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[50] About the summary of all the initiatives of the E.U. In the field of bioterrorism, see at *http://ec.europa.eu/health-eu/my_environment/bio_terrorism/index_en.htm.*

[51] In reality since 1998, Decision 2119/98 (24th September 1998 in *O.J.* L 268/1998) focused on the surveillance of transmissible diseases, stressing the importance of monitoring infective diseases and activating rapid responses all over Europe, also creating an EU network of communicable diseases.

[52] See Communication from the Commission to the Council and the European Parliament, "On Cooperation in the European Union on Preparedness and Response to Biological and Chemical Attacks", COM (2003) 320, 2nd June 2003.

[53] See Communications of the Commission COM (2001) 707 def. and COM (2002) 302 def.; Council Decision 2007/779/EC, establishing a Community Civil Protection Mechanism and Council Decision establishing a Civil Protection Financial Instrument (2007/162/EC).

[54] EMEA/CPMP/4048/01*, Guidance document on use of medicinal products for treatment and prophylaxis of biological agents that might be used as weapons of bioterrorism*, London, 25th July 2002.

[55] 14627/02, C.B.R.N. Programme to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats.

[56] Communication from the Commission to the Council and the European Parliament, "On Cooperation in the European Union on Preparedness and Response to Biological and Chemical Attacks", COM (2003) 320, 2nd June 2003.

[57] 15708/03 and SN 400/03, n. 68, E.U. Strategy against proliferation of weapons of mass destruction (W.M.D.) adopted by the European Council on 12th December 2003.

[58] 17172/08, 17th December 2008, Council Conclusions and new lines for action by the European Union in combating the proliferation of weapons of mass destruction and their delivery systems.

Then, in 2005, a Communication[59] about the coordination of sanitary emergency intervention and one about the establishment of a general rapid alert system called "ARGUS"[60] for multisector crisis were enacted.
In 2007, a "Green Book on Biopreparedness about the preparation in case of biological attack"[61] was released, in order to introduce a process of consultation for the reduction of biological risks, and thus underlining the need to build up a strong culture of awareness among scientific community. The Green Book received over 80 responses, all of which agreed with the importance of tackling the issue of biosecurity at the European level. Thus, this indicates the E.U.'s central role in co-ordinating the biopreparedness of its Member States according to an "all hazards" approach, which involves the police and judicial bodies, health and civil protection services[62].
The Commission also elaborated on a system of medical information (called "MediSys") that assembles information about sanitation and methods for treating epidemics, even in emergency contexts. With a "White Book on health policies for the period 2008-2013"[63], the Commission clarifies the need for a consideration of the benefits of new technologies on health and, at the same time, a need for progressing in the development of measures to respond to health pandemic risks, such as bioterrorism.
In 2006, a Council Joint Action in support of the Biological and Toxin Weapons Convention was adopted[64], in order to promote the universality of B.W.C. and support for implementation of the B.W.C. by States Parties.
In 2009, the Action Plan, which was put in force to strengthen the C.B.R.N. Programme, was enucleated by the Commission[65]. It presented an "all hazard" approach, focusing on the prevention, preparation, detection and response against threats, which is to be applied through cooperation among the States, and the use of E.U. mechanisms (such as contacting E.U. civil protection, the Committee of Sanitary Security, the European Centre for Disease Prevention and Control, located in Stockholm and instituted by Regulation 851/2004). However, such C.B.R.N. Action Plan is not a legal instrument, and so the implementation of it would be required by future instruments.

2.3. IN THE UNITED STATES OF AMERICA.

The attention by the U.S.A. towards biosecurity as threatened by new technologies can be seen since the years 1974 and 1975, when the concerns over the safe and ethical manipulation of genetic material using recombinant DNA techniques emerged at the Asilomar Conference[66]. On that occasion, the members of scientific community claimed self-governance for biotechnology, and drafted a set of voluntary guidelines that restricted recombinant DNA research to the K12 strain of *E. coli*, which was believed to be disabled from generations of use in the laboratory and to be not likely to survive in the environment.
In response to the same fears, the National Institute of Health established the Recombinant DNA Advisory Committee (R.A.C.) in 1974[67]. The R.A.C. was first charged by the N.I.H. to develop a set of guidelines for the safe conduct of recombinant DNA research, which were issued in 1976 as the "*N.I.H. Guidelines for Research Involving Recombinant DNA Molecules*". The N.I.H. also required the creation of an Institutional Biosafety Committee (I.B.C.) at each funded research institution.
Concerns were also raised with respect to academic freedom and the freedom of research, and in this regard the 1982 Corson Report was enacted, followed in 1985 by the National Security Decision Directive n.

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[59] Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on strengthening coordination on generic preparedness planning for public health emergencies at the E.U. level, COM 605/2005, 28th November 2005.
[60] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Commission provisions on "ARGUS" general rapid alert system, COM 662/2005, 23rd December 2005.
[61] Green book No. 11951/07 containing the Communication COM 399/2007 of 11th July 2007.
[62] See Commission, Synthesis of the replies to the Green paper on bio-preparedness, SEC (2008) 2374, 4th August 2008.
[63] White paper - Together for Health: A Strategic Approach for the EU 2008-2013 {SEC(2007) 1374} {SEC(2007) 1375} {SEC(2007) 1376}, COM 630/2007, 23rd October 2007.
[64] Council Joint Action 2006/184/CFSP of 27th February 2006 in support of the Biological and Toxin Weapons Convention, in the framework of the EU Strategy against the Proliferation of Weapons of Mass Destruction, in O.J. L 65/2006.
[65] 273/2009, 24th June 2009. See also SEC (2009) 874, Commission Staff Working Document, entitled "Bridging Security and Health: Towards the identification of good practices in the response to CBRN incidents and the security of CBR substances", accompanying the Communication of Commission "Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union".
[66] See BERG, Paul et al., "Potential Biohazards of Recombinant DNA Molecules", *Science,* No. 4148, Vol. 185, 1974, pp. 303 ff.; BERG, Paul et al., "Summary Statement of the Asilomar Conference on Recombinant DNA", *Proceedings of the National Academy of Sciences of the U.S.A.,* No. 6, Vol. 72, 1975, pp. 1981-1984.
[67] See *http://oba.od.nih.gov/rdna_rac/rac_about.html.*

189 (N.S.D.D. n.189). The Corson report[68] was drafted by the National Academy of Sciences, and it stated that it was not necessary to restrict research and international scientific communication, as the censorship or secrecy would have weakened U.S. technological development. Directive 189[69], then, fixed the national policy for controlling the flow of scientific and technology information generated in universities and laboratories, by supporting the openness of scientific inquiry, including the right to pursue and publish, without government restrictions, all the research and placing the onus on the scientific community to regulate itself.

In 1989, the B.W.C. was implemented in the national system through the United States Biological Weapons Anti-Terrorism Act[70].

After the anthrax attacks of October 2001, Congress took a series of legislative actions[71] directed at securing potentially dangerous biological agents, including the 2001 Patriot Act, and the 2002 Public Health Security and Bioterrorism Preparedness and Response Act.

The Patriot Act[72] determines the case of "possession" of select agents for the first time (Section 817), establishing the possession standards for *bona fide* research and requiring assurances from research institutions that no "restricted persons" could have access to such select agent research. The Patriot Act makes it illegal for anyone in the United States to possess any biological agent, including any genetically engineered organism, for any inappropriate reason[73].

The second statute, i.e. the Public Health Security and Bioterrorism Preparedness and Response Act[74], adds new requirements for the listing of potentially dangerous biological agents and the prevention of unlawful access to agents during transfers. It requires that all persons possessing biological agents or toxins deemed a threat to public health to notify the Secretary, Department of Health and Human Services (D.H.H.S.). The U.S. Department of Agriculture is called for regulating toxins and biological agents posing threats to plants and animals. The Act also establishes penalties for those failing to notify the proper authorities about the possession of select agents (registered in the National Select Agents Registry)[75].

In 2004, in addition to prohibiting possession and transportation of material, the U.S. restricted the use of synthesis technology to produce one specific pathogen. The Intelligence Reform and Terrorism Prevention Act contains, in fact, an amendment that «*imposes severe penalties for attempts to engineer or synthesize the smallpox virus*»[76].

In the same years (2004-2005), the U.S. Congress passed the Project Bioshield Act[77], which provided $5 billion for vaccines in case of a bioterrorist event, and the Biodefense and Pandemic Vaccine and Drug Development Act ("Bioshield 2")[78] cut the approval time for new drugs to hit the market in the case of a pandemic[79].

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[68] PANEL ON SCIENTIFIC COMMUNICATION AND NATIONAL SECURITY, NATIONAL ACADEMY OF SCIENCES, NATIONAL ACADEMY OF ENGINEERING, INSTITUTE OF MEDICINE, *Scientific Communication and National Security*, Washington, U.S.A., 1982.

[69] NSDD-189, 21st September 1985, *National Policy On The Transfer Of Scientific, Technical And Engineering Information*.

[70] On the basis of this Act, for example, a man from Illinois was sentenced on 24th September 2012 to 7 years and 8 months for possession of a toxin (Tetrodotoxin) with intent to use it as a weapon.

[71] For a review of all the legislative framework about bioterrorism in the U.S.A., see RICHARDS, Edward P. / O'BRIEN, Terry / RATHBUN, Katharine C., "Bioterrorism and the Use of Fear in Public Health", *The Urban Lawyer*, No. 3, Vol. 34, 2002, pp. 685-726.

[72] 115 Stat. 272 (2001), signed on 26th October 2001 and effective since 1st February 2002.

[73] Two meaningful applications of the Patriot Act were in (a) the case of a graduate student in Connecticut, who was charged with violations of the Patriot Act because he did not possess the anthrax for *bona fide* research (he was found to own two vials of anthrax from a 1960 cow necropsy) and (b) the case of a researcher at Texas Tech University (Dr. Thomas Butler), who was convicted of mislabelling plague samples being shipped from overseas.

[74] The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) was signed into law on 12th June 2002.

[75] About the U.S. legislation, see BUCHSBAUM, Lori L., "The U.S. Public Health Response To Bioterrorism: Need For A Stronger Legislative Approach", *Journal Of Medicine And Law*, No. 1, Vol. 7, 2002, pp. 2-36.

[76] The Intelligence Reform and Terrorism Prevention Act of 2004 (I.R.T.P.A.), 118 Stat. 3638, was enacted on 17th December 2004.

[77] The Project Bioshield Act, whose full name is "An Act To amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures" (118 Stat. 835–864), was signed on 21st July 2004.

[78] The Biodefense and Pandemic Vaccine and Drug Development Act of 2005, nicknamed "Bioshield Two", is the Act S. 1873/2005.

[79] About the Project Bioshield I and II, see MAYER, Lincoln P., "Immunity For Immunizations: Tort Liability, Biodefense, And Bioshield II", *Stanford Law Review*, No. 6, Vol. 59, 2007, pp. 1753-1790.

With regards to the control of movement of pathogenic biological agents, the main regulation is the Export Administration Regulations (E.A.R.)[80]. It was enacted to implement the 1979 Export Administration Act which confers legal authority to the President for controlling the U.S. exports for reasons of public national security. The U.S. Department for Commerce is the actor called for implementing E.A.R., and since then it has provided a list of substances to be controlled (such as microorganisms, viruses, bacteria, toxins) and license requirements, which differ from each State of the U.S..
While the international orders are regulated by E.A.R., the internal ones follow Select Agent Regulation (S.A.R.)[81], which was endorsed in 2005 for implementing the Public Health Security and Bioterrorism Preparedness and Response Act. This results in the notification required by people possessing those agents to be more specified, the deepening the role of D.H.H.S. in listing biological agents and toxins, and the approval of the safety measures, the containment and response plan to accidents developed by labs, in order to confer the certificate of registration that has three years validity.
Regarding the preparedness and response against bioterrorism, the Centre for Disease Control and Prevention (C.D.C.) has a meaningful role in alerting the emergency[82]. In 2001, it drafted a Model State Emergency Health Powers Act (M.S.E.H.P.A.)[83] and, in 2009, the United States developed their first National Health Security Strategy[84], which offers a response for cases of natural disasters, naturally-occurring infectious disease epidemics and bioterrorism, and focuses on the preparedness, planning, surveillance, people protection, communication and public information. Coercive public health powers can be exercised only after the governor has declared a state of emergency, and public health officials can carry out examinations necessary for diagnosis and treatment, and conduct isolation and quarantine when they aim to prevent a substantial risk of transmission of infection. However, they must adhere to human rights principles, adopting the least restrictive alternative, and safe measures. Moreover, the C.D.C. has the authority to control and monitor the possession, use and transfer of select agents and toxins.
The Pandemic and All Hazards Preparedness Act[85], enacted in 2006 to improve the organization, direction, and utility of preparedness efforts, has centralised federal responsibilities, and proposed new national surveillance methods, by placing the Department of Health and Human Services (D.H.H.S.) as the lead agency for federal public health and medical response to public health emergencies covered by the National Response Plan. It also focuses on volunteers for the oversight, through the Emergency System for Advance Registration of Volunteer Health Professionals (E.S.A.R.-V.H.P.) and Medical Reserve Corps (M.R.C.). The Act establishes a new Biomedical Advanced Research and Development Authority (B.A.R.D.A.) within the D.H.H.S. which is charged with fostering collaboration, supporting research, and encouraging innovation.

2.4. IN THE UNITED KINGDOM.

The U.K's attention on bioterrorism began in 2001 and intensified after London bombings on 7th July 2005.
In general, the current legislation in the U.K. in relation to terrorism is represented by the 2000 Regulation of Investigatory Powers Act[86], the 2000 Terrorism Act[87], the 2001 Anti-Terrorism, Crime and Security Act[88], the 2005 Prevention of Terrorism Act[89], the 2006 Terrorism Act[90], and the 2008 Counter Terrorism Act[91]. With regards to emergency response to health threats, the 1984 Public Health (Control of Diseases) Act[92] and the 2004 Civil Contingencies Act[93] and could be applied.

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[80] See at *http://www.bis.doc.gov/policiesandregulations/ear/index.htm*
[81] See at *http://www.selectagents.gov/Regulations.html*
[82] See at *http://www.cdc.gov/*
[83] The Model State Emergency Health Powers Act (M.S.E.H.P.A.) is a proposal (21st December 2001) by the Center for Law and the Public's Health, a joint venture of Georgetown University and Johns Hopkins University, to aid America's state legislatures in revising their public health laws to respond to bioterrorism. For the text of the proposal, see at *http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf*. About M.S.E.H.P.A. and bioethical issues linked to bioterrorism, with reference to the U.S, see MORENO, Jonathan D., "Bioethics And Bioterrorism", *The Oxford Handbook Of Bioethics*, STEINBOCK, Bonnie (Ed.), Oxford University Press, New York, 2007, pp. 721-733.
[84] See at *http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Pages/default.aspx*
[85] The Pandemic and All-Hazards Preparedness Act (P.A.H.P.A.), Public Law No. 109-417, was signed on 29th December 2006.
[86] With regards to the U.K. legislations, see at *http://www.legislation.gov.uk*. The Regulation of Investigatory Powers Act 2000 (R.I.P. or R.I.P.A.) was approved on 28th July 2000.
[87] The Terrorism Act was approved on 20th July 2000.
[88] The Anti-terrorism, Crime and Security Act came into force on 14th December 2001.
[89] The Prevention of Terrorism Act was approved on 11th March 2005.
[90] The Terrorism Act was approved on 30th March 2006.
[91] The Counter Terrorism Act was approved on 26th November 2008.
[92] The Public Health (Control of Diseases) Act was approved on 26th June 1984.
[93] The Civil Contingencies Act was approved on 18th November 2004.

In response to the threat of bioterrorism, section 113 of the 2001 Anti-terrorism, Crime and Security Act, concerning the "Use of noxious substances or things to cause harm and intimidate", indicates the different hypothesis of crimes of bioterrorism. Part 6 of the same statute amends the Biological Weapons Act 1974, which gave application to B.W.C.. A meaningful reference is given to private actors that operate for bioterrorist purposes (section 43). Then, in case that someone keeps or uses biological agents or toxins, he/she is charged with: (1) the duty of notification to the Secretary of State before any dangerous substance is kept or used, (2) the duty of notifying, on demand, the police about the security provisions for those substances, (3) the duty to identify, within one month of the service of the notice, those having access to such substances, where the substances are kept or the building and site where are located, and (4) the duty to give directions to disposal of such substances by others. These measures are accompanied by powers of entry and search warrants, and offences relating to the security of pathogens and toxins. Schedule 5 of the Act sets out a list of pathogens and toxins[94]. The Secretary of State has the possibility to extend the list to include further pathogens or toxins if suspected of being used for bioterrorism[95]; then, he/she could specify the manner and time in which the substances must be disposed of (section 63), and prevent a particular individual from having access to the substance (section 64).
The 2002 Export Control Act[96] also allows the Secretary of State to make provision for the imposition of transfer controls in relation to suspected technology, but he cannot make a control order, having the effect of interfering with the communication of information in the ordinary course of scientific research.
With regards to preparedness and response to bioterrorism, the Cabinet Office (aimed at co-ordinating the operation of government departments[97]) deals with the so-called "U.K. Resilience" by indicating two areas within it: the "Emergency Preparedness" and the "Emergency Response and Recovery"[98], which are governed in part by the 2004 Civil Contingencies Act.
The general responsibility of counter-terrorism and planning and organization in emergencies is vested on the Home Office[99]. The U.K. Government has published its strategy for countering international terrorism (named CONSENT) in the document "*Pursue Prevent Protect Prepare: The United Kingdom's Strategy for Countering International Terrorism*"[100], where a reference to "Chemical, biological, radiological and nuclear weapons, and explosives" is given in Part 2. The CONSENT strategy is overseen at a Ministerial level by the Cabinet Committee on National Security, International Relations and Development (N.S.I.D.), chaired by the Prime Minister, and by the Home Secretary as the lead Minister for counter-terrorism, and it involves the heads of the security and intelligence agencies, the police, and Armed Forces. Other public authorities are also involved, such as the Cabinet Office, the Joint Terrorism Analysis Centre, the Association of Chief Police Officers and Local Authorities.
In relation to health implications, the Health Protection Agency[101], created under the 2004 Health Protection Agency Act[102], plays a role in bioterrorism responses[103]. The Agency is articulated into three research centres: the Centre for Emergency Preparedness and Response, the Centre for Infections, and the Centre for Radiation, Chemical and Environmental Hazards. Physicians are also under a general duty to report incidences of communicable or infectious diseases (under the 1984 Public Health (Control of Disease) Act[104]). There is also a surveillance strategy, which provides the examination, hospitalization and detention of an individual who has or is suspected to have a listed disease, and the regulations extend to measures to be taken when dealing with people who have died from such diseases[105].

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[94] About the list, see at http://www.nactso.gov.uk/AreaOfRisks/PathogensToxins.aspx.
[95] See also The Security of Pathogens and Toxins (Exceptions to Dangerous Substances) Regulations 2002 (S.I. 2002/1281).
[96] The Export Control Act was approved on 24th July 2002.
[97] See at *http://www.cabinetoffice.gov.uk/about-cabinet-office.aspx*
[98] See at *http://www.cabinetoffice.gov.uk/ukresilience.aspx*
[99] See at *http://www.homeoffice.gov.uk/counter-terrorism/*
[100] See at *http://webarchive.nationalarchives.gov.uk/20100418065544/http://security.homeoffice.gov.uk/news-publications/publication-search/contest/contest-strategy/contest-strategy-2009?view=Binary*
[101] See at *http://www.hpa.org.uk/.*
[102] The Health Protection Agency Act was approved on 22nd July 2004.
[103] See *C.B.R.N. Incidents: Clinical Management and Health Protection* at *http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947377166*. See also *C.B.R.N. incidents: clinical management & health protection Biological incident action guide*, at *http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947377166.* About vaccination against smallpox, see *http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4083964.pdf.*
[104] See also now the Health Protection (Notification) Regulations 2010.
[105] See A. McCormick, *The Notification of Infectious Diseases in England and Wales,* Communicable Diseases Report, No. 2, Vol. 3, 1993, pp. R19-R34, *http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1205310733613*.

2.5. IN ITALY.

In Italy, specific norms are not in place with regards to bioterrorism attack, except the Law that ratifies the B.W.C.[106]. There are only references to terrorism (such as in the Law n. 438/2001 and Law n. 155/2005, coming from the Law Decree n. 144/2005 and giving application to the Council Framework Decision 2002/475/JHA on combating terrorism).
However, single pieces of legislation cover this issue, such as a new norm that has been introduced in 2005 within the Criminal Code, about the possession and misuse of biological agents (art. 270 *quinquies*). This provision is aimed at prosecuting those who give instructions about the preparation and utilization of dangerous chemical or batteriological substances.
The control of the import, export and transit of dual use materials is left upon the Ministry of Productive Activities (Department for the Internationalization). A Decree of this Ministry (4th August 2003) has classified and listed the kind of dual use products exportable and the State to which the export is allowed, through a general national authorization[107].
Furthermore, the National Committee for Biosafety, Biotechnology and Life Sciences has been created and, within it, a Working Group for Biosafety and Bioterrorism, which has the purpose of enacting a "*Code of conduct for the dual use products*"[108]. Such Code has been released in 2010, and it recommends that (1) a culture of responsibility and awareness should be developed among scientists about the risks connected with their research, (2) laboratories of high risk should be monitored and controlled, (3) the Ministry of Health and Agriculture should authorize detention and importation of agents, (4) programmes of formation and education of scientists should be pursued, and (5) participation at international networks for biosecurity is essential.
The control of laboratories has a central importance. Indeed, laboratories that respect the "Labs Good Practice" will receive a certificate of conformity by the Ministry of Health[109]. Moreover, a system of control and inspection of those centres has been shaped[110]. In each centre the level of risk should be determined (from 1 to 4) and, on the basis of it, the type of containment is taken.
Specific norms about food protection[111], water protection[112], and environmental protection[113], establish systems of traceability, control and compliance as well.
With reference to response measures, in 2001 a set of guidelines as "*Emergency National Plan against biological, chemical and radiological terrorist attacks*" has been drafted by Ministry of Health and Ministry of Inner Affairs. In the light of a bioterrorist attack, a Crisis Unity should intervene, along with some Centres for Counselling and Support in all national territory. Regional and local entities should be involved as well. For the Rapid Alert System, a Police Unity for Health Protection has been chosen as the National Contact Point. Military Specialized forces must intervene in case of attack and work in collaboration with civilian Authorities. Then, police, civilian authorities and health bodies are involved in response to bioterrorism, and they are coordinated and supported by the National Centre for Diseases Prevention and Control[114].
Moreover, according to the "*National Defence Program - Health Sector*", measures of risk contention are presented. Two Centres (the "Spallanzani" Hospital in Rome and the "Sacco" Hospital in Milan) have to deal with clinic management of the crisis and for coordination of measures, while the Institute of Health must deal with the assessment of the prophylactic therapeutic measures and the rapid identification of the relevant biological agents.

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[106] See Law 618/1974 that ratifies B.W.C..
[107] See Law 185/1990, as integrated by the Legislative Decree 96/2003.
[108] COMITATO NAZIONALE PER LA BIOSICUREZZA, LE BIOTECNOLOGIE E LE SCIENZE DELLA VITA, "Codice di Condotta per la Biosicurezza", *http://www.governo.it/biotecnologie/documenti/Codici_condotta_biosicurezza.pdf,* 2005.
[109] See Decree 4th July 1997 and Legislative Decree n. 206/2001. About dangerous substances and how to treat them in labs, see Legislative Decree n. 81/2008.
[110] See Legislative Decree n. 50/2007.
[111] In line with the E.U. Directives 2004/1/CE, 2004/13/CE and 2004/19/CE, a system of notification, traceability and labelling of food (with the role of the Ministry of Health and Local Sanitary Agencies for the compliance) has been articulated.
[112] See Document of the National Institute of Health, Rapporti ISTISAN, 05/4, 2005, on Safety of water system.
[113] The National Institute of Health (Istituto Nazionale di Sanità) has the function of evaluating the risk for human health and the environment, indicating measures to take for the management and reduction of risks and also controlling and inspecting the respect of them.
[114] See Law n. 138/2004 (for the National Centre for Diseases Prevention and Control, see *http://www.ccm-network.it*).

3. HOW TO DRAW A SOLID REGULATORY FRAMEWORK AGAINST BIOTERRORISM? THE IMPORTANCE OF FUNDAMENTAL RIGHTS.

After considering the existing regulations about bioterrorism, it is important to check whether they are in line with the respect of fundamental rights. In my view, indeed, the "constitutional" framework (meant, in a broad sense, as all the bills of fundamental rights that are settled at the highest level of the hierarchy of sources of law within "Civil Law" systems, or as the set of human rights that are part of the constitutional - even non written – tradition, especially within "Common Law" systems) ought to be at the basis of any regulation, from the statutory level up to the level of the codes of conduct. So, before evaluating the possibility of applying the aforementioned regulations to synthetic biology or not, it is necessary to check their compliance with fundamental rights that represent the way for building a solid regulation of the matter.

3.1. THE RIGHT TO SECURITY AND ITS RELATIONSHIP WITH OTHER RIGHTS AND FREEDOMS: PROPORTIONALITY AND REASONABLENESS.

When discussing about bioterrorism and biosecurity, the question lies in the type of rights that needed to be considered and the method in which to shape a constitutional frame to address them.
Fundamentally, the regulation against bioterrorism aims to protect human health of populations (in the form of life and integrity of single individuals belonging to the community), to the point that it could be rational to conceive the existence of a "right to security"[115], which entails that all these aspects of public health are to be safeguarded. In this area, it is evident that the right to security acquires a legal status that is «*in part autonomous – as a right to a protected existence, indispensable for the enjoyment of other rights vested into the subject – and in part indirect, in the sense that it is complementary to other rights, i.e. [...] rooted in the notion of quality and wellbeing of individual and collective life. Therefore, security can be qualified as a good intrinsically linked to life, physical integrity, well being, and quality of existence and dignity of person. From this, it comes out that it can be recognised as a right vested upon the State, in the form of interest to guarantee a situation of social peace, and as a right vested upon each individual [...]*»[116].
So, in deciding how to regulate bioterrorism, public health and security needs are central in both the prevention and response phases, but the very core issue is whether such rights to health and security should prevail over other rights and the need to "suspend" them for security reasons. Indeed, in the light of a bioterrorist attack, the tendency to make security overcome any other rights is strong. The relationship between security and other rights in "normal" conditions would be one of "cohabitation" among the rights. Here, security would have to promote other rights and be at the basis of the enjoyment of them or at least be complementary to them. In "emergency" conditions, instead, like the one of bioterrorism, such a relationship risks becoming one in which only security survives and other rights are suppressed.
For instance, the imposition of vaccines and quarantine for bioterrorism prevention risks to suppress the individual right to refusal of treatments. The manner in which to manage to relate public health needs and the individual right to health (whose protection entails self-determination and the right to refusal of treatments) must be dealt with.
Moreover, security reasons could be used to stifle the freedom of scientific research. Indeed, the freedom to investigate some issues that could provoke a malevolent use (even for bioterrorism, such as research about synthetic biology) could be suppressed in the name of protecting security.
So, in presence of the risks of bioterrorism, the trend would be for security to be the dominant value that justifies the "sacrifices" of other human rights and freedoms. In fact, «*there is reason to think that as a general matter in times of crisis, we will overestimate our security needs and discount the value of liberty*»[117].

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[115] It is worth mentioning that after Hobbes's works the notion of security and the State's role of ensuring it had a meaningful value. In the French Declaration of the Rights of Men and Citizen (1789), the right to security was mentioned as a natural and inalienable right, together with freedom, property and resistance to oppression (art. 2). For these aspects, see FROSINI, Tommaso, "Il diritto costituzionale alla sicurezza", *Teoremi e problemi di diritto costituzionale*, FROSINI, Tommaso (ed.), Giuffrè, Milano, Italia, 2008, p. 495 ff.

[116] FROSINI, Tommaso, *work cit*., p. 1. Such right is mentioned in Latin American Constitutions and in some European ones, such as Finnish, Spanish, Swiss, Portuguese ones, where the right to security is linked to freedom. Symptomatic is also E.C.H.R., art. 5, stating the same connection between freedom and security. Moreover, the reference to the right to security can be found in some judicial decisions, such as the decision n. 15/1982 of the Italian Constitutional Court, and the decisions of the U.S. Supreme Court in the case of *Korematsu v. United States* (323 U.S. 214 (1944)) where the Executive Order 9066, which ordered Japanese Americans into internment camps during World War II regardless of citizenship, was considered constitutional for security reasons; case of *Hirabayashi v. United States* (320 U.S. 81 (1943)), together with the ruling in the case of *Yasui v. United States* (320 U.S. 115 (1943)), where the Court stated that the application of curfews against members of a minority group were constitutional when the nation was at war with the country from which that group originated.

[117] COLE, David, "Enemy Aliens", *Stanford Law Review*, Vol. 54, 2002, pp. 953-955.

This view, though, would alter the set of human rights and, as affirmed by many authors[118], even in emergency situations, human rights cannot be suppressed. Eventual limitations of rights could be admitted because of security, but not up to the point of "deleting" some rights and, however, on the basis of some rules. The principle of proportionality and of reasonableness seem the most suitable ones to be recalled here. They should be used for drawing the balance between security and other rights, such as the individual right to health and the freedom of scientific research that are at stake in cases of bioterrorism. As known, the principle of proportionality allows a limitation of rights only for temporary periods, for necessity reasons, and using the least restrictive means for doing it[119]. In this way, the "core nucleus" of rights is never suppressed and its limitations are established in a way that is proportionate to the aim to be pursued (i.e., for protecting security). The reasonableness, then, must guide the balance between purposes and means, tools, time, methods to adopt[120].
In doing so, security cannot become an instrument for legitimising public powers to suppress any right. Instead, even in conditions of emergency, it cannot annul other rights, but only limit them for short periods of time in a proportioned and balanced manner[121]. As Ridola says, the growing needs of security, in relationship to new technologies as well, must find «*orienteering lines in the constitutional frame*»[122]: indeed, «*rather than being competing goals, human rights and national security are [...] complementary*»[123].

3.2. THE BALANCE BETWEEN SECURITY AND THE INDIVIDUAL RIGHT TO HEALTH.

In a concrete sense, the balance between security/public health and the individual right to health[124], which includes the right to refusal of treatments (such as the vaccines for contagious diseases determined by biological agents), ought to be done in such a way to «*permit public health officials to quarantine individuals who have a serious communicable disease who either cannot or will not accept treatment for it or agree to stay in their home, and who threaten to infect others with it [...]. Even then, however, we require public officials to use the "least restrictive alternative" and resort to quarantine only after other interventions, such as directly observed therapy, have failed*»[125]. In this way, individual consent to treatments should always be asked in principle, but when compulsory treatments are required, they should follow the principle of proportionality, so that the absence of asking consent can be imposed only in a state of necessity and emergency, to people that are really dangerous (i.e., pose a significant risk of transmission of disease), for a temporary time and provided that it is shaped as the least restrictive possibility[126]. Moreover, they should

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[118] See, among the many, BONETTI, Paolo, *Terrorismo, emergenza e costituzioni democratiche*, Il Mulino, Bologna, Italia, 2006, p. 79 ff; BALDINI, Vincenzo (ed.), *Sicurezza e stato di diritto: problematiche costituzionali,* Edizioni dell'Università degli studi di Cassino, Collana scientifica 04, Studi economico-giuridici, Cassino, Italia, 2005.
[119] ALEXY, Robert, "Constitutional Rights, Balancing, and Rationality", *Ratio Juris*, No. 2, Vol. 16, June 2003, pp. 131-140.
[120] About proportionality and reasonableness, see BIN, Roberto, *Diritti e argomenti. Il bilanciamento degli interessi nella giurisprudenza costituzionale*, Giuffrè, Milano, Italia, 1992; MODUGNO, Franco, *I* «*nuovi diritti*» *nella giurisprudenza costituzionale*, Giappichelli, Torino, Italia, 1995.
[121] About the balance of security right with others, see RUOTOLO, Marco, "La sicurezza nel gioco del bilanciamento", *http://www.astrid-online.it/Sicurezza-/Studi--ric/Ruotolo_AIC.pdf*, 2009. See also, BARAK, Aharon, "I diritti umani in tempi di terrorismo. Il punto di vista del giudice", *I diritti fondamentali della persona alla prova dell'emergenza*, MOCCIA, Sergio (ed.), Editoriale Scientifica Italiana, Napoli, Italia, 2009, p. 39 ff.
[122] RIDOLA, Paolo, "Libertà e diritti nello sviluppo storico del costituzionalismo", *I diritti costituzionali*, RIDOLA, Paolo / NANIA, Roberto (eds.), Giappichelli, Torino, Italia, 2006, vol. I, p. 143.
[123] BURKE-WHITE, William W., "Human Rights and National Security: The Strategic Correlation", *Harvard Human Rights Journal,* Vol. 17, 2004, pp. 249-280, here p. 254.
[124] In general, the notion of health has come to a progressive elaboration: from being perceived as a the absence of diseases, it has obtained the status of a complete physical and psychological well-being of the person, as stated by the World Health Organization (see W.H.O., Constitution, Basic Documents, Official Document n. 240, Washington, D.C., 1991). The right to health entails has been stated at the international level in the Universal Declaration on Human Rights (art. 25), the American Declaration on the Rights and Duties of Man (art. XI), the American Convention on Human Rights (art. 26), the European Social Charter (artt. 7, 8, 11, 13, 17, 23), the International Covenant on Economic, Social and Cultural Rights (art. 12), the African Charter on Human and Peoples' Rights (art. 16), the 2005 U.N.E.S.C.O. Universal Declaration on Human Rights and Bioethics (art. 14 and 15), and the 1997 U.N.E.S.C.O. Universal Declaration on the Human Genome and Human Rights (art. 12, 15, 17); at the European level, in the Treaty on the Functioning of European Union (artt. 9, 11, 168), and the European Charter on Fundamental Rights (art. 25); at the national constitutional level, in the Austrian (art. 10), Belgian (art. 23), Cypriot (art. 7); Estonian (art. 20 and 28), Finnish (art. 19), German (art. 2), Greek (art. 21), Irish (art. 45), Maltese (art. 36), Dutch (art. 22), Polish (art. 39 and 68), Portuguese (art. 26 and 64), Slovenian (art. 51 and 52), Spanish (art. 43); Swedish (art. 5) Constitutions.
[125] ANNAS, George J., "Legal Aspects of Bioterrorism", *Legal Medicine*, SANDY SANBAR, Shafeek (ed.), Mosby Elsevier, Philadelphia, U.S.A., 2007, pp. 679-689, here p. 684.
[126] See GOSTIN, Lawrence O., *Public Health Law: Power, Duty, Restraint,* California/Milbank Books on Health and the Public, Berkeley, California, U.S.A., 2000, pp. 213-216. See also HODGE, James G., "Bioterrorism Law and Policy: Critical Choices in Public Health", *The Journal of Law, Medicine & Ethics,* No. 2, Vol. 30, 2002, pp. 254-261.

never trump the respect of human dignity, as stated, for instance, in the Italian Constitution (art. 32). In the situation of bioterrorism, therefore, public health powers should be exercised without suppressing civil liberties, and the principle of proportionality is very apt for indicating how to balance the different rights at stake.

3.3. SECURITY AND THE FREEDOM OF SCIENTIFIC RESEARCH: CENSORSHIP OR PUBLICATION?, AND OTHER MEANS FOR A BALANCE.

Looking at the relationship between public health/security and the freedom of scientific research, in this case the principle of proportionality and reasonableness should be adopted as well.
Scientific research and discoveries could have harmful effects, because they could be used for bioterrorist purposes. Therefore, the need to find how and where to draw the line among admitted research must be fixed. In the light of the principle of proportionality, the nucleus of the freedom of research should be left untouched, and it coincides with the right to choose the topics of investigation and to exercise theoretical speculations. However, when such theory meets the executive phase (i.e., the spread of research results) and the application phase (such as the use of synthetic biology for developing bioterrorist applications), the freedom of research should be limited in a balanced way. In the case of bioterrorism, though, the distinction between research and its products is not so clear because even a "mere" discovery could be interesting for a bioterrorist[127]. This touches the core of "dual use dilemma". Indeed, considering that science could be used for malevolent or benevolent purposes, the question now lies in the method to control its diffusion. In other words, the main question is the following: is there a need to apply censorship or open access, in the light that the same discoveries that could generate bioweapons could also produce drugs and medicines? For instance, in the case of the accidental production of a superstrain of mousepox by Australian scientists, they decided to publish their research in the *Journal of Virology*[128] and later in the *U.S. New Scientist*[129] reported the same experiment. This was just one case that gave rise to the issue of the regulation of scientific research in comparison to security needs. The same happened, more recently, with the case of the possible publication of 5 variations to the virus of influenza H5N1, that have been produced at the Erasmus Medical Center in Rotterdam, and with analogous research conducted by Yoshihiro Kawaoka at the University of Wisconsin[130].
According to one position, the publication could be useful in order to make the people know of the existence of bioweapons and their risks, and in order to prepare an adequate response to bioterrorism. In this view, censorship would limit research and would represent an infringement to the freedom of research[131]. On others' perspective, censorship would be a better option, as the spread of such "sensitive" information that could be misused by malevolent people is a danger in itself[132].
As Selgelid states, «*scientific openness and the progress of medicine matter, but security matters, too. There is no reason to give absolute priority to the former over the latter; rather, a balance must be struck between the two*»[133], and such balance must be done, according to him, through an evaluation of potential (but tangible and not merely imagined) harms and (tangible) potential benefits. If the harms outweigh benefits, it would be better to opt for censorship. Otherwise, the open access could be admitted. Of course, such a position could be criticized in the sense that, in a context of an uncertainty about benefits and harms

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[127] See RINDSKOPF PARKER, ELIZABETH / GIELOW JACOBS, Leslie, "Government Controls of Information and Scientific Inquiry", *Biosecurity And Bioterrorism: Biodefense Strategy, Practice, And Science,* No. 2, Vol. 1, 2003, pp. 83-95, here p. 92.
[128] JACKSON, Ronald J. et al., "Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox", *Journal of Virology,* No. 3, Vol. 75, 2001, pp. 1205-1210.
[129] MACKENZIE, Debora, "U.S. Develops Lethal New Viruses", *New Scientist Online News*, 2003.
[130] In 2001, at the annual conference of the *European Scientific Working Group on Influenza*, one scientist from the Erasmus Medical Center of Rotterdam, Ron Fouchier, announced to have been capable of modifying the genetic code of virus H5N1, and thus obtaining a very dangerous virus. Analogous research was being done in the University of Wisconsin. The two studies about H5N1 should have had to be published in *Science* and *Nature,* but the U.S. National Science Advisory Board for Biosecurity (N.S.A.B.B.) intervened for blocking the publication. The National Institutes of Health stated that they needed to review the studies and asked the authors to select some of their results and methods (see at *http://www.nih.gov/news/health/dec2011/od-20.htm*). Then, the authors opted for a suspension of the publication for 60 days and for an international forum to discuss about the issue. In the end, the N.S.A.B.B. approved the publication, provided that some guidelines were followed (see BUTLER, Declan / LEDFORD, Heidi, "U.S. biosecurity board revises stance on mutant-flu studies. Decision comes one day after release of new guidelines for dual-use research", *Nature,* 2012). In May 2012, Yoshihiro Kawaoka published its study.
[131] See TREVAN, Tim, "Do not censor science in the name of biosecurity", *Nature*, Vol. 486, 2012, p. 295.
[132] About the history of censorship, see MARTIN, Brian, "Science: contemporary censorship", *Censorship: A World Encyclopedia,* JONES, Derek (ed.), Vol. 4, Fitzroy Dearborn, London, U.K., 2001, pp. 2167-2170.
[133] SELGELID, Michael J., "A Tale of Two Studies", cit., p. 40.

as the one of new technologies, it is difficult to imagine what the benevolent and malevolent effects of it could be, and so the cases for censorship and publication are vague and fuzzy to determine and it would leave the place to arbitrariness. Nevertheless, it seems to me that this solution is the most rational one and the most proper for respecting the proportionality and reasonableness principles. So, the restriction of freedom of research for security reasons should be shaped only after a balance between benefits and harms, in presence of real threats and when other alternatives do not occur for protecting security. Such position of "reasonable balance" between benefits and harms looks like a utilitarian one, from the ethical point of view, following a cost-benefits scheme, and it certainly is. However, it can cohabit with other views, as Miller and Selgelid explain. The balance to pursue can be framed in utilitarian terms, in deontological ones (balancing the right to free inquiry against rights to security and health), and according to virtue ethics as well[134].

Such balance seems to be applied in the case of the research about the mutation of virus H5N1. Indeed, after the big debate about censorship or publication of the results of the study, the publication was admitted. Such an evaluation between benefits and risks led to prefer the spread of knowledge, in order to allow researchers to have access of data for realising methods for fighting against H5N1. However, a narrow censorship of some methods that were adopted for reaching the results was applied[135].

Beyond the aspect of censorship or publication of research results, there are other ways to balance the freedom of research with the right to security, without hindering progress and studies and at the same time protecting public health. This can be achieved through the establishment of controls to research, through a periodic assessment of how research is going on and of biosecurity measures, the screening of orders of biological materials by scientists or other people working in the area (such as Do-It-Yourself members), the control of access, transport, the export of "sensitive" materials (such as some virus strains), the registration and the licensing of facilities that work with pathogens, and the screening of laboratory personnel[136].

4. ANALYSIS OF THE EXISTING REGULATIONS AGAINST BIOTERRORISM ON THE BASIS OF THE CONSTITUTIONAL FRAME AND THEIR POSSIBLE APPLICABILITY TO SYNTHETIC BIOLOGY.

From the regulatory "landscape" individuated above at the international, European and national level, it follows that the constitutional frame that should be taken into account has been, more or less, respected, even if some gaps remain.

All the mentioned regulations try to limit the spread by State and non State actors of organisms, genetic elements and toxins that have already been defined as hazardous, but there are no references or very little attention to the possibility of creating new genetic agents and biological weapons though synthetic biology. The definitions of biological agents, toxins and genetic elements are quite the same in the international, European and national legislature. As a result, a sort of harmonization and common standard has been reached.

However, the possibility of extending those regulations to synthetic biology is not so automatic. For instance, the B.W.C. refers to agents that are obtained by chemical synthesis, and in doing so, it seems to "cover" the developments of genetic modification and the creation of artificial life forms as well[137], as the "*Additional Understanding of art. 1*" explains. The B.W.C., indeed, «*unequivocally covers all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components, whatever their origin or method of production*». Such a chemical synthesis, though, must lead to the production of already controlled toxins and agents or, at least, to agents having a structure that is identical to, or similar to the one of known agents. So, only one type of synthetic biology seems to be included (the one of re-designing biological structures). It should be noted that it is not the one working with DNA sequences that code for novel organisms, toxins and pathogens. The same provisions are given by the Australia Group, whose rules cover genetically-modified organisms that contain nucleic acid sequences coding for the toxins in the list (not coding for new ones).

Other problematic "extensions" to synthetic biology could be individuated again in the B.W.C. provisions, where the Convention refers only to malevolent use of bioweapons by States, not mentioning non state actors, such as the "lone operators" or "biohackers" or bioterrorists not belonging to States. Such imprecision is problematic with regards to synthetic biology, which is becoming a field where private enterprises have a

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[134] SELGELID, Michael J. / MILLER, Seumas, "Ethical and Philosophical Consideration of the Dual-use Dilemma in the Biological Sciences", *Science of Engineering Ethics,* No. 4, Vol. 13, 2007, pp. 523–580.

[135] See EDITORIAL, "Publishing Risky Research", *Nature,* No. 5, Vol. 485, 2012.

[136] See TUCKER, Jonathan B., *Biosecurity: Limiting Terrorist Access to Deadly Pathogens*, United States Institute of Peace, Peaceworks n. 52, Washington, U.S.A., 2003, p. 28 ff.

[137] KELLE, Alexander, "Synthetic biology and biosecurity awareness in Europe", *http://www.synthetibiologysafe.eu/uploads///pdf/Syntheticbiologysafe-Biosecurity_awareness_in_Europe_Kelle.pdf,* 2007.

meaningful role and the States usually do not have enough measures for effective oversight of the progress of the area[138].
Moreover, synthetic biology challenges the Convention, in the part in which B.W.C. focuses only to control of the materials, without quoting the control to the access to information and knowledge.
Then, the U.N. Resolution 1540/2004 does not contain any reference to materials obtained through DNA technologies and manipulation (genetic engineering), and so synthetic biology could not be, at present, regulated by it.
In the Council of Europe, the openness to changes determined by new technologies and by the development of biology and genetics is mentioned within biosecurity regulations, but it is a vague reference.
With regards to E.U. regulation, it can be observed that toxins are not covered by the routine epidemiological surveillance and the early warning and response system provided by the Decision 2119/98 (that deals only with communicable diseases). Moreover, some new agents could be introduced but they would not be covered by legislation. The model of preparedness and response is in line with the constitutional frame and with the suggested balance of rights. However, this model should be implemented with (a) a system of licensing for the possession of instruments used in biological research and a registry of people working within the biodefence usage of synthetic biology, (b) the definition of criteria for the publication of data on highly pathogenic viruses or toxic agents at Member State and E.U. level, and (c) the creation of a centralised database at least at E.U. level, or preferably at international level, where all DNA synthesisers would be registered by competent Authorities[139]. Moreover, the Database Directive[140] should be applied for regulating databases where sequences of DNA for synthesis are screened.
Looking at the U.S.A. model, it could be observed that the Export Administration Regulation and Select Agent Regulation contemplate the awareness that DNA could be modified for creating toxins or other hazardous biological agents or the hypothesis that GMOs contain genetic sequences carrying on pathogenic features. However, such regulations aim to control DNA sequences that are modified to be malevolent, provided they are similar to the already existing and controlled organisms and toxins. As highlighted in the previous sections, this entails that a lot of fields within synthetic biology are not covered by most of U.S. legislation. The only exception is the Patriot Act, which carries with it criminal and civil penalties for those who possess biological agents that cannot be justified for prophylactic, protective, or peaceful purpose, regardless of whether a biological sample is synthetic, occurs naturally, is infectious, or is a select agent.
It is clear that in the U.S. the attention to bioterrorism and biosecurity seems to be higher than in Europe and it certainly derives from the Anthrax attacks that made the U.S. very afraid of the risk. Yet, a certain negligence in respecting the balance between security and health seems to be present in M.S.E.H.P.A.. It has been defined as a "draconian law", as criminal sanctions are provided for people who refuse to stay in quarantine. This is on the basis of a written directive by a public health official where a person can be quarantined before a hearing must be held. However, there is a certain vagueness about standards for quarantine, thus allowing for the arbitrary use of force and the permitting of public health authorities to quarantine anyone who refuses to be examined or treated, for whatever reason[141]. In these provisions, a proper balance between public health needs and individual right to health (and refusal) is absent.
In the U.K. a reference to the international lists of pathogens and biological agents is chosen, but there is an "open door" to the admissibility of synthetic agents as well. This is visible in the part of legislation where the Secretary of State is vested with the possibility to extend the list to include further pathogens or toxins if suspected of being used for bioterrorism.
In Italy, no references to synthetic biology are made, except in the "*Code of Conduct*" promulgated by the National Committee for Biosafety, Biotechnology and Life Sciences. The Code recommends to monitor the production of substances obtained by a synthetic organisms if they are not equivalent to the known ones, and to forbid research on synthetic organisms when they can be covered by prohibitions that are stated in B.W.C.. Moreover, the drafting of guidelines by journals about publication of results of research that could be "dual use" should be boosted.
In general, the measures of prevention, surveillance and response adopted both in the U.K. and in Italy appear to be compatible and in line with the aforementioned constitutional balance of rights.

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[138] See, at this regard, Germany's observation with regards to art. 4 at the 6th Conference (BWC/Conf.VI/WP.2, 2006).
[139] See EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (E.G.E.), "Opinion on Ethics of Synthetic Biology. Opinion No. 25", *http://ec.europa.eu/european_group_ethics/docs/opinion25_en.pdf*, 2009. See Recommendations n. 9, 10, 11, 12, 13, 14, 15.
[140] Directive 96/9/EC of 11th March 1996, on the legal protection of databases in *O.J.* L 77/1996.
[141] For this criticism, see ANNAS, George J., "Bioterrorism, Public Health, And Civil Liberties", *New England Journal of Medicine*, No. 17, Vol. 346, 2002, pp. 1337-1342.

5. DIFFERENT PROPOSALS FOR THE GOVERNANCE OF BIOSECURITY RISKS OF SYNTHETIC BIOLOGY.

After considering the regulatory framework that has been enacted so far for the management of bioterrorism, its compatibility with the constitutional balance of rights and its applicability to the new challenge represented by synthetic biology, it is necessary now to consider whether specific frameworks of governance of biosecurity risk for synthetic biology have been proposed, and what they are. Up till this point, I have tried to check the application of the existing legislative framework about bioterrorism to synthetic biology, keeping in mind that it was not born for addressing the risk generated by synthetic biology. In this section, the focus will be put on those proposals which are drafted precisely for synthetic biology.

5.1. THE INITIATIVE OF INTERNATIONAL JOURNAL PUBLISHERS.

One of the first initiatives about biosecurity risks of synthetic biology is represented by the "*Statement on Scientific Publication and Security*", enacted in 2003 by international journal publishers (i.e., the American Society for Microbiology and the editors of *Science, Nature* and *Proceedings of the National Academy of Sciences of the U.S.A.*) warning that «*there are occasions that an editor may conclude that the potential harm of publication outweighs the potential societal benefits*»[142], and in that case, the publication should be modified or not be published. The statement is a clear recognition of the fact that «*journals and scientific societies can play an important role in encouraging investigators to communicate results of research in ways that maximize public benefits and minimize risks of misuse*»[143]. So, the dual-use feature of life science research urges scientists to be careful of abuses and misuses, and it calls for the journal editors to exercise responsibility, when confronted with research papers that could be "sensitive" from the biosecurity standpoint. However, it should be noted here that the methods in which to recognise such "sensitive research" remain to be determined.

5.2. THE U.S. NATIONAL RESEARCH COUNCIL AND NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY, AND THEIR RECOMMENDATIONS.

In 2003, the National Research Council which is not a government body, but can give recommendations to the Government, formed a Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology. The committee enacted a report entitled "*Biotechnology Research in an Age of Terrorism*", commonly called the "*Fink Report*" after the committee chairman, Dr. Gerald Fink[144].
The report outlines the steps that the U.S. government should take to prevent the misappropriation of legitimate biotechnologies by terrorists. However, it should be noted that it does not mention synthetic biology *per se*, but the reference to the development of biotechnology and the possibility of using it in a malevolent way allow for the interpretation that the recommendations can be referred to synthetic biology as well. In the report there are relevant recommendations for educating the scientific community about risks of "dual use", the need of employing local institutional biosafety committees and of creating a new entity, namely the National Science Advisory Board for Biosecurity (N.S.A.B.B.). The report further recommends that the scientific community continues to adopt a self-governance model for scientific publications and to look for a better means of communication between law enforcement and the scientific community. It also suggests the necessity for a set of codes of conduct for scientists. It underlines seven experiments of concern: (1) the demonstration how to render a vaccine ineffective, (2) the confer of resistance to antibiotics or antiviral agent, (3) the enhancement of the virulence of a pathogen, (4) the increase of transmissibility of a pathogen, (5) the alteration of a pathogen's host range, (6) the enablement of evasion of diagnostic tools, and (7) the weaponization of a biological agent. The Committee also intervenes in the discussion about whether or not to publish some of the experiments that could entail potential misuse, and it urges for the prevention of «*the destructive application of biotechnology research while still enabling legitimate research to be conducted*».
After the Fink Committee, the U.S. National Academy of Sciences set up the Committee on Advances in Technology and the Prevention of their Application to Next Generation Bioterrorism and Biological Warfare

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[142] ATLAS, Ronald M. et al., "Statement on scientific publication and security", *Science,* No. 5610, Vol. 299, 2003, p. 1149.
[143] Ibid.
[144] NATIONAL RESEARCH COUNCIL, *Biotechnology Research in an Age of Terrorism*, Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, Washington, U.S.A., 2004.

Threats, the so-called "Lemon-Relman Committee", named after its two co-chairmen[145]. This Committee broadened the work of the "Fink Committee" in several directions, in particular putting the focus globally, and specifically referring to synthetic biology as a new source of threat for biosecurity.
Then, the N.S.A.B.B. was established within the N.I.H. in 2004 in response to the "*Fink Report*". It is composed of scientists and national security experts, governmental and non, with the role of advising institutional biosafety committees and recommending specific strategies for the oversight of potential dual-use biological research, while taking into consideration both the national security concerns and the needs of the research community. More specifically, the N.S.A.B.B. is meant to advise on (1) the strategies for local and federal biosecurity oversight towards life sciences research, (2) the development of guidelines for biosecurity oversight, (3) strategies to work with journal editors and other stakeholders to ensure the development of guidelines for the publication, public presentation, and public communication of potentially sensitive life sciences research, and (4) the development of guidelines for mandatory programs for education and training in biosecurity issues. The N.S.A.B.B. usually indicates the scientists as the only judges for identifying the "sensitive research" of colleagues and for addressing conduct issues.
Since 2006, one specific group is formed within N.S.A.B.B. that focuses specifically on synthetic biology, and it has enacted a report on biosecurity implications of *de novo* synthesis of select agents (2006), recommending: «*(1) a specific definition of which sequences are covered by the Select Agents Registry, (2) a formal and consistent process for comparing synthesis orders to the registry by using software, and (3) the maintenance of records of orders for five years*»[146].
In 2009 the National Security Council has published the "*National Strategy for Countering Biological Threats*"[147], taking into account the evolution of synthetic biology and calling for government action in addressing new threats and responsible conduct, but without referring to specific federal actions.

5.3. THE SCIENTIFIC ACADEMY'S AND SCIENTISTS' INTERVENTION.

Among the scientists, an important intervention is represented by the Inter Academy Panel (I.A.P.) on International Issues, i.e. a worldwide network of scientific academies. It drew up the "*I.A.P. Statement on Biosecurity*" at the end of 2005[148]. This statement gives the guidelines for the compilation of codes of conduct. Four principles are crucial: (1) awareness (i.e., making researchers aware of biosecurity risks in life sciences and new technologies), (2) Safety and Security (the necessity of indicating safety and security requirements for research activities), (3) Education and Information (to scientists), and (4) Accountability and Oversight (that is, researchers should signal abuses and supervise activities).
From I.A.P. Statement, the International Union of Microbiological Societies (I.U.M.S.) and the International Union of Biochemistry and Molecular Biology (I.U.B.M.B.), respectively in 2005 and 2006, adopted their codes of conduct accordingly[149].
Single scientists, such as Michele S. Garfinkel and Robert M. Friedman (from The J. Craig Venter Institute), Drew Endy (from Massachusetts Institute of Technology), and Gerald L. Epstein (from the Center for Strategic and International Studies), have enacted the report "*Synthetic Genomics: Options for Governance*" (2007)[150], which has three targets: (a) gene synthesis firms, oligonucleotide manufacturers and DNA synthesizers, (b) owners of a laboratory that synthesise DNA, and (c) users or consumers of synthetic DNA and the institutions that support or oversee their work. The policy options that must be enacted in order to prevent incidents of bioterrorism consist of, for the first category of addressees, the screening and checking orders of synthetic DNA, then their certificating through a biosecurity responsible officer, and finally the proper storage of the records. Then, the owners of the DNA synthesizers must register their machines and be licensed. Finally, the legitimate users should incorporate education about the risks and the best practices as part of university curricula, follow biosafety manual and best practices in labs, increase responsibilities

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[145] U.S. NATIONAL RESEARCH COUNCIL, *Globalization, Biosecurity, and the Future of the Life Sciences,* Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Washington, U.S.A., 2006.
[146] N.S.A.B.B., "Addressing Biosecurity Concerns Related to the Synthesis of Select Agents", *http://oba.od.nih.gov/biosecurity/pdf/FinalNSABBReportonSynthetic Genomics.pdf,* 2006. See pp. 10-13.
[147] N.S.A.B.B., "National Strategy for Countering Biological Threats", *http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf*, 2009.
[148] INTER ACADEMY PANEL ON INTERNATIONAL ISSUES, "IAP statement on Biosecurity", *http://www.nationalacademies.org/morenews/includes/IAP_Biosecurity.pdf*, 2005.
[149] I.U.M.S., *Code of Ethics against Misuse of Scientific Knowledge, Research and Resources*, Presented at the I.U.M.S. General Assembly on 28th April 2006; I.U.B.M.B., "Code of ethics of the International Union of Biochemistry and molecular biology", *Biochemistry and Molecular Biology Education*, No. 3, Vol. 34, May 2006, p. 167.
[150] GARFINKEL, Michele S. / ENDY, Drew / EPSTEIN, Gerald L. / FRIEDMAN, Robert M., *Synthetic Genomics. Options For Governance,* Rockville, M.D., Washington, D.C., Cambridge, M.A., U.S.A., 2007.

and oversight of Institutional Biosafety Committees. The authors of this report implicitly affirm the need for further regulation of the field.

5.4. THE GOLDMAN SCHOOL OF PUBLIC POLICY'S PROPOSAL AND THE DECLARATION OF CIVIL ORGANIZATIONS AT THE SECOND INTERNATIONAL MEETING ON SYNTHETIC BIOLOGY (SB 2.0).

During the Second Conference about synthetic biology (2.0), taken at Berkeley in 2006, a White Paper written by Stephen Maurer et al. from the Goldman School of Public Policy (California) began to circulate[151]. It insisted that (1) commercial gene synthesis companies adopted the best-practice screening methods, (2) a list of software tools was drafted, (3) "experiments of concern" could obtain independent expert advice before proceeding, (4) members had an ethical obligation to report dangerous behaviours, (5) a clearinghouse for helping community to identify and respond to the biosafety/biosecurity implications was created, and (6) investments in biosafety and biosecurity measures should be taken. The document placed a lot of emphasis on the governance options for synthetic biology, which could be implemented through community self-governance without outside intervention.
Against this position, some civil organizations (E.T.C., for example) drafted a Declaration[152], asking for stricter governance that did not allow the scientific community to govern by itself. In particular, the Declaration focuses on DNA synthesis that could give rise to safety or security concerns, and suggests the improvement of existing software tools for screening DNA sequences.

5.5. THE DNA-SYNTHESIS COMPANIES' CHOICES.

The suppliers of synthetic DNA in the U.S.A. and Europe are several. In the 2000s, some of them started screening sequence orders voluntarily, but the procedure was not clear. For this reason, a few companies assembled for constituting an International Consortium for Polynucleotide Synthesis (I.C.P.S.)[153], which elaborated on a DNA synthesis order screening process (2007), suggesting that (a) people who ordered DNA synthesis should identify themselves, their home organisation and all relevant biosafety information; (b) the single companies should use validated software tools to check synthesis orders; (c) the companies should work together through the I.C.P.S., and interface with appropriate government agencies (worldwide), in order to identify potentially dangerous sequences[154].
In the same time (2007), a group of German companies formed another consortium called the International Association of Synthetic Biology (I.A.S.B.)[155]. The Association has pushed for the development of guidelines, codes of conduct and best screening practices for scientific community. In its report "*Technical Solutions for biosecurity in synthetic biology*" (2008) about the First Meeting of the I.A.S.B., the importance of reaching these aims has been underlined:
(1) Harmonization of screening strategies for DNA synthesis orders, realising a forum to discuss shortcomings and to share technical resources;
(2) Creation of a central virulence factor database, i.e., a web-based, publicly accessible database containing the annotated genomes of selected viruses, bacteria, pathogens;
(3) Publication of an article on the status quo of synthetic biology;
(4) Establishment of a technical biosecurity working group with members from the I.A.S.B. and the I.C.P.S., in order to discuss improvements and next steps for biosecurity measures, and
(5) Commitment to security screening: each member, that already screens incoming gene orders for potential biosecurity risks and customers, should advertise these practices[156].
At the 2009 Second Meeting, a "*Code of Conduct and Best Practices*" has been drafted[157], which stresses the importance of (a) public discussion, (b)distribution, (c) a review of the Code, (d) the necessity of

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[151] MAURER, Stephen / LUCAS, Keith / TERRELL, Starr, *From Understanding to Action: Community-Based Options for Improving Safety and Security in Synthetic Biology*, Goldman School of Public Policy, University of California at Berkeley, U.S.A., 2006.
[152] The text of the Open Letter is available at *http://www.etcgroup.org/en/materials/publications.html?id=8.*
[153] The I.C.P.S. is composed of Blue Heron Biotechnology, GENEART, Codon Devices, Coda genomics, BaseClear, Bioneer and Integrated DNA Technologies.
[154] BÜGL, Hans et al., "DNA Synthesis and Biological Security", *Nature Biotechnology,* No. 6, Vol. 25, 2007, pp. 627-629, here p. 627.
[155] It is composed of ATG:biosynthetics, Biomax Informatics, Entelechon, febit Holding, and Sloning BioTechnology.
[156] INTERNATIONAL ASSOCIATION SYNTHETIC BIOLOGY, Report on the Workshop "Technical Solutions for Biosecurity in Synthetic Biology", *http://www.ia-sb.eu,* 2008, p. 16.
[157] INTERNATIONAL ASSOCIATION SYNTHETIC BIOLOGY, "Code of conduct for best practices in gene synthesis", *http://tinyurl.com/asbcode/,* 2009.

screening all gene synthesis orders and the customers for ensuring the legitimacy of the order, (e) keeping the records (the positive and suspected ones are stored for 8 years), (f) avoiding the delivery to private addresses, (g) cooperating with authorities and the community, and (h) informing about orders indicating illegal procurement activities. When a potential pathogen is identified by a software, the order is reviewed by an expert and it can be accepted, or rejected. Potential customers are screened against available lists provided by state authorities. This Code is considered as binding to its I.A.S.B. signatories, but is also a guideline for non I.A.S.B. companies.

In 2009, after the Second I.AS.B. meeting, five gene-synthesis companies (GENEART, DNA 2.0, Blue Heron Biotechnology, Integrated DNA Technologies and GenScript) decided to separate and form another group, called the International Gene Synthesis Consortium (I.G.S.C.), which is not open to all companies, but restricts membership to companies with more significant market shares. The Consortium has proposed lower requirements for sequence screening, by placing the emphasis on fast and cheap computerized checks against a predefined list of threats. Thus, the I.G.S.C. has enacted "*Harmonized Screening Protocol*"[158], which opts for automated screening as a filter to identify pathogen and toxin DNA sequences.

Both the I.A.S.B. and the I.G.S.C. codes involve an automated step, in which the genes in a customer's order are compared against those from organisms on lists such as the U.S. Centre for Disease Control and Prevention's "select agents" list. Although the I.A.S.B.'s standards specify that a human expert will follow up on possible "hits" identified in the automated screening step, the I.G.S.C.'s code ends with the automated screening step. Only when there is any suspicion of potential threat in the ordered sequence or in the customer's identity, should the I.G.S.C. companies report the request to authorities. This system is simpler and less costly because it creates a list of genes and a threshold, under which orders are considered as dangerous and thus refused. The system, however, «*worries some observers, because it is difficult to translate the list of select-agent organisms into lists of dangerous genes*»[159] and because the element of human screening is completely absent.

5.6. THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE VOLUNTARY SCREENING GUIDELINES FOR PROVIDERS OF SYNTHETIC DNA.

In 2010, the U.S. Department of Health and Human Services (D.H.H.S.) released the "*Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*"[160]. It refers to synthetic products, so that the order of them could be in line with S.A.R. and E.A.R.. The compliance with the Guidance is not compulsory but voluntary. The Guidance suggests that all double-stranded DNA orders are screened ("sequence screening") against GenBank, the National Institutes of Health (N.I.H.) genetic sequence database, which is an annotated collection of all publicly available DNA sequences. When receiving an order for synthetic double-stranded DNA, providers perform also a "customer screening" (checking the identity and affiliation of the customer). If the customer is a suspected one (as indicated in lists of people forbidden of access) or the agent is a select one, a "follow-up screening" must be pursued, by controlling the certificates and asking for the purposes of the usage of the agent. If the "follow-up screening" does not resolve the concerns about the order, the U.S. Government or the F.B.I. or the C.D.C. should be contacted for further assistance.

These Guidelines are voluntary, but they are meaningful, because they represent the first set of specific rules issued by a government with regards to synthetic biology, and they take into account the role of industries and scientific community as well. Thus, this guidance is a mix of government and self-regulation model of governance.

6. SUGGESTION OF A NEW MODEL: A "PRUDENT VIGILANCE" APPROACH FOR MANAGING BIOSECURITY RISKS OF SYNTHETIC BIOLOGY.

As it has been established thus far, different models of governance have been suggested with reference to the risks of biosecurity in the field of synthetic biology[161]. However, each of them shows some gaps and missing points. So, a new model is needed. In my opinion, a proper "road" to follow, in order to govern this

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[158] See *http://www.genesynthesisconsortium.org/wp-content/uploads/2012/02/IGSC-Harmonized-Screening-Protocol1.pdf*.

[159] CHECK HAYDEN, Erika, "Keeping genres out of terrorists' hands", *Nature*, No. 22, Vol. 461, 2009.

[160] See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, "Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA", *http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndnaguidance.pdf*, 2010. For a commentary, see KWIK GRONVALL, Gigi, "HHS Guidance on Synthetic DNA Is the Right Step", *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* No. 4, Vol. 8, pp. 373-376.

[161] About the evolution of the governance of biosecurity risks of synthetic biology, see the analysis developed by MAURER, Stephen, "End of the Beginning or Beginning of the End? Synthetic Biology's Stalled Security Agenda and the Prospects for Restarting It", *Valparaiso University Law Review*, No. 4, Vol. 45, 2011, pp. 73-132.

type of risks of synthetic biology, should be the so called "prudent vigilance" model. This expression is borrowed from the U.S. Presidential Commission for the Study of Bioethical Issues (P.C.S.B.I.)'s report on synthetic biology. In 2010, this advisory panel of the nation's leaders in medicine, science, ethics, religion, law and engineering has adopted, on request of the President Obama, a report containing 18 Recommendations for a proper governance and regulation of the field[162].

Developing the ideas contained within such report and taking some references from the International Risk Governance Council's report and its guidelines about synthetic biology[163], and from Innogen Centre Report[164], my proposal consists of adopting a model, which has the following featyures:

(1) From the point of view of its features: a model that consists of an ongoing and periodically revised assessment of biosecurity risks. It should be conducted with the involvement of all the stakeholders (governments, industries, scientific community, researchers, consumers, and so on) in a flexible way, so as to take into account all the scientific, economic, social, political, and ethical aspects involved within biosecurity needs. The purpose must be to assume proportioned measures of governance, i.e., measures based on the principles of proportionality and reasonableness among rights, and thus finding a proper balance between rights and interests to protect, without sacrificing or suppressing any of them.

Kelle, in this instance, suggests an approach that «*(a) includes all stakeholders in the development of synthetic biology as a discipline and its potential future applications, and (b) is flexible enough to accommodate a range of scenarios of how the field might develop*»[165];

(2) From the point of view of actors that have to be engaged and sources of law to adopt: this model opts for a mixed model of "hard law" and "soft law", that integrate reciprocally. The institutions are not the sole actors, but the scientific community, the stakeholders and general public are involved as well in an "engagement" approach;

(3) From the point of view of the enforcement, oversight and control of the policies that have been adopted: this model calls upon for the involvement of judges, government bodies, independent professional bodies, and multi-stakeholders' bodies. These subjects should cooperate and integrate each other. The tools that could be used are case-law, administrative law, and an autonomous set of measures that are decided on the basis of "soft law".

Applying these general characteristics of the "*prudent vigilance*" model to the specific case of biosecurity risks, it results that the governance should be reached through an involvement of all the stakeholders. This is established through the "top down" and "bottom up" sources of law, and a mixture of instruments for the enforcement and control. This means that, on the one hand, single laboratories and the whole scientific community should be called to draft the guidelines and the codes of conduct[166] ("soft law"), that are needed for increasing the awareness of risks posed by new technologies and for assigning to professionalization a tool for governance[167]. In this way, synthetic biologists are conceived as scientists having ethical obligations and deontological rules to follow. Indeed, the involvement of scientists «*offers them an identity as 'guardians of science' in the fight against biological weapons and bioterrorism, rather than the passive recipients of bureaucratic regulations*»[168]. The drafting of deontological codes and codes of conduct can also increase the

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[162] U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES (P.C.S.B.I.), "Report New Directions. The Ethics of Synthetic Biology and Emerging Technologies", *http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12.16.10.pdf*, 2010.

[163] INTERNATIONAL RISK GOVERNANCE COUNCIL, "Concept note: Synthetic Biology: Risk and Opportunities of an emerging field", *http://www.irgc.org/IMG/pdf/IRGC_Concept_Note_ Synthetic_Biology_191009_FINAL.pdf*, 2008. See also INTERNATIONAL RISK GOVERNANCE COUNCIL, "Policy Brief. Guidelines for the Appropriate Risk Governance of Synthetic Biology", *http://www.genomicsnetwork.ac.uk/media/irgc_SB_final_07jan_web.pdf*, 2010.

[164] TAIT, Joice / CHATAWAY, Joanna / WIELD, David, "Appropriate Governance of the Life Sciences – 2: The Case for Smart Regulation", Innogen Policy Brief, *http://www.genomicsnetwork.ac.uk/media/AGLS2%20-%20The%20Case%20for%20Smart%20Regulation.pdf.* The ESRC Centre for Social and Economic Research on Innovation in Genomics is based at the University of Edinburgh, Scotland (for further details, see *http://www.genomicsnetwork.ac.uk/innogen/*).

[165] See KELLE, Alexander "Security Issues Related to Synthetic Biology. Between Threat Perceptions and Governance Options", *Synthetic Biology. The Technoscience and Its Societal Consequences*, SCHMIDT, Markus / KELLE, Alexander / GANGULI-MITRA, Agomoni / DE VRIEND, Huib (eds.), Springer, Dordrecht, Germany, 2009, pp. 101-120, here p. 114.

[166] It can be noted that a lot of codes of conduct for scientific community have been proposed at many levels (for instance, by the American Society for Microbiology, Australian Society for Microbiology, American and British Medical Association, and others) after the 5th Review Conference B.W.C.. For further details, see LENTZOS, Filippa, "Managing Biorisks: Considering Codes Of Conduct", *Nonproliferation Review*, No. 2, Vol. 13, July 2006, pp. 211-226.

[167] WEIR, Lorna / SELGELID, Michael J., "Professionalization as a governance strategy for synthetic biology", *Systems Synthetic Biology*, No. 1-4, Vol. 3, 2009, pp. 91–97.

[168] MCLEISH, Caitríona / NIGHTINGALE, Paul, *work cit.,* p. 1648.

trust of the general public on the scientific community[169], because people could hold the biologists accountable[170].
On the other hand, the intervention of the States and governments through "hard law" cannot be neglected. However, it must be meant to be complementary with the one of the scientific community, and it should consist in delineating the general rules to scientists (such as the introduction of licenses for dealing with products or the duty to keep the State informed of developed research). Governments could also have a role in the phase of control of the sources of risk coming from the outside and from the State itself (in particular, by means of a decision-making authority embodying both science and security values and composed of specialists in the field).
Moreover, the engagement approach based on "*prudent vigilance*" entails that scientists are made aware of their responsibilities through programs for education and training that allow the creation of a "culture of responsibility". Scientific publishers and journals are also involved in the process and are invited in drafting their rules, on the basis of general frameworks coming from governments and legislators.
In this way, different levels of governance could be noted for addressing the biosecurity risks of synthetic biology:
(a) the level of individual scientists (that are the target of education programmes and must respect the whole set of biosecurity rules);
(b) the level of single laboratories (that are called to draft their own security guidelines, in line with the set of rules and standards adopted in the international and national frame);
(c) the level of educational and research institutions (that must supply scientists with educational training and control the compliance with the security rules);
(d) the level of scientific communities and/or organisations (that are called to settle their codes of conduct, respecting what provided in higher sources of law);
(e) the level of science publishers (invited to establish their deontological rules (about publication or censorship of scientific researches that arise "dual use" concerns);
(f) the level of national governments (that use laws, binding statutes, decrees for defining the regulation in biosecurity field); and
(g) the level of international (governance) bodies, such as United Nations, B.W.C. Review Conferences, W.H.O., and other bodies dealing with biosecurity and called to set a harmonized and shared set of standards.
So, the self-governance approach chosen by the "*Fink Report*", by the "*Lemon-Relman*" report, by Garfinkel's and Goldman School's reports should be integrated by the "top down" intervention. Similarly, the approach that has been assumed by civil organizations at the Second International Conference (SB 2.0) consisting of supporting the external regulation should not deny the importance of the "bottom up" contribution. The options given by the I.A.S.B., the I.C.P.S. and the I.G.S.C. appear more balanced as seem in the focusing of their activities on the technical solutions to the problem of the potential misuse of DNA sequences, and the suggestion of codes of conduct and best practices, without excluding the role of government and external authorities for oversight and enforcement of these standards. Yet, as Kelle affirms, «*although the proposals for technical solutions to DNA synthesis are certainly to be welcomed as useful building blocks for an overarching biosecurity governance structure, they do not represent an integrated approach that would, for a start, include a coherent set of measures to raise awareness across the synthetic-biology community*»[171].
A mixed approach is the one chosen by the D.H.H.S. with the "*Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA",* and an openness in the same direction is given by National Security Council in its last report (2009).
In a nutshell, a proper model for dealing with biosecurity risks of synthetic biology is the one characterized by an ongoing assessment of the risks and the involvement of all the actors and all the sources of law in the process, as well as the presentation of measures that range from ensuring the awareness of risks upon single scientists, to formulating laboratory guidelines, and from codes of conduct to national laws, and European and international provisions.
For the moment, the results of such approach are visible only with regards to the technical issue of controlling the DNA sequence trade[172]. The screening of customer orders for potentially dangerous DNA

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[169] SELGELID, Michael J., "Dual-Use Research Codes of Conduct: Lessons from the Life Sciences", *Nanoethics*, No. 3, Vol. 3, 2009, pp. 175-183, here p. 180.
[170] It could be observed at this regard, that since from the 1990s Joseph Rotblat formulated the proposal of a "Hippocratic Oath for Scientists", i.e., a universal code of conduct for scientists. The idea has been criticised because such code would be too general and vague to apply to any kind of science, and so it would be, in the end, useless (see ROTBLAT, Joseph, "Remember your humanity", *Nobel Lectures, Peace 1991–1995,* ABRAMS, Irwin (ed.), World Scientific Publishing, Singapore, 1999). See also REVILL, James / DANDO, Malcolm, "A Hippocratic Oath for life scientists", *EMBO Reports*, Vol. 7, 2006, pp. S 55-S60.
[171] KELLE, Alexander, "Synthetic biology and Biosecurity", *EMBO Report,* Vol. 10, 2009, pp. S 23-S 27, here p. 26.
[172] For deepening the issue, see SAMUEL, Gabrielle / SELGELID, Michael / J., KERRIDGE, Ian, "*Back* to the future: Controlling synthetic life science trade in DNA sequences", *Bulletin of the Atomic Scientists*, No. 5, Vol. 66, 2010, pp. 9–20.

sequences, the limitation of sale of DNA sequences, the storage of records of orders are the most adopted measures. Indeed, at the international level the Australia Group has elaborated on a system of controls on the export of select biological agents belonging to the list. The U.S., the E.U. and national regulations offer rules about the export controls. The I.A.S.B. has enacted a code of conduct about screening of orders and the U.S. D.H.H.S. has drafted a set of guidance in the same regard. The level of single laboratories and researchers is not controllable, but it is wishful that similar rules could be enacted in line with such a multi-level framework.

The applicability of this approach only to the control of DNA sequence trade shows how embryonic the multilevel governance model is. However, this example demonstrates that such approach can work. Therefore, what is necessary now is to implement it. This allows for the facing of the biosecurity risks of synthetic biology in a comprehensive way, both at the global and at the local level.

Furthermore, moving to the phases of enforcement and control of the policies that have been adopted through "hard law" and "soft law", through "top down" and "bottom up" sources and through the involvement of the public as well, it should be noted that the mixed model based on coordination and integration of tools should be applied in the case of biosecurity risks. It would entail that judges, government bodies, professional bodies which represent scientific community should intervene for the check of the respect of the rules that have been adopted. Moreover, such role of oversight should also be vested upon a multi-stakeholders' bodies that assemble people from all the different areas of the society, and thus representing the interests of everyone.

CONCLUSION.

Synthetic biology could be misused and could lead to bioterrorist scenarios, if handled by malevolent people, "lone operators" and biohackers. Thus, a set of regulations at the international, European, national level has been developed in the course of the years, not precisely with reference to synthetic biology, but in the fight against bioterrorism. However, provided that some modifications and updates are done to this set of regulations, while keeping in mind the constitutional frame that requires finding a balance between public health or security needs and the freedom of research, such system of rules could be applied to synthetic biology as well. The importance of governing biosecurity at a global level, as it is a global issue, is evident. For this reason, there is a need to accommodate to synthetic biology and to the constitutional frame that set of "hard law", which has been presented in the first part of this chapter. However, a mere "hard law" system ("command and control" model[173]) is not sufficient for tackling with biosecurity needs. Indeed, the fact of assigning to the governments the role to fix rules onto a scientific community from the outside could be too costly to implement and too limiting to the development of scientific progress. For instance, if decisions about what research is to be done and what papers are published are left in the hands of bureaucrats and governments, they will probably make security prevail over science values[174]. Furthermore, a "command and control" system is «*less effective where the target and scope of regulation are not easily defined. [...] [It is] also difficult to implement or enforce when the institutional behaviour to be influenced is complex, diffuse, and rapidly changing—all traits that characterize the diverse bioscience community*»[175].

On the other side, if a "pure" self governance model is preferred, the opposite situation is likely to be generated, i.e., the situation of favour for an absolutely free research, without any limit.

So, a proper balance between controlling research and letting it proceed can be rationally and adequately reached only through a new model of governance, in which governmental governance is applied in concert with other ways of governance. Taking in mind that «*governance systems that rely on voluntary standards or institutional practices cannot, alone, guarantee the prevention of bioterrorism or protect against malignant uses of biology. But international treaties or national top-down regulation cannot, on their own, deliver such promises either*»[176], the solution is a convergence of multilevel sources and actors. The regulatory multiplicity[177] and the co-presence of external regulation and codes of conduct, guidelines, deontological rules[178] enacted by scientific community itself could determine a more complete regulatory and governance

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[173] See BALDWIN, Robert / SCOTT, Colin / HOOD, Christopher, *A Reader on Regulation*, Oxford University Press, Oxford, U.K., 1998.

[174] See RAPPERT, Brian, "Codes of conduct and biological weapons: an in-process assessment", *Biosecurity and Bioterrorism*, No. 2, Vol. 5, 2007, pp. 145–154.

[175] KWIK, Gigi / FITZGERALD, Joe / INGLESBY, Thomas V. / O'TOOLE, Tara, "Biosecurity: Responsible Stewardship of Bioscience in an Age of Catastrophic Terrorism", *Biosecurity And Bioterrorism: Biodefense Strategy, Practice, And Science*, No. 1, Vol. 1, 2003, pp. 27-35, here p. 30.

[176] Ibid.

[177] See LENTZOS, Filippa, "Countering misuse of life sciences through regulatory multiplicity", *Science and Public Policy*, No. 1, Vol. 35, February 2008, pp. 55–64.

[178] About the moral duties to be embedded within deontological codes for life scientists (such as the obligations to prevent bioterrorism; to engage in response activities; to consider negative implications of research; not to publish or

system, that appears as more suitable for balancing freedom of research and security needs. Such framework should assess and monitor in a constant way the developments of science and its risks.
The implementation of "hard law" and "soft law" rules for countering bioterrorism would have to deal with (1) the level of scientific practice (security and safety rules for laboratories), (2) the level of information dissemination (giving external rules for publication and supporting the enactment of codes of conduct by journals and scientific editors), (3) the level of technology application (rules about the monitoring of all DNA synthesis orders from all suppliers in a coordinated way, the supplying people with a system of epidemiological surveillance and response in case of bioterrorist attack, the possession, trade and transfer of biological material), (4) the necessity of creating a culture of responsibility and cooperation between the scientific community and authorities[179], (5) the need to make scientists aware of their responsibilities and the risks of their work, and finally (6) the boosting of the research on synthetic biology, and using it as a means for fighting against bioterrorist threats coming from itself (for instance, adopting synthetic biology for designing new ways of resistance to bioterrorism, such as new vaccines, drugs and anti-viral therapies against pathogens and biological agents)[180].
In addition, a mixed model for the oversight and control of those policies should be adopted. The cooperation and integration between different subjects seems the best way for enforcing those codes of conduct and for ensuring the application of international and national laws. In particular, bodies aimed at the oversight of the security rules and composed of government, security, scientific community members, and other stakeholders should be implemented and boosted.

BIBLIOGRAPHY

ALBERTS, Bruce / MAY, Robert, "Scientist Support for Biological Weapons Controls", *Science,* Vol. 298, 2002, p. 1135.
ALEXY, Robert, "Constitutional Rights, Balancing, and Rationality", *Ratio Juris*, No. 2, Vol. 16, June 2003, pp. 131-140.
ALPER, Joe, "Biotech in the basement", *Nature Biotechnology*, No. 12, Vol. 27, 2009, pp. 1077-1078.
ANNAS, George J., "Bioterrorism, Public Health, And Civil Liberties", *New England Journal of Medicine*, No. 17, Vol. 346, 2002, pp. 1337-1342.
ANNAS, George J., "Legal Aspects of Bioterrorism", *Legal Medicine*, SANDY SANBAR, Shafeek (ed.), Mosby Elsevier, Philadelphia, U.S.A., 2007, pp. 679-689.
ATLAS, Ronald M., "Toward global harmonization for control of dual-use biothreat agents", *Science and Public Policy*, No. 1, Vol. 35, February 2008, pp. 21–27.
ATLAS, Ronald M. / DANDO, Malcolm R., "The Dual-use Dilemma for the Life Sciences: Perspectives, Conundrums, and Global Solutions", *Biosecurity Bioterrorism,* No. 3, Vol. 4, 2006, pp. 276–286.
ATLAS, Ronald M. et al., "Statement on scientific publication and security", *Science,* No. 5610, Vol. 299, 2003, p. 1149.
BALDINI, Vincenzo (ed.), *Sicurezza e stato di diritto: problematiche costituzionali,* Edizioni dell'Università degli studi di Cassino, Collana scientifica 04, Studi economico-giuridici, Cassino, Italia, 2005.
BALDWIN, Robert / SCOTT, Colin / HOOD, Christopher, *A Reader on Regulation*, Oxford University Press, Oxford, U.K., 1998.
BARAK, Aharon, "I diritti umani in tempi di terrorismo. Il punto di vista del giudice", *I diritti fondamentali della persona alla prova dell'emergenza*, MOCCIA, Sergio (ed.), Editoriale Scientifica Italiana, Napoli, Italia, 2009, p. 39 ff.
BASSIOUNI, M. Cherif, *International Humanitarian Law and Arms Control Agreements*, Transnational Publishers, Ardsley, New York, U.S.A., 2000, p. 17 ff.
BERG, Paul et al., "Potential Biohazards of Recombinant DNA Molecules", *Science,* No. 4148, Vol. 185, 1974, pp. 303 ff.
BERG, Paul et al., "Summary Statement of the Asilomar Conference on Recombinant DNA", *Proceedings of the National Academy of Sciences of the U.S.A.,* No. 6, Vol. 72, 1975, pp. 1981-1984.
BIN, Roberto, *Diritti e argomenti. Il bilanciamento degli interessi nella giurisprudenza costituzionale*, Giuffrè, Milano, Italia, 1992.
BONETTI, Paolo, *Terrorismo, emergenza e costituzioni democratiche*, Il Mulino, Bologna, Italia, 2006.
BUCHANAN, Allen / POWELL, Russel, *The Ethics of Synthetic Biology: Suggestions for a Comprehensive Approach* (to the U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES), *http://bioethics.gov/sites/default/files/The-Ethics-of-Synthetic-Biology-Suggestions-for-a-Comprehensive-Approach.pdf,* 2011.
BUCHSBAUM, Lori L., "The U.S. Public Health Response To Bioterrorism: Need For A Stronger Legislative Approach", *Journal Of Medicine And Law*, No. 1, Vol. 7, 2002, pp. 2-36.
BÜGL, Hans et al., "DNA Synthesis and Biological Security", *Nature Biotechnology,* No. 6, Vol. 25, 2007, pp. 627-629.
BURKE-WHITE, William W., "Human Rights and National Security: The Strategic Correlation", *Harvard Human Rights Journal,* Vol. 17, 2004, pp. 249-280.

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share sensitive information; to oversee and limit access to dangerous material; and to report activities of concern), see KUHLAU, Frida / ERIKSSON, Stefan / EVERS, Kathinka / HÖGLUND, Anna, "Taking Due Care: Moral Obligations In Dual Use Research", *Bioethics*, No. 9, Vol. 22, 2008, pp. 477–487.

[179] See ALBERTS, Bruce / MAY, Robert, "Scientist Support for Biological Weapons Controls", *Science,* Vol. 298, 2002, p. 1135. See also ATLAS, Ronald M., "Toward global harmonization for control of dual-use biothreat agents", *Science and Public Policy*, no. 1, Vol. 35, February 2008, pp. 21–27.

[180] About this proposal, see MUKUNDA, Gautam / OYE, Kenneth A. / MOHR, Scott C., "What Rough Beast? Synthetic Biology, Uncertainty, And The Future Of Biosecurity", *Politics and Life Sciences*, No. 2, Vol. 28, August 2009, pp. 2-26.

BUTLER, Declan / LEDFORD, Heidi, "U.S. biosecurity board revises stance on mutant-flu studies. Decision comes one day after release of new guidelines for dual-use research", *Nature,* 2012.
CHECK HAYDEN, Erika, "Keeping genres out of terrorists' hands", *Nature*, No. 22, Vol. 461, 2009.
COLE, David, "Enemy Aliens", *Stanford Law Review*, Vol. 54, 2002, pp. 953-955.
DE LA CUESTA ARZAMENDI,José Luis, "Armas biológicas o exterminadoras e ingeniería genética: perspectiva juridico-penal", *Genética e Derecho Penal. Previsiones en el Código Penal Español de 1995*, ROMEO CASABONA, Carlo María (ed.), Ed. Cátedra Interuniversitaria de Derecho y Genoma Humano - Comares, Bilbao-Granada, Spain, 2001, pp. 239-265.
EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (E.G.E.), "Opinion on Ethics of Synthetic Biology. Opinion No. 25", *http://ec.europa.eu/european_group_ethics/docs/opinion25_en.pdf*, 2009.
FIDLER, David P., "Legal Issues Surrounding Public Health Emergencies", *Public Health Reports,* Suppl. No. 2, Vol. 116, 2001, pp. 79-86.
FORGE, John, "A Note on the Definition of "Dual Use", *Science of Engineering Ethics,* No. 1, Vol. 16, 2010, pp. 111–118.
FROSINI, Tommaso, "Il diritto costituzionale alla sicurezza", *Teoremi e problemi di diritto costituzionale*, FROSINI, Tommaso (ed.), Giuffrè, Milano, Italia, 2008, p. 495 ff.
GARFINKEL, Michele S. / ENDY, Drew / EPSTEIN, Gerald L. / FRIEDMAN, Robert M., *Synthetic Genomics. Options For Governance,* Rockville, M.D., Washington, D.C., Cambridge, M.A., U.S.A., 2007.
GOSTIN, Lawrence O., *Public Health Law: Power, Duty, Restraint,* California/Milbank Books on Health and the Public, Berkeley, California, U.S.A., 2000, pp. 213-216.
HODGE, James G., "Bioterrorism Law and Policy: Critical Choices in Public Health", *The Journal of Law, Medicine & Ethics,* No. 2, Vol. 30, 2002, pp. 254-261.
INTERNATIONAL RISK GOVERNANCE COUNCIL, "Concept note: Synthetic Biology: Risk and Opportunities of an emerging field", *http://www.irgc.org/IMG/pdf/IRGC_Concept_Note_Synthetic_Biology_191009_FINAL.pdf*, 2008.
INTERNATIONAL RISK GOVERNANCE COUNCIL, "Policy Brief. Guidelines for the Appropriate Risk Governance of Synthetic Biology", *http://www.genomicsnetwork.ac.uk/media/irgc_SB_final_07jan_web.pdf*, 2010.
KELLE, Alexander "Security Issues Related to Synthetic Biology. Between Threat Perceptions and Governance Options", *Synthetic Biology. The Technoscience and Its Societal Consequences*, SCHMIDT, Markus / KELLE, Alexander / GANGULI-MITRA, Agomoni / DE VRIEND, Huib (eds.), Springer, Dordrecht, Germany, 2009, pp. 101-120.
KELLE, Alexander, "Synthetic biology and biosecurity awareness in Europe", *http://www.synthetibiologysafe.eu/uploads///pdf/Syntheticbiologysafe-Biosecurity_awareness_in_Europe_Kelle.pdf,* 2007.
KELLE, Alexander, "Synthetic biology and Biosecurity", *EMBO Report,* Vol. 10, 2009, pp. S 23-S 27.
KUHLAU, Frida / ERIKSSON, Stefan / EVERS, Kathinka / HÖGLUND, Anna, "Taking Due Care: Moral Obligations In Dual Use Research", *Bioethics*, No. 9, Vol. 22, 2008, pp. 477–487.
KWIK GRONVALL, Gigi, "HHS Guidance on Synthetic DNA Is the Right Step", *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* No. 4, Vol. 8, pp. 373-376.
KWIK, Gigi / FITZGERALD, Joe / INGLESBY, Thomas V. / O'TOOLE, Tara, "Biosecurity: Responsible Stewardship of Bioscience in an Age of Catastrophic Terrorism", *Biosecurity And Bioterrorism: Biodefense Strategy, Practice, And Science*, No. 1, Vol. 1, 2003, pp. 27-35.
LENTZOS, Filippa, "Countering misuse of life sciences through regulatory multiplicity", *Science and Public Policy*, No. 1, Vol. 35, February 2008, pp. 55–64.
LENTZOS, Filippa, "Managing Biorisks: Considering Codes Of Conduct", *Nonproliferation Review*, No. 2, Vol. 13, July 2006, pp. 211-226.
MACKENZIE, Debora, "U.S. Develops Lethal New Viruses", *New Scientist Online News*, 2003.
MARTIN, Brian, "Science: contemporary censorship", *Censorship: A World Encyclopedia,* JONES, Derek (ed.), Vol. 4, Fitzroy Dearborn, London, U.K., 2001, pp. 2167-2170.
MAURER, Stephen / LUCAS, Keith / TERRELL, Starr, *From Understanding to Action: Community-Based Options for Improving Safety and Security in Synthetic Biology*, Goldman School of Public Policy, University of California at Berkeley, U.S.A., 2006.
MAURER, Stephen, "End of the Beginning or Beginning of the End? Synthetic Biology's Stalled Security Agenda and the Prospects for Restarting It", *Valparaiso University Law Review*, No. 4, Vol. 45, 2011, pp. 73-132.
MAYER, Lincoln P., "Immunity For Immunizations: Tort Liability, Biodefense, And Bioshield II", *Stanford Law Review*, No. 6, Vol. 59, 2007, pp. 1753-1790.
MCLEISH, Caitríona / NIGHTINGALE, Paul, "Biosecurity, bioterrorism and the governance of science: The increasing convergence of science and security policy", *Res. Pol.,* Vol. 36, 2007, pp. 1635–1654.
MODUGNO, Franco, *I «nuovi diritti» nella giurisprudenza costituzionale*, Giappichelli, Torino, Italia, 1995.
MORENO, Jonathan D., "Bioethics And Bioterrorism", *The Oxford Handbook Of Bioethics*, STEINBOCK, Bonnie (Ed.), Oxford University Press, New York, 2007, pp. 721-733.
MUKUNDA, Gautam / OYE, Kenneth A. / MOHR, Scott C., "What Rough Beast? Synthetic Biology, Uncertainty, And The Future Of Biosecurity", *Politics and Life Sciences*, No. 2, Vol. 28, August 2009, pp. 2-26.
NATIONAL RESEARCH COUNCIL, *Biotechnology Research in an Age of Terrorism*, Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, Washington, U.S.A., 2004.
PANEL ON SCIENTIFIC COMMUNICATION AND NATIONAL SECURITY, NATIONAL ACADEMY OF SCIENCES, NATIONAL ACADEMY OF ENGINEERING, INSTITUTE OF MEDICINE, *Scientific Communication and National Security*, Washington, U.S.A., 1982.
RAPPERT, Brian, "Codes of conduct and biological weapons: an in-process assessment", *Biosecurity and Bioterrorism*, No. 2, Vol. 5, 2007, pp. 145–154.
REVILL, James / DANDO, Malcolm, "A Hippocratic Oath for life scientists", *EMBO Reports*, Vol. 7, 2006, pp. S 55-S60.
RICHARDS, Edward P. / O'BRIEN, Terry / RATHBUN, Katharine C., "Bioterrorism and the Use of Fear in Public Health", *The Urban Lawyer*, No. 3, Vol. 34, 2002, pp. 685-726.

RIDOLA, Paolo, “Libertà e diritti nello sviluppo storico del costituzionalismo”, *I diritti costituzionali*, RIDOLA, Paolo / NANIA, Roberto (eds.), Vol. 1, Giappichelli, Torino, Italia, 2006, p. 143 ff.
RINDSKOPF PARKER, ELIZABETH / GIELOW JACOBS, Leslie, “Government Controls of Information and Scientific Inquiry”, *Biosecurity And Bioterrorism: Biodefense Strategy, Practice, And Science,* No. 2, Vol. 1, 2003, pp. 83-95.
ROTBLAT, Joseph, “Remember your humanity”, *Nobel Lectures, Peace 1991–1995,* ABRAMS, Irwin (ed.), World Scientific Publishing, Singapore, 1999.
RUOTOLO, Marco, “La sicurezza nel gioco del bilanciamento”, *http://www.astrid-online.it/Sicurezza-/Studi--ric/Ruotolo_AIC.pdf*, 2009.
SAMUEL, Gabrielle / SELGELID, Michael / J., KERRIDGE, Ian, “*Back* to the future: Controlling synthetic life science trade in DNA sequences”, *Bulletin of the Atomic Scientists*, No. 5, Vol. 66, 2010, pp. 9–20.
SAWAYA, David B., “Biosecurity at the OECD”, *Biosecurity Origins, Transformations and Practices*, RAPPERT, Brian / GOULD, Chandr (eds.), Palgrave Macmillan, England, 2009, p. 79 ff.
SCHMIDT, Markus / GIERSCH, Gregor, “DNA Synthesis And Security”, *DNA Microarrays, Synthesis and Synthetic DNA*, CAMPBELL, Melissa J. (ed.), Nova Publishers, New York, U.S.A., 2011, pp. 285-300.
SELGELID, Michael J. / MILLER, Seumas, “Ethical and Philosophical Consideration of the Dual-use Dilemma in the Biological Sciences”, *Science of Engineering Ethics,* No. 4, Vol. 13, 2007, pp. 523–580.
SELGELID, Michael J., “A Tale of Two Studies. Ethics, Bioterrorism, and the Censorship of Science”, *Hastings Center Report*, No. 3, Vol. 37, 2007, pp. 35-43.
SELGELID, Michael J., “Dual-Use Research Codes of Conduct: Lessons from the Life Sciences”, *Nanoethics*, No. 3, Vol. 3, 2009, pp. 175-183, here p. 180.
TAIT, Joice / CHATAWAY, Joanna / WIELD, David, “Appropriate Governance of the Life Sciences – 2: The Case for Smart Regulation”, Innogen Policy Brief, *http://www.genomicsnetwork.ac.uk/media/AGLS2%20-%20The%20Case%20for%20Smart%20Regulation.pdf*
TREVAN, Tim, “Do not censor science in the name of biosecurity”, *Nature*, Vol. 486, 2012, p. 295.
TUCKER, Jonathan B., *Biosecurity: Limiting Terrorist Access to Deadly Pathogens*, United States Institute of Peace, Peaceworks n. 52, Washington, U.S.A., 2003.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, “Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA”, *http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndnaguidance.pdf*, 2010.
U.S. NATIONAL RESEARCH COUNCIL, *Globalization, Biosecurity, and the Future of the Life Sciences,* Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Washington, U.S.A., 2006.
U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES (P.C.S.B.I.), “Report New Directions. The Ethics of Synthetic Biology and Emerging Technologies”, *http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12.16.10.pdf*, 2010.
WEIR, Lorna / SELGELID, Michael J., “Professionalization as a governance strategy for synthetic biology”, *Systems Synthetic Biology*, No. 1-4, Vol. 3, 2009, pp. 91–97.
WHITTALL, Simon, “The Ethics of Synthetic Biology”, *Ethical Aspects of Synthetic Biology*, EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (EDS.), Proceedings of the Round Table, *http://ec.europa.eu/bepa/european-group-ethics/docs/publications/round_table_ethical_aspects_of_synthetic_biology.pdf*, 2009, p. 27.