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Review Article

Synthetic Biology, Dual-Use and Biosecurity

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Abstract

An industrial process is the set of operations designed to obtain, transform or transport one or more products. Industrial processes include the development and manufacture of chemicals, food and beverages, gasoline, paint and the pharmaceutical industry, among others. The purpose of an industrial process is based on the effective use of natural resources so that they become materials, tools and substances capable to satisfy the needs of human beings and improve their quality of life. However, the role that industry plays in the production of products known as "dual use" is becoming more and more relevant every day. For this reason, today governments around the world increasingly recognize that partnering with industry is a prerequisite for preventing, or at least increasing barriers to the proliferation of nuclear, chemical and biological weapons and their systems. Vectors (the means in which these weapons can be transported such as insects, tanks, airplanes, etc.). In recent years, these factors have changed the nature of the relationship between the government and the private sector in the field of dual-use product controls.

Keywords: synthetic biology; biosecurity

Background

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Synthetic biology and dual-use processes

Synthetic Biology is defined as the intersection area of Biology and Engineering oriented to the design and manufacture of biological components and systems that do not exist in the natural world and to the re-design and manufacture of biological systems [1, 2]. Researchers dedicated to this discipline can be divided into two branches according to their activities: the use of non-natural components to reproduce emergent behaviors of natural Biology, with the goal of creating artificial life; and the search for natural interchangeable parts to assemble into an unnaturally functioning system. When the specific field of intersection is between engineering and genetics, we are talking specifically about Genetic Engineering, a key tool of modern Biotechnology.

This field of research has the ability to increase our understanding of biological and genetic processes and suggests a human potential that goes beyond evolutionary processes. However, adequate regulation must be generated. The executive vice president of the industrial and environmental section of the Industrial Biotechnology Organization Brent Erickson, comments that Synthetic Biology can be considered as an extension of genetic science that has been used safely for more than 40 years by the biotechnology industry in the development of commercial products and that their use by biotechnology companies illustrates the potential of this new discipline for reducing research, development and production times of a product in the market. The increase in the speed of DNA synthesis and the decrease in the cost that it represents, allow scientists to design modified bacterial chromosomes that can be used in the production of: renewable chemical compounds, biofuels and health care products among others. And he says that regulatory options should support innovation and commercial development of new products, while protecting the end consumer from potential harm [3].

Biotechnology is the set of commercial techniques that uses living organisms or substances of these organisms to produce or modify a product, including techniques to improve the characteristics of animals, plants or microorganisms of economic importance. It combines with the academic objectives and the needs of the industry, the scientific foundations of microbiology, molecular biology, cell biology, biochemistry, genetic engineering and synthetic biology [4].

The term "dual use" in the industry is applied to any technology that uses its knowledge and tools differently from the original idea. Previously this definition applied only for military purposes and viable commercial applications; however, it has a second meaning in the context of potential weapons development: tools, equipment and knowledge can lead to the search and development of these technologies for the development of biological, chemical and nuclear weapons.

In the life sciences, dual-use research "encompasses biological research for legitimate scientific purposes, the results of which may be misused and pose a biological threat to public health and/or national security" (NSABB dual-use definition). In general, the term "dual use" tends to refer to technologies that have both civilian and military use. The dilemma that exists in dual-use research in the life sciences refers to the fact that the production and publication of scientific research whose purpose is to improve public health, animal health or agricultural productivity, can be used for other purposes. That threaten public health in the hands of a rogue State, terrorist group, or individual. That is, "dual-use research" is research that generates new technologies or information with the potential use of beneficial and hostile applications.

The European Commission defines "dual use of technology" as materials, equipment, including software and technology that can be used for commercial and military purposes. On the other hand, the Code of Federal Regulations of the United States government defines it as "the elements that can be used both in the military field and in other uses ... and in commercial applications". Both definitions focus on the characteristics of the technology and are consistent in the way it is used in discussions of nuclear technology. However, there are other definitions that are based on the context in which the technology is used or those who use it. This is reflected in the 004 National Academy of Sciences (NAS) discussing how Biotechnology Research in an era of terrorism can have dual use "when the same technologies can be legitimately used for human well-being and misused for bioterrorism." Biotechnology research that is intended for beneficial purposes can also cause harm, either inadvertently or as a result of intentional misuse.

Control mechanisms It is important to mention the most important international conventions for the prevention, regulation and prohibition of the use of chemical and biological weapons, in relation to dual use processes.

Cartagena Protocol on Biosafety (CPB)

The Cartagena Protocol on Biosafety (CPB) is an international agreement ratified in the Convention on Biological Diversity on September, This Protocol, which applies to the 6 member countries, provides an international regulatory framework to ensure in the field of genetically modified organisms (GMO), safe use and handling, result of modern biotechnology. However, the protocol is controversial; many of the major GMO exporting countries, such as the United States and Canada, are not members. All GMOs, defined as organisms that possess a novel combination of genetic material obtained through the use of modern biotechnology, are contained under the CPB. However, regulations are primarily concerned with the safe transfer, handling and use of those that may have adverse effects on the conservation of biological diversity. The CPB establishes a comprehensive and transparent regulatory framework, as well as legal obligations to assess and manage the risks of GMOs, including emergency procedures for involuntary release. The benefits of the framework include its guidance on how to assess and compare risks between GMOs.

Australia Group

The Australia Group (AG) is a consultative group made up of nations in addition to the European Commission, which meets annually with the objective of "ensuring, licensing measures for the export of certain chemicals, biological agents, facilities and equipment manufacturing dual-use chemical and biological agents". This group was formed in 995, in response to evidence of the use of chemical weapons in the Iraq-Iran war, in which Iraq obtained many of the materials for the development of these weapons from the CW (Chemical Weapons) programs of the United States. The international chemical industry. The main theme in the discussions about the misuse of biotechnology is about the role played by the scientist, the need to develop strategies for awareness and concretization of scientists, as well as the important role that the code of conduct of scientists plays. Scientists. The conduct of each scientist is of vital importance for the successful management of dual-use technology, in addition to there being greater responsibility on the part of the scientific community regarding the natural dispersion of materials and dual-use agents found in their environment. The most recent change has been the development of a code for dual-use biological agents and the technology associated with their development. Dual-use goods and technology export controls are some of the targets that intervene in the fight against the proliferation of weapons of mass destruction. These controls include products and technologies (including software and technologies such as fax or electronic media) that may be destined for civilians or military bases. These products and technologies should be periodically reviewed in order to take into account scientific and technological advances.

Risks of Synthetic Biology

As Synthetic Biology introduces biological architectures not present in nature and go beyond the natural limit that currently exists, many ethical questions must be addressed. What will be the limits of Synthetic Biology research? And therefore, what will be the limits of its applications? The risk generated by the development of Synthetic Biology is of two types according to EASAC [5]: biosafety, where the adverse consequences are the result of accidental or unforeseen events, and bio protection: where knowledge, technology, and products generated from Synthetic Biology are used for destruction purposes, for example in the production of weapons.

Biosafety

Many areas of biological research raise safety concerns, but Synthetic Biology shows some particular threats. It takes a bit of imagination to appreciate that a completely new self-replicating organism escaping from the laboratory and entering an environment could cause all kinds of damage depending on the properties and activities with which said organism was designed. It could be a GMO or a bioweapon and could be accidentally or intentionally released; it could happen from problems in a very safe laboratory or disputes with groups of ideological, religious or political origin. The range of possibilities and, therefore, of consequences, is enormous.

One method to minimize the probability of unforeseen consequences could be to generate organisms that can survive only on nutrients or other materials that are not found in nature. However, this solution may not be a completely efficient solution because many microorganisms have the ability to transfer genes horizontally, that is, to exchange genetic information with other microorganisms of the same type, and even with members of other species. A new, self-replicating microorganism could presumably evolve, and could develop dangerous properties. Any synthetic organism will need to be treated with the highest safety standards, and these standards will probably have to be adapted from those that apply to genetically modified organisms, and subject to global regulation. A further complication is that the introduction of a synthetic organism is not accidental. For example, a new microorganism designed to reduce environmental pollution must be released into the environment. Scientists consider that an action of this type must have an exceptionally high certainty, which guarantees that the probability that said microorganism does not generate events that are not contemplated.

Bio protection

Good regulation, while essential, can offer only limited protection against bioterrorism, which is probably interested in Synthetic Biology as a weapon. The true extent of this threat is widely debated. Some scientists point out that it would be much easier to misuse natural pathogens than to misuse new pathogens. However, as suggested by The Darker Bioweapons Future report, published in 00 by the CIA, "The effects of some of these engineered biological agents could be worse than any disease known to man [6]." Improving biosecurity is clearly prudent. The issue of biosecurity has already been taken into consideration by a panel that has listed the principles that must be taken into account when formulating codes of conduct to minimize the misuse of Synthetic Biology research [7]. These principles include:

- Become aware of the potential consequences of Synthetic Biology research and, as a consequence, refuse to undertake work that has potentially negative consequences.

- Stick to good laboratory work practices.

- Know and support national and international laws and policies, to prevent the misuse of research.

- The acceptance of generating a report of activities that violate biosafety codes, for example the Biological and Toxin Weapons Convention.

- The increase in the ease of access to DNA sequences will cause Molecular Biology techniques to be adopted by disciplines such as Engineering, which have little experience of working with biological agents in comparison. If the biosecurity and biosecurity standards are maintained, it will be very important to ensure that all those involved in bioscience are aware of the risks involved [8].

In parallel with these developments there is a continuous debate on the correct balance between scientific decentralization and regulation by statute. The scientific community has not shied away from raising awareness of the potential risks of synthetic life. Ethics has played a role in international conferences, during which the need for an ethical debate around Synthetic Biology, internal regulation and safe practices has been indicated. In a statement made by members of the second international meeting of Synthetic Biology (Synthetic Biology 2.0), the importance of international guidelines, national laws, and safe practices is recognized and supported, accompanied by public education and awareness-raising initiatives about of Synthetic Biology. An ethics and guidelines similar to those that have emerged for Engineering must emerge for Synthetic Biology [9].

At the international level, there is an agreement on the need to evaluate the possible risks and follow up, case by case, based on solid scientific knowledge, on the release of GMOs into the environment. Once a GMO has been released, it is necessary to monitor in the short, medium and long term the presence of GMOs in different ecological niches. The analysis must consider both the benefits and the risks as a result of the use of transgenic organisms, as well as the risks of not using them if current production processes continue [10].

Bioterrorism

The use of biotechnology for the development of weapons is not new, it goes back to the use of advanced recombinant DNA techniques for the generation of military databases [11], and the evident concern expressed by the CIA in its report The Darker Bioweapons Future, published in 2003, where it describes a very dark panorama due to the potential use of designed biological agents for the manufacture of weapons. Alex David Hatch in 2010 proposes four steps to help specifically address the problem of synthetic bioterrorism that are listed below [12].

1. Initiative by the community to regulate the reception of DNA constructs.

In conjunction with the Synthetic Biology 2.0 and 3.0 conferences held in 2006 and 2007 respectively, it is suggested to establish best practices for gene synthesis companies. It is suggested that the community refuse to do business with companies that do not implement a safety and security routine. A license or registration of the individuals and equipment necessary to carry out automated DNA synthesis. Carrying out this search could significantly diminish the ability of terrorist groups to obtain the necessary equipment to carry out potentially dangerous actions through the use of Synthetic Biology.

2. International Regulation.

When dealing with bioterrorism and Synthetic Biology in general, the existing regulation should be international. A failure could have consequences at the international level, the fusion of cultures to generate a global international policy, which covers all the needs of the international community, can be very complicated due to the differences that exist between cultures and the technological development that exists between countries. However, the generation and implementation of international regulation is still urgent.

3. Increased investment in risk research and public perception.

David Rejeski in 2009 in front of the National Academy of Sciences stated that approximately 0 million dollars of federal funds from the United States of America are to finance Synthetic Biology each year. It points out that, despite the existence of studies that ensure that public opinion wishes there to be greater risk research and regulation regarding Synthetic Biology, the financing made by the United States of North America is not directed to risk research, nor to improve public perception regarding Synthetic Biology. The direction that Synthetic Biology research takes, as well as its applications for the production of consumer products, will largely depend on public perception, and on technological advances, which are constantly changing and progressing.

4. Education

While Bioterrorism is a valid concern, a major attack using weapons generated derived from Synthetic Biology research is not realistic, Zilinskas R assures in 2006[13], Synthetic Biology is presented to the public by the media when there is talk of bioterrorism; In addition to this, the lack of investment in dissemination about Synthetic Biology, have generated a negative public perception and full of mistrust about Synthetic Biology. To change this perception, investment in dissemination, regulation, and safe practices within Synthetic Biology must be increased.

The development and distribution of foundational technologies that facilitate engineering biology will have a direct impact on exposure to natural and synthetic biological hazards. However, analyzing the risk impact of such technology is not straightforward; For example, DNA synthesis has recently aided in the "resurrection" of the 1918 strain of influenza virus, and it is believed that there is a possibility of producing the smallpox genome; variants of these viruses and other pathogens could be easily constructed. However, in the face of a synthetic or designed biological threat, DNA synthesis could be used to accelerate a risk analysis, and therefore the response to this risk. Meanwhile, at present, it is known that DNA synthesis is engaged in constructive experimental research.

Conclusions

Dual-use processes must be subject to such regulations that, without restricting freedom of research, reduce international biosafety risks, collaborate in the biosecurity of countries and their inhabitants, and avoid monopolistic practices that could be generated by abuse or misconduct. Handling of patent registrations in this sector.

Science plays an important role in human development. During the last years, biotechnology has had a decisive advance in the development of new techniques (such as genetic engineering) and research methods that allowed obtaining biological products (such as genetically modified organisms), novel methods for isolation, identification and purification of biologically active products. Thanks to this development, to mention a recent example, progress has been made in obtaining vaccines against SARS-CoV-2 that has the world in suspense in the 21st century, but in less than two years there are already vaccines being applied to most of the humanity. Genetic engineering, biotechnology and, above all, synthetic biology, have played a major role in this great advance. Let's just hope that sanity prevails in humanity and that science is not perverted by interests beyond our reach. Paraphrasing the Organization for the Prohibition of Chemical Weapons may science serve to enhance mankind by unrestricted respect for the environment?

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