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BIOLAW AND THE 'DUAL-USE DILEMMA': THE FREEDOM OF SCIENTIFIC RESEARCH IN RELATIONSHIP WITH 'TRADITIONAL' AND EMERGING SCIENCES AND TECHNOLOGIES

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ABSTRACT.

Science and technology require an intervention by the law, and law is called upon to intervene in front of their evolution, and to look for proper solutions of governance and rational responses to their risks. One of the main issues to be investigated from the legal viewpoint is represented by the 'dual-use dilemma' that arises both in 'traditional' and new areas of techno-sciences. Indeed, any kind of research has the potential to be used both for bad as well as for good purposes. Therefore, it is important to reflect upon the ways to control possibly dangerous research without preventing the progress from going further. Such 'dual-use dilemma', then, entails the study of one of the fundamental freedoms in the biolaw area: the freedom of scientific research, its limits, and relationship with other rights/needs/freedoms (such the need of security).
This work focuses on two areas of the techno-scientific world. One is more 'traditional', i.e. nuclear science, in whose context the reflections on 'dual-use' were born and developed, and the other one is a new emerging technology, which is synthetic biology. The aim is to understand how the freedom of scientific research could be shaped in relationship with other rights/needs/interests for dealing with 'dual-use' issues in the aforementioned areas of science and technology.

KEY WORDS. Synthetic biology – nuclear science – freedom of research – security – balance.

INTRODUCTION.

In front of the evolution of science and technology, the law cannot remain silent, but it is called upon to change accordingly.

The field that is labeled as 'biolaw' aims to cope with such challenge of finding a legal answer to the problems emerging in the techno-scientific area.

Even if there is no universal agreement about what 'biolaw' means (Casabona 2011), this branch of the law entails a set of rights, freedoms and principles that aim to: (a) regulate science and technology, (b) govern, prevent and manage the risks connected to these areas,

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and (c) face with their challenges. It is, then, an interdisciplinary area of law, which assembles notions from constitutional law, family law, intellectual property rights, human rights law, etc., in the attempt to deal with an undetermined and ever-changing object. Indeed, science and technology are continuously progressing; they usually go faster than the law, and most of the times they cannot be predicted. Such uncertainty of science clashes with the 'rigid' need for certainty of the law (the principle of legal certainty is, for instance, one of the most important legal principles, especially in 'civil law' countries), and it determines an inevitable delay of the law (Casonato 2014, 1).

Furthermore, science and technology challenge the 'traditional' categories of 'civil law' and 'common law', and produce significant cross-fertilization between different legal systems.

Beyond the 'classical' areas which biolaw has focused on (i.e., the cases of the beginning of life, the end of life, abortion, euthanasia, medically assisted procreation, etc.), and other recent fields (genetics, life sciences, biotechnology), the 'landscape' is showing new and emerging streams: synthetic biology, nanotechnology, neurosciences, robotics, artificial intelligence are just a few examples of the rich variety of scientific and technological evolution (Santosuosso *et al.* 2015).

All these areas are, of course, the result of investigation and scientific research. So, they entail one of the inherent problems of any type of research: the 'dual-use dilemma' (UK Parliamentary Office of Science and Technology 2009; Atlas and Dando 2006).

Such dilemma is particularly increased in relation to emerging sciences and technologies, since they generate both benefits and risks (Miller and Sagan 2009).

This work aims to legally explore the dilemma, as referred to two areas: one, which is more 'traditional', is the field of nuclear science and technology, and the other one, which is a new emerging area, is synthetic biology.

1. THE 'DUAL-USE DILEMMA'.

The notion of 'dual-use dilemma' is twofold:

a) it arises when the same piece of research could benefit or harm the humanity (Miller and Selgelid 2007); or
b) it can mean that research can have both a civil or a military application (Atlas and Dando 2006).

‘Dual-use’ is an aspect that could be referred to: (a) scientific research, or (b) technological items that are the result of that research.

For instance, a case of dual-use as intrinsic to research is the case of the experiments conducted by Nazis doctors during the World War II (i.e., the Nazi programs in extermination camps, such as Aktion T4 and Neue Aktion 14F13 (Browning 2005)), or the “Tuskegee Study of Untreated Syphilis in the Negro Male” pursued in the U.S.A., which concerned 616 African American males, who were not treated in order to study the long term effects of untreated syphilis (URL: <http://www.cdc.gov/tuskegee/timeline.htm>, last accessed: 31/07/2015).

An example of dual-use pertaining to the application of research could be the one of dynamite, which could be used for digging water wells in Poor countries, or for killing people (Forge 2010).

Such a dilemma also arises in the context of nuclear science and technology on the one hand, and synthetic biology, on the other one.

With ‘nuclear science’, we refer to the study of the atomic world (URL: <http://www.ansto.gov.au/NuclearFacts/AboutNuclearScience/>, last accessed: 31/07/2015), i.e. the study of nuclear dimension (where ‘nuclear’ means “of, or relating to, or constituting the nucleus of an atom”). In particular, the attention is posed on nuclear fission (i.e., the process by which a nucleus is split into two or more smaller parts) and nuclear fusion (the process of ‘fusing’ two lighter nuclei into a heavier nucleus). ‘Nuclear technologies’ entails a technology involving the reactions of atomic nuclei. Some of the most prominent examples are nuclear reactors, nuclear medicine and nuclear weapons.

As for ‘synthetic biology’, the definition relates to a converging science and technology, which assembles knowledge coming from different fields, such as biology, genetics, engineering, nanotechnology, computer sciences, biotechnology, and chemistry. Its purposes are both (1) to redesign existing biological systems, improving their properties, and (2) to design completely new parts and devices that are artificial and do not exist in nature as such (URL: <http://www.syntheticbiology.org>, last accessed: 31/07/2015).

Some differences can be drawn between these two areas: as the “Fink Report” (National Research Council 2004, 23) states, nuclear materials do not exist in nature as such, they are difficult to reproduce and can be managed by expert people only; they entail the risk of being used for producing nuclear weapons. Instead, biological materials can be found in nature, are enough easy to replicate and do not need a deep expertise. At this regard, it is meaningful to mention the phenomenon of “do-it-yourself biology” (DIY), as well as clandestine and

'garage' laboratories (URL: <http://diybio.org/>, last accessed: 31/07/2015). Biological items can be used for producing biological weapons within State programs, or by non-conventional actors (bioterrorists).

However, despite these differences, the aforementioned fields generate the same 'dual-use dilemma'.

Nuclear science could be used for producing nuclear power (energy), for medical applications (e.g., medical radiography or radiopharmaceuticals), for industrial and commercial applications (construction of aircrafts, road construction, oil and gas exploration, etc.), or in agriculture for food radiation (in order to induce mutations to modify or build new species, or destroy pathogens in food).

The applications of synthetic biology are numerous, and fall into several areas of interest (such as health, agriculture, food production, environment, energy production, biomedicine, industries, etc.). Indeed, this emerging area promises to radically revolutionise the next few years. It could lead to the production of energy (through the development of biofuels), and environmental and agricultural substances to be used for bioremediation (in order to degrade pesticides, detect and remove pollutants), for the creation of biosensors and new types of pesticides, or for increasing food properties. It could also be adopted for obtaining new biopharmaceuticals, new vaccines, and new molecular devices composed of sensors and enzymes to be used for tissue repair or regeneration, or as vectors for therapy.

At the same time, nuclear research may result in the creation of bombs and weapons designed to distribute hazardous nuclear material in enemy areas, or for terroristic purposes: these are one of the most harmful weapons of mass destruction, whose usage would lead to indiscriminate deaths and it could even put into risk the survival of humanity as such. The episodes of the release of a uranium bomb, called "Little boy", on Hiroshima, and a plutonium-based one, "Fat Man", on Nagasaki are sadly known in this regard.

Similarly, synthetic biology entails the possibility of creating synthetic viruses having harmful purposes for environment, human and animal health: this is not a mere hypothesis, but a concrete reality, especially following the events of September 11, 2001 (Schmidt and Giersch 2011, 285-300). An early Central Intelligence Agency (CIA)'s report in 2001 (URL: <https://www.cia.gov/index.html>, last accessed: 31/07/2015) warned that synthetic biology could produce engineered agents worse than any disease known to man, and it proposed that a qualitatively different working relationship was now required between the intelligence and biological sciences communities.

Some examples of 'suspected' experiments are the *de novo* synthesis of poliovirus (Cello *et al.* 2002), the sequencing of the 1918 Spanish flu (Tumpey *et al.* 2005), the creation of a super mousepox virus (Jackson *et al.* 2001), and the genetic modification of virus H1N1 (Hersft *et al.* 2012; Imai *et al.* 2012). In the poliovirus case, for instance, 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. Indeed, 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.

As for H1N1 virus, a parallel research was conducted by Erasmus Medical Center in Rotterdam (managed by Ron Fouchier), and by University of Wisconsin (Yoshihiro Kawaoka's team). Both of them obtained a genetic modification of that virus, thus opening new scenarios for medical and pharmacological studies, but at the same time generating risks for human and animal health, and the environment, should the hypothesis of bioterrorists using the virus for provoking a general pandemic become real.

The historically political, social, ethical and legal discussions occurred in the area of nuclear science and technologies can be useful for life sciences and synthetic biology. It should be borne in mind that the issue of 'dual-use', in fact, was born in the years of nuclear energy and atomic weapons research, as demonstrated by Feynman's speech: "*Once in Hawaii I was taken to see a Buddhist temple. In the temple a man said, "I am going to tell you something that you will never forget". And then he said: "To every man is given the key to the gates of heaven. The same key opens the gate of hell". And so it is with science. In a way it is a key to the gates of heaven, and the same key opens the gate of hell, and we do not have any instructions as to which is which gate*" (Schweber 2000, 64).

In a nutshell, in front of the enormous possibilities given by both the 'traditional' and new technologies, and in the light if their risks, the 'should' issue needs to be discussed. It leads to reflect upon one of the fundamental freedoms in biolaw: the freedom of scientific research, its limits and relationship with other rights.

2. THE FREEDOM OF SCIENTIFIC RESEARCH.

Since nuclear science and technologies, and synthetic biology are fruit of the human 'instinct' of broadening knowledge and enriching the scientific progress and life conditions, the freedom of scientific research comes into question in these areas (Colussi 2014).

In general terms, in the comparative constitutional 'landscape', the freedom of scientific research is shaped as: (a) part of the content of the freedom of thought and expression (see Universal Declaration of Human Rights, art. 19; 1st Amendment of the U.S. Constitution), (b) a fundamental freedom having an autonomous content (European Charter of Fundamental Rights, art. 13; the Constitutions of Germany, art. 5; Italy, art. 33; Spain, art. 20; the U.N. Covenant About Economic, Social, Cultural Rights, art. 15), and (c) a freedom which is connected to a duty for the State in improving and promoting science and research (Italian Constitution, art. 9; Spanish Constitution, art. 44; title XIX of The Treaty on the Functioning of European Union).

One important distinction to be drawn is between the freedom of scientific research as such, meant as the freedom to investigate on one topic and conducting experiments, and the application and diffusion of scientific discoveries.

The first layer can be conceived as the 'nucleus' of this freedom, which can be prohibited and limited only when it affects human dignity and fundamental rights (as stated, for instance, in the 1997 Universal Declaration on the Human Genome and Human Rights and in the 2005 UNESCO Declaration on Bioethics).

Moving to the layer of the applications and spread of scientific research (which includes the issue of publication of results as well), the limitations become broader (theoretically, but not always practically). In fact, not everything that could technically be done must be done (from an ethical and legal point of view), and not everything should nor could be spread out. For instance, considering the case of the genetic modification of virus H1N1, or in case of some research activities in the nuclear area leading to proliferation of weapons of mass destruction, the questions are the following: to what extent the freedom of research should be allowed? If possible, does it have to be controlled, or even forbidden? How to control it? Do we have to opt for censorship or publications of research results?

In general, public powers and regulators are required, in virtue of their *ratio existendi*, to limit the spread of discoveries that could damage humanity or put it in peril, and thus they try to control the free circulation of research. On the other hand, instead, if a research discovery could benefit the whole humanity, it is a duty for public powers to favor the spread of it, so as to improve humankind (as declared by the 1999 UNESCO Declaration on Science and the use of scientific knowledge). However, the assumption that the freedom of research should be

limited if it threatens other rights/freedoms/needs (Santosuosso *et al.* 2007) is not so easy to be 'translated' into practice. In the next paragraphs, this issue will be deepened further.

Beyond the limitations of the freedom of research in relationship with the 'external' world, there are other limits related to the internal research community. Indeed, the freedom has multiple dimensions: it can be referred to the single researcher (including his/her right to investigate on the topic that he/she freely chooses; to spread the knowledge to others; to communicate results to other colleagues or community; to check the hypothesis according to the scientific method; and to pursue an economic exploitation of the products or results of research), and to the whole community of researchers. Professional and deontological rules that govern research world can be conceived as norms providing internal limits to this freedom: for example, the duty upon each single researcher not to manipulate data, not to incur into plagiarism or theft of others' ideas, not to forge contents, etc.

According to some positions (Bin 2005, 11), this freedom is conferred not only upon the single academic or the whole community, but even upon the society: if we look at the freedom from another perspective, that is not the one of whom work in the field, but the addressees (i.e., the society), it is possible to draw this freedom as including the right to have access to the benefits of results, and such access should be indiscriminately ensured to everyone.

Then, considering the role of the State, it appears that on the one hand, there is the duty for the State not to interfere in the choice of topics of research ('freedom from', typical of liberal societies): this is a 'negative obligation'. On the other hand, the State has the 'positive' duty to boost the freedom of research ('freedom to', typical of welfare states) in the name of the general interest to contribute to the benefit of the whole humanity. A proper balance should be found between these two duties. Indeed, if the State interferes too much in the determination of tools and structures for the realization of research, and thus orienting research, it could infringe the individual's liberty. However, research requires structures, laboratories, university centres, and resources that a State cannot deny. It should also intervene for ensuring that the benefits of research reach every citizen without any discrimination in terms of geographical, cultural, economic provenience (Salvi 2002, 125-134).

3. THE RELATIONSHIP BETWEEN THE FREEDOM OF SCIENTIFIC RESEARCH AND OTHER RIGHTS/FREEDOMS/NEEDS.

In the context of 'dual-use dilemma' there is, on the one hand, the freedom of research, and on the other side there are other rights/freedoms/needs to be evaluated, such as:

(a) the right/need to security;

(b) the right to life;

(c) the right to health; and

(d) the right to environment.

3.1 The right/need to security.

The right/need to security, which after Hobbes's works has obtained an important role as a need that the State has to ensure, started being mentioned in the French Declaration of the Rights of Men and Citizen (1789) as a natural and inalienable right, together with freedom, property and resistance to oppression (art. 2).

In the current constitutional texts, security is considered either as a basic need for the existence and survival of societies, or as a real right. It has 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. as a need rooted in the notion of quality and wellbeing of individual and collective life. [...] 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 as a right to a protected existence, indispensable for enjoying other rights*» (Frosini 2008, 495).

The UN Universal Declaration of Human Rights Charter enucleates a right to security in its Article 3 ("Everyone has the right to life, liberty and security of person"), where the security of the person is meant as a basic entitlement and it is associated with liberty. It can also be seen as an expansion of rights based on prohibitions of torture and inhuman treatments.

The same entitlement is contained in Article 6 of the European Charter of Fundamental Rights (EU) and in Article 5 of the European Convention on Human Rights and Fundamental Freedoms from the Council of Europe.

Canadian Charter of Rights and Freedoms (Section 7) and South African Constitution (Section 12) shape it as a human right.

The American Convention protects the right to life (Article 4), physical integrity (Article 5), and liberty (Article 7) among others, relating to citizen security.

The Inter-American Commission on Human Rights, although it has never defined security as a right, has stated that there is a positive obligation upon a State to prevent the threats to public security and to intervene in case of violation of security[2]. In these cases, citizen security is conceived as a public policy.

3.2 The right to life.

The right to life entails both a negative and a positive obligation for the State. In the first sense, it means that the State must avoid any behaviour that could alter or damage the life of its members. In the second one, the State has, at the same time, the duty to intervene for removing any situation that potentially affects life and puts life into risk. Thus, this right is meant as both a fundamental individual right and a collective interest to be safeguarded, in connection with the right to physical integrity and public health issues.

With the Universal Declaration of Human Rights (art. 3) and then the International Covenant on Civil and Political Rights (art. 6), the Organization of United Nations opted for a solemn proclamation of the right to life, so as to make the need of respecting and protecting human life visible to all the nations at global level. Although the Universal Declaration of Human Rights is a mere declaration, and is not a binding legal covenant, however, its influence on the development of international human rights is meaningful, as it continues to send a strong message of the rights it lists (Lauren 2003). The UN posed the right to life as a basis and source of the other rights (UN 1998), and it links the right to life with the notion of dignity, thus creating a strong binomial between the two.

At the international law level, with reference to the regional human rights systems, the reference to right to life is given by the European Convention on Human Rights and Freedoms (art. 2), in the American Convention of Human Rights (art. 4.1), in the African Charter on Human and Peoples' Rights (art. 4). In the Asian context (art. 3.2 of the Asian Human Rights Charter) and in the Arab Charter on Human Rights (art. 5) the right to life is linked to the notion of human dignity.

In the EU context, the Nice Charter of Human Rights has a similar structuring: meaningfully, it has decided to start the catalogue of rights from the title entirely dedicated to dignity, and it

[2] See, for instance, case *Baldeón García v. Peru Case*. Judgment of April 6, 2006. Series C No. 147, paragraph 81; *Massacre of Pueblo Bello v. Colombia Case*. Judgment of January 31, 2006. Series C No. 140, paragraph 111.

has put the right to life (art. 2) immediately after the article about dignity, thus linking them intrinsically.

Some National Constitutions, then, clearly state the right to life, such as the Spanish one (art. 15) or the Canadian Charter of Rights and Freedoms (art. 7), or the Human Rights Act in the UK (art. 2).

The implementation of this right occurs through the intervention of the courts, such as the European Court of Human Rights[3]; the UN Committee on Human Rights[4] (established by the International Covenant on Civil and Political Rights as a non-judicial body), which has defined the right to life as «*the supreme right*» (Office of the High Commissioner for Human Rights 1982); and the African Commission on Human and Peoples' Rights[5].

3.3 The right to health.

If traditionally the right to health has been conceived as the right to healthcare, being the primary object of care for the State (i.e. the State had to intervene in the cases of epidemic or pandemic diseases by providing adequate sanitation and quarantines and better work conditions: Riedel 2009), it is after the Second World War that it has started developing as a human right, especially in response to the terrible experiments pursued by Nazi doctors that undermined human dignity and health for research purposes (Katz 1972). From the Nazi doctors' trial, the so-called "Nuremberg principles" were derived, and they inspired the International Code of Medical Ethics of the World Medical Association International (1949) and Declaration of Helsinki (1964).

This right to health, thus, has two faces: (a) an individual dimension, which focuses on health as a status, i.e. a situation of wellness belonging to the single human being whose respect and promotion can be claimed by everyone towards both the State and the other citizens, and (b) a collective or public dimension, which shapes this right as belonging to the whole society.

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[3] The case law of the Strasbourg Court about the right to life is very broad. Just to mention a few meaningful judgments, see: (a) about the killing by state agents, case *McCann v. United Kingdom* n. 18984/91, 27 September 1995; (b) about the positive obligation for the State to protect life, case *L.C.B. v United Kingdom* n. 23413/94, 9 June 1998; (c) about death penalty, case *Soering v. United Kingdom,* n. 14038/88, 7 July 1989; (d) about the issues as regard the beginning of life, case *Vo. v. France,* n. 5324/00, 8 July 2004; case *S.H. and others v. Austria,* n. 57813/00, 1 April 2010; case *Costa e Pavan v. Italy,* n. 54270/10, 28 August 2012; (e) about the end of life see case *Sanles v. Spain,* n. 48335/99, 20 October 2000; *Pretty v. United Kingdom,* n. 2346/02, 29 April 2002; *Haas v. Switzerland,* n. 31322/07, 20 January 2011.

[4] See case *Lubuto v. Zambia* (Communication 390/1990) about death penalty; case *Suarez de Guerrero v. Colombia* (Communication 45/1979) about police shooting; case *Dermit Barbato v. Uruguay* (Communication 84/1981) about deaths in custody.

[5] See case of *Kazeem Aminu v. Nigeria* (205/97).

In its individual dimension it should be protected by States and operators without discriminations and inequalities, thus granting equal access to each individual to the results of research. It should also pursue a rational distribution of resources within States for making it effective.

In its public dimension, it emerges when indicating the importance of preventative and reactive responses by the States in the face of emergencies and threats. In the context of the protection of public health, a connection between the right to health in its collective facet and the right to life is set up.

In the context of the World Health Organization the accent is posed on the individual level: the notion of health has been developed as corresponding to «*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*» (WHO Constitution, Basic Documents, Official Document n. 240, Washington, DC, 1991), thus integrating physical with social elements of well being. This means that comprehensive health care systems to ensure effective and equitable distribution of resources for maintaining health have to be developed by States as a means to give application to the right to health. In line with the WHO, the right to health is embedded in several documents as connected to the right to food, to adequate housing, to healthy environment, to education, to work and working conditions, to right to life, to access to healthcare systems and to benefits of research for health, to physical integrity, to wellness and development, such as provided by the International Covenant on Economic, Social and Cultural Rights (art. 12), UN Charter (art. 55), the Universal Declaration of Human Rights (art. 25), the American Declaration on the Rights and Duties of Man (art. XI), the European Social Charter, which complements the European Convention of Human Rights as for social rights (art. 3, 11, 13), and the African Charter on Human and Peoples' Rights (art. 16).

At the EU level, the attention on public health (Hervey and McHale 2004) is particularly stressed, as a policy to be pursued by Member States and Institutions (art. 168 Treaty on the functioning of the EU) in the definition and implementation of all Union policies and activities. With regards to the individual side, the EU Charter of Fundamental Rights refers to it in art. 25.

Moving to the national frameworks, it appears that the right to health is expressly mentioned in Constitutions as a freedom or an entitlement to some benefits guaranteed by States (for instance, in the Constitutions of Belgium, art. 23; Germany, art. 2; Spain, art. 43; Italy, art. 32).

Therefore, the right to health has a core and a penumbra, a maximum and a minimum (Gostin and Lazzarini 1997): under such "maxi-min" definition, the States have a duty to, at the very minimum, to protect individuals against serious health threats (and here the right to health is related to the right to life), while at the maximum, they have the duty to fulfil the attainment of the highest possible standard of health for all individuals without any discrimination (and thus, the right to health is linked to the principle of equality).

3.4 The right to environment.

As for the right to environment (Merrills 2007, 663-680), there are different positions among scholars and within legal texts. It has been conceived as: (1) a pre-requisite for the enjoyment and realisation of human rights (Stockholm Declaration on the Human Environment, 1973, U.N. Doc. A/CONF.48/14/Rev.1); (2) an object to be cared of in the enactment of other rights, thus "greening" some civil and political rights, for example recognising the right of access to environmental information, or the access to justice in environmental matters (The Rio Declaration on Environment and Development, 1992, and Aarhus Convention on Access to Information, Public Participation and Access to Justice in Environmental Matters, 1998); or (3) a right in itself, thus a right to a safe, healthy, sustainable environment (as in the 1992 Framework Convention on Climate Change (UNEP), the 1992 Convention on Biological Diversity (UNEP), Art. 12 of South African Constitution). The latter position considers the right to environment as a right that transcends the categories of individual social or economic rights and of collective or solidarity rights (Cullet 1995, 25-40). Environment is read as a specific good to be protected and preserved by human beings, in line with the principle of solidarity and for the benefit not only of the current but also of the future generations (Chet Tremmel 2006). In this perspective, the right to environment is linked to the right to health and development.

4. PROPORTIONALITY AND REASONABLENESS IN ORDER TO DRAW THE RELATIONSHIP AMONG FREEDOMS AND RIGHTS.

After describing the features of the rights and needs that enter into relationship with the freedom of scientific research in the context of the 'dual-use dilemma', it should be analysed how to draw such relationship in a rational way.

In other words, what is described hereafter is a proposal as to how to shape the freedom of scientific research without suppressing it, but at the same time protecting other rights at stake, so that the progress is not hindered and the human lives, their health, safety and security, and the environment are not neglected.

The suggested method is based on the principle of proportionality and of reasonableness.

The principle of proportionality consists of three sub-principles (Alexy 2003, 131-140): the principles of suitability, necessity, and proportionality in the narrow sense. The principle of suitability consists of opting for a rational relationship between the means chosen and the ends pursued. The principle of necessity requires that, when two means promoting one goal are equally suitable, the one that interferes less intensively in another goal ought to be chosen. The principle of proportionality in the narrow sense means that, if possible, a right cannot be suppressed in the face of the competing one, and its 'essential core' must be protected.

The reasonableness should also guide the balance between purposes and means, tools, time, and methods to adopt (Modugno 1995).

Adopting a metaphor, it is possible to conceive each right and freedom as a person under an umbrella on a rainy day (Bin 2005, 11). The area under the umbrella is the 'core nucleus' of a right/freedom, and it should be preserved untouched. However, as soon as we go further the 'borders' of the umbrella, each person should relate to the others surrounding him/her. So, out of metaphor, beyond the 'nucleus' of the right/freedom, the limitations to the rights should be drawn.

This means that the intangible 'nucleus' of the freedom of research cannot be modified: it refers to the choice of topics of investigation and the exercise of theoretical speculations. However, when such theory meets the application phase and the results of research are used for specific purposes, i.e. out of the 'umbrella' zone, the freedom of research should be limited, and for doing so an operation of balance between rights and freedoms has to be pursued.

When coming to nuclear technologies and synthetic biology, it appears that the freedom of scientific research moulds like a rubber band: (a) if these technologies affect other fundamental rights and freedoms, the research should be limited; (b) on the contrary, if they increase and promote the achievement of other rights and freedoms, the research ought to be encouraged.

More specifically, if nuclear technologies and synthetic biology pose at risk humanity for their use in the warfare and terrorist context, it is legally and ethically convincing that the

freedom of scientific research should be limited and balanced with other rights and interests at stake. Instead, if these technologies encourage the progress in medicine, agriculture, etc. for beneficial purposes, this freedom should be boosted and broadened. However, the proportionality principle entails that the limitation of this freedom in the light of other rights is allowed only (a) for temporary periods, (b) for necessity reasons, and (c) using the least restrictive means for doing it, without infringing the 'core nucleus' of any right. 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).

Therefore, when governing nuclear sciences/technologies and synthetic biology, and managing their 'dual-use dilemma', the proportionality principle and reasonableness should be adopted as a tool to enact all the different policies and legal acts.

5. HOW TO (CONCRETELY) MANAGE THE 'DUAL-USE DILEMMA'?

The above described framework – consisting of the balance among rights and freedoms according to proportionality and reasonableness - should find a 'translation' in the concrete governance of both 'traditional' and new technologies.

It means that it should be taken into account at the 'top down' level (legislators, governments, States in the international community, international organizations, etc.) and at the 'bottom up' level (scientific community, researchers, institutions, laboratories, etc.), while drafting: (a) 'hard law' sources, which are legally binding acts (e.g.: international conventions, or treaties, EU regulations and directives, national statutes/laws/decrees, etc.); and (b) 'soft law' sources, i.e. the non-legally binding acts (e.g.: international declarations, resolutions and guidelines, EU recommendations, national guidelines, professional codes of conduct, standards, etc.).

These sources of law are called upon to deal with different topics, in order to manage properly the 'dual-use dilemma', and the different 'actors' on the stage ought to be involved in the application of the rules.

More precisely, the law should intervene in the following fields:

1. At the level of scientific practice;
2. At the level of information dissemination;
3. At the level of technology application.

1. As for the level of scientific practice, the law (both 'hard' and 'soft') should give proper rules to scientists, providing an ongoing and periodically revised assessment of people

working in the nuclear field and within synthetic biology: for instance, a continuous screening of the personnel, their equipment, and the compliance with safety and security rules should be ensured. The regulators, in fact, should constantly control both people and dual-use materials.

Then, the education of scientists should be boosted: the promotion of a 'culture of responsibility' and awareness of risks through codes of conducts (Kuhlau *et al.* 2008), and educational and deontological programs is a real necessity in the scientific community (Dando 2009). Indeed, it is important that academics/researchers are aware of the potential risks of their research, and the possible bioterrorist and WMD (weapon of mass destruction) application of their activities and therefore inform timely the authorities about potential risks. At the same time, the regulators should have a comprehensive view of the scientists' activities, and be in constant exchange with researchers to be informed of activities potentially at risk of being misused (Michel 2013). However, in reality, it occurs that the control of research by regulators and the awareness of risks by scientists clash with the concrete difficulty of mapping/controlling research and with researchers' interests in spreading their research as soon as possible, without caring of the risks concerned. Thus, any type of policy in the area should address these problems and focus on strong assessment, identification and registration of people and materials, and on developing a proper education and 'sensitiveness' among scientists.

2. As for the level of information dissemination, the core question is whether, in front of 'sensitive' and 'dual-use experiments of concern', the censorship of publication and spread of news should be chosen, or whether the free publication and open access should be promoted.

Indeed, especially in front of the risks of bioterrorism through the manipulation *ad hoc* of synthetic biology, or the proliferation of nuclear weapons in nuclear field, the 'natural' tendency would be the one that 'sacrifices' the freedom of research and information in name of the protection of security, lives, and public health. As Cole explains, «*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*» (Cole 2009, 953-955).

This 'conflict' between censorship and publication has been emblematically demonstrated by the opposite views by Leo Szilard and Enrico Fermi in the nuclear area.

While Szilard thought that only keeping information secret the projects to build the atomic bomb by Nazi could be avoided, Fermi stated, on the contrary, that the secrecy would have meant a victory for the Nazi, since another fundamental freedom would have been suppressed (Rhodes 1986).

Nowadays, these two positions are still vivid: indeed, according to some scholars, censorship would limit research and would represent an infringement to the freedom of research (Trevan 2012, 295). Only the spread of information would permit other scientists to come into contact with data and experiments, encourage the progress, also in reference to the search for other means for fighting against bioterrorism and nuclear misuse.

From another 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 (Martin 2001).

As Selgelid states, «*scientific openness and the progress [...] 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*» (Selgelid 2007, 40).

Managing the freedom of research and security interests seems a 'mission impossible' (Michel 2013). However, in the light of the proportionality approach presented above, a proper balance could be reached by evaluating the harms and benefits of both the publication and the censorship of results, and opting for the hypothesis where benefits overcome the harms (according to a risk-benefit analysis). This evaluation should be the fruit of discussion and debate between scientists, journal publishers and governments, so as to avoid a unilateral self-governance by scientific community, on the one hand, and an imposition by the State, on the other one.

It should be, yet, kept in mind that there are some problematic issues that can make the control of information dissemination very difficult, even before starting the discussion as whether the best option is the censorship or the publication of data. These problems are: (a) the rapidity of circulation of research information (especially with social networks and internet exchanges), (b) the diversity of information means (oral transmission, email, etc.), (c) the difficulty of individuating a clear addressee of information and a clear source of information, because the information could come from, and be spread by, the scientist himself immediately after his/her discovery, or by his/her institution, or by audience at a conference or a student (in cases of oral transmission or teaching), or by a reader online (in case of immediate web publication of research results). Therefore, the debate about risks and benefits of censorship or free publication could start too late, and thus be ineffective or even useless, as the information will be already known around. It is for these reasons that it is extremely relevant to assess information on time, and put in place appropriate measures for ensuring a continuous engagement between scientists and regulators about research results.

A significant case in order to see how to face with the issue of censorship or publications is the one of the mutation of genetic sequence of H5N1, obtained in parallel by Fouchier and Kawaoka. It happened that both the research teams submitted their research to two scientific journals, *Science* and *Nature.*

The US National Science Advisory Board for Biosecurity (NSABB) recommended against publication of the study, as it could be misused, and generate 'dual-use' concerns. However, after additional consultations at the World Health Organization, the NSABB modified its position and recommended publication of revised versions of the two papers (Malakoff 2012). So, the authors suspended their work for a moratorium period of 60 days and, after the international forum, were allowed to publish their articles, provided that they followed the NSABB's guidelines (Butler and Ledford 2012). A 'compromise' solution has been preferred, as the publication of the news and research results has been allowed, but the methods adopted have been censored (Editorial 2012).

Following the course of events, then it happened that, while Kawaoka's paper was immediately published, Fouchier had to cope with the Dutch government's blockage. Indeed, the Dutch government requested Fouchier to apply for an export permit in the light of EU Regulation n. 428/2009 on dual use goods, as it considered the publication in violation of export rules for 'sensitive materials'. Fouchier complied with Dutch government demand (Greenfieldboyce 2012), and his license was granted, so that the paper was finally published in *Science.* However, Fouchier also started a legal battle against the government's request of a special authorization for such publication, stating that 'basic scientific research' did not fall under the application of EU Regulation for dangerous goods. In 2013, a Dutch district court confirmed the righteousness of the government (URL: <http://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:RBNHO:2013:8527>, last accessed: 31/07/2015). At the later stage, the Court of Appeal in Amsterdam reversed that verdict, but in fact it stated that Fouchier did not have the legal interest to sue the Dutch government any more. He should have had to object the government's request, instead of obeying to the request of authorization license (Enserink 2015). Therefore, the Court annulled the first sentence, but avoided to face with the substantial issues.

This case shows the risks of possible conflicts between researchers and regulators, and the need to establish clear rules as for review, publication and spread of research.

3. As for the level of technology application, the law is called upon to draft rules about the access, possession, trade, transport, export and transfer of nuclear and biological material,

such as the screening of orders of materials by scientists or other people working in the area (like the DIY members).

A SORT OF CONCLUSION...

From the analysis conducted above, it results that in front of the risks arising in the area of 'new' technologies, the contribution of the 'traditional' sciences cannot be neglected. In particular, the debate about 'dual-use' is still a living matter, and needs to be continued and improved. It should be faced from both an ethical and legal perspective, focusing on the fundamental freedoms and human rights connected to it. Indeed, the threat to use legitimate research in improper way is not a far away hypothesis. The 'mushroom cloud' is an iconic image for the nuclear field that shows how the potentialities of a technology could have devastating effects, if the technology is adopted for malevolent purposes. In the biological area there are also experiments of concern that must be reflected upon by scientists, regulators and society. So, the 'dual-use dilemma' is a dilemma for researchers, governments, institutions, and the global community as such, and a multi-level response is needed.

The freedom of scientific research, which is central in this context, has to be protected, but at the same time the other rights and freedoms at stake cannot be 'suppressed' or 'sacrificed'. Therefore, the most rational options to face with the inherent 'dual-use' dilemma that some sciences and technologies arise seem to be the following: (a) the adoption of a proportioned and balanced approach towards freedoms and rights ('translated' in into laws and regulations), (b) the engagement of the 'actors' on the stage (i.e., mainly scientists and regulators) through a pluralistic and continuous dialogue, (c) a system of control and verification of information and people, and a licensing system for equipments, materials and laboratories, and (c) the awareness upon scientists of the 'dual use' features of their research, and the 'insistence' on their sense of responsibility through educational programs.

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