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SYNTHETIC BIOLOGY AND GENETIC MANIPULATION: Risks, promises and responsibilities

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Abstract: As a result of the biotechnological advance, synthetic biology has been applied from the improvement of food to the creation of new organisms. This article investigates, from a bioethical perspective, the benefits, risks and threats to life, arising from the production, manipulation and, especially, the creation of synthesized DNAs that do not exist in nature. Bioethics reports from the White House and the Bioethics Committee of Portugal and Spain contributed to the discussion. The progress of technoscience, without the proper ethical capacity for evaluation, can produce results that compromise the social development, environmental preservation, human dignity, and biosphere life in the future. In this sense, the achievements of synthetic biology have been shown to be ambivalent, because hopes are mixed with threats, with unpredictable results to the diversity of life of the biosphere, which makes prudence the virtue par excellence.

Keywords: Synthetic Biology; Bioethics; Responsibility; Prudence

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Introduction

The advances in biotechnology bring in the same time hopes and constant challenges, both for the understanding of its discoveries and applications, and for the understanding of an ethical approach that is revealed in its application. With regard to synthetic biology, there is a gap in the approach of this theme in Brazil, in the scientific area and in the socio-environmental impact of products derived from such technology. On Bioethics, as applied ethics, seeks to evaluate new advances in technoscience, its products, and their implications for life in general, in order to ensure greater awareness and autonomy to individuals and society in their choices in view of a responsible future and survival (ZANELLA; SGANZERLA, 2018).

The science, says Morin, "has become too dangerous to be left in the hands of statesmen and states (...) it has become a civic problem, a problem for citizens (...) and it is unacceptable that these problems remain within four walls" (2013, p. 133), because it is up to society to ethically assess the new technoscientific possibilities, in order to demand that development be even more accelerated, when necessary to guarantee human health, social well-being, and "rethought" when the progress endangers the dignity of human life and the biosphere.

The hallmark of technoscience is ambivalence, and thus its danger is not only when it is used for purposes considered to be harmful in advance, but "even when benevolently used for its most legitimate and proper purposes, it has a threatening side to it, which in the long run it could have the last word" (JONAS, 2013, p. 52). And the thinker adds that "the price paid for posterity must be taken into account against the pressures of the hour (...)" (JONAS, 2013, p. 120), therefore, responsibility must be a necessary complement to freedom.

The synthetic biology, mainly with the creation of new biological "products" and innovative medicines, presents itself as one of the alternatives to improve the condition of human life. However, the dangers and threats, in view of the exaltation of the promise, are ignored or underestimated, which makes it more difficult to assess more serenely what is presented. Even in this condition, in which the promises overlap, the ability to question cannot be lost, asking: how to guarantee the necessary security for the experiments? How to ensure control of nature's organisms? How to avoid the loss of biodiversity through the creation of artificial microorganisms that can act unpredictably in the environment? How to prevent synthetic microorganisms from acting as invaders and starting to deregulate entire ecosystems? What is the possibility of these new organisms to present an unwanted evolution with risks to the environment and consequently to the human being?

If the danger nowadays "resides more in success than in failure" as stated by Jonas (2013, p. 52), then it is necessary to ethically guide the development of technoscience, so that the desires for conquest and overcoming, do not constitute an evil for humanity. The increase in "responsibility in relation to nature and in relation to the future of humanity is due precisely to the technical power" (BRÜSEKE, 2005, p. 11), which has become capable of fulfilling the promising wishes of homo faber. The creation of the "science of human survival" as proposed by Potter (2016, p. 27) and called by him bioethics, seeks to build a bridge between technical knowledge and ethics, as it is not possible to separate science from man and of the environment.

Therefore, in the face of the advances in manipulation and the creation of new forms of life intended by synthetic biology, this discussion will seek in the ethical-philosophical, scientific, documentary, and technical reflections for guidance in the conduct of this process, given that the mark of technoscience is ambivalence. Considering the relevance of international documents dealing specifically with synthetic biology, and in view of the scarce documentation related to this area in Brazil, it was decided to consider the bioethics reports of the White House and the Bioethics Committee of Portugal and Spain as references for the critical analysis of the topic under discussion.

Synthetic biology

The synthetic biology aims, based on the developed technique of recombinant DNA, combined with genetic engineering, information systems, and organic chemistry to remodel organisms, or even to create new organisms that do not exist in nature. Barak (2010, p.183) states that synthetic biology represents a "line of research that tries to produce, by reengineering, life forms from its simplest building blocks". According to the report of the European Academies Science Advisory Concil (EASAC), on synthetic biology, it can produce from a particular substance that is not produced naturally, to more ambitious goals such as producing completely new living beings (2011, p. 3). One of the events that marked synthetic biology was the creation in 2010, by the team led by researcher Craig Venter in his laboratory of basic DNA units, the bacterium Mycoplasma mycoides in a synthetic way, and after introducing the synthetic material in another cell receiving species different (Mycoplasma capricolum), it managed to reproduce naturally (GIBSON, et al., 2010).

As stated in the report of White House Bioethics Commission, the development of DNA synthesis technology allowed scientists to build entire genes, and eventually the complete genome of a microorganism using only synthetic methods (WHITE HOUSE, 2010, p.41). [1]

The deeply technical language of synthetic biology refers to a mechanistic view of biological processes in which it addresses its experiences and discoveries. In synthetic biology research, there is a clear combination of language and engineering and information technology techniques, which together propose a systemic look, treating DNA as an information system that can be remodelled, and / or created synthetically. In the same way that a software is programmed, by the logic of synthetic biology, organisms can be programmed or created with a new synthetic programming.

Thus, synthetic biology can be understood as "extreme genetic engineering" (CTA,

1 - Since January 15, 2017, the White House Bioethics Commission website has been disabled and no longer updated. Georgetown University maintains a mirror of the website with the work of the 2009-2017 Presidential Commission for the study of bioethical issues. https://bioethicsarchive.georgetown.edu/pcsbi/node/851.html.

S / D, p.1), making it possible to redesign existing organisms or even create new organisms that do not exist in nature. Currently, there are databases of DNA and synthetic RNA sequencing where parts of DNA sequences can be included and consulted, enabling the exchange of sequences and experiences. Schneider (2007, p. 1) states that the DNA sequence of a BioBrick and other characteristics are stored at MIT, in a bank accessible via the Internet, at no cost to those interested, called the Registry of standard biological parts.[2] The physical materials and components are not available, but the biochemical description of the genes is ready to use. This database accepts contributions in the form of new designs and improvements to the disposable genes. Synthetic biology, as an integral part of bioengineers, is characterized as a field of research that works on the formulation, projection and synthesis of new DNA sequences, culminating in new biological structures (LIANG et al., 2011).

The synthetic biology, insofar as it is not limited to combining existing DNA's in nature, but opens up a whole new arsenal of possibilities, makes it possible organisms engineered by computer (genetic code drawn on the computer) that can later be included in other organisms, from which the original DNA can be removed and replaced with synthetic DNA.

Applications, benefits and risks

The application of synthetic organisms can be found in different sectors, such as: in the production of energy with the development of microorganisms designed to produce hydrogen and fuels or even the realization of photosynthesis in an artificial way; in bulk production for the chemical industry of various elements of fine chemistry, including proteins, which can be an alternative to natural fibers or those produced synthetically with current technology; in the production of new types of drugs, vaccines and diagnostic agents and the production of new tissues; in the creation of new food additives, among others (WHITE HOUSE, 2010, p. 55).

The expectations regarding the synthetic biology are enormous and large industrial conglomerates demonstrate interest, both in the development of research and in patenting it and producing it on a large scale. The InterAcademy Partnership (IAP) statement for synthetic biology states that many scientists believe that this technique, using the principles of systems biology, engineering and chemical design will lead to new applications of value to society. Affirms the statement that

> the proof of the concept was demonstrated with the creation of less expensive ways of producing molecules for the pharmaceutical sector and other high-value chemicals, with the likelihood of other developments, related to the optimized generation and use of biofuels. Further on, there are possible applications of this biological tool in biomedicine, agriculture, land and water decontamination, bio-sensing, new materials, nano-machines and new approaches to

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information processing (IAP, S / D, p.1).

The real possibilities of synthetic biology are so many that they seem to resemble the realities produced in science fiction. The Royal academy of Engineering, in the report entitled Report synthetic biology: scope, applications, and implications, made some speculative predictions for synthetic biology for the next 10 to 25 years. Prospect the document that among the main possibilities, we have: [1] the production of more advanced biofuels; [2] the reduction of CO2 levels through the development of artificial leaf technology that will produce a synthetic version of the photosynthetic process; [3] the production of new types of pesticides that are more environmentally friendly; [4] the development of light biological bases and very resistant materials, which will have direct application in the aeronautical and automotive industries; [5] the development of bio-based memories (the direct equivalent of computer memory) for humans. After winning this first stage, the objective will be the production of microprocessors of different types of biological basis. Like their electronic analog, they will perform control functions applicable to living systems. In about 25 years we will have biosensors that permanently reside in the body to detect a certain type of abnormality, for example arterial disease. In the example of arterial disease, the biosensor will be part of an engineering machine through synthetic biology, which then manufactures or launches the ‘drug’ to disperse arterial plaque (ROYAL ACADEMY, 2009, p. 7-8).

It is in this perspective that the promises of synthetic biology are found, that is, in the development of promised products and procedures that aim at the “common good”, only with the possibility of improving life, but also with zeal in relation to care and care. prevention of accidents that can damage human health and nature.

Risks

The economic and social potential of synthetic biology is indeed very significant, but this potential represents only part of the issues at stake. The bioethics committees themselves, both in the United States, Spain, and Portugal point out that, like promises, risks can also be significant (WHITE HOUSE, 2010, p. 62; PORTUGAL & ESPANHA, 2011, p.16).

The question is: How to act in the face of uncertainties and unpredictable consequences? The principles of precaution and responsibility seem to be able to guide us in this questioning; since they affirm that we should not take risks in what the evidence is not so clear, a prudent, and responsible posture is necessary, which does not bet on “everything or nothing” in order to achieve certain successes. And as Jonas (2006) argues, a slower development of science (although some need a faster development to meet their immediate needs) but that does not put the image of man at risk, should prevail over the present idea of self-overcoming in the utopia of progress.

The Bioethics Committee of Portugal and Spain list some observations related to the risks of this innovative technology. The main risk pointed out is related to the consequences in relation to living beings and ecosystems. By manipulating living beings and adapting them in a synthetic way, it is worked with a way of life that has no similarity in nature, which compromises their interactions. This, however, raises doubts about how this being can interact with the environment, in addition to the ever-present possibility of dual use of the technique, such as the production of biological weapons (PORTUGAL & ESPANHA, 2011, p.16). The report presents the precautionary principle as the fundamental guide to be observed in researches.

The opinion of the WHITE HOUSE Committee, in turn, finds that, despite the various benefits that the development of synthetic biology presents, it brings a series of risks involved to a greater or lesser extent that can be overlooked. The document points out that the main risk at the current stage of the development of the technique is the possible contamination that occurred as a result of accidental release of organisms developed through synthetic biology. The report stresses that, unlike synthetically produced chemicals, which generally have well-defined and predictable qualities and functions, biological organisms can be more difficult to control. Any accidents or releases not properly managed can lead to crossings with other organisms and uncontrolled proliferations, threatening biodiversity itself (WHITE HOUSE, 2010, p. 62).

The report cites a didactic example of an eventual accident in a biofuel production system, which uses algae modified through synthetic biology, to generate this biofuel. In the case of an unwanted release of this organism, through leaks in the tanks in which they are processed, this organism derived from synthetic biology can spread to natural water courses, and with that, multiply inhibiting other species and imposing itself in the ecosystem and in the natural habitat with unpredictable consequences for the environment (WHITE HOUSE, 2010, p. 63). Although this scenario is theoretical, the report encourages to consider it as a practical consequence, in order to develop adequate precautions to prevent it from happening.

The report also highlights, that one of the advantages of synthetic biology is that many of the tools that will be developed include in its scope strategies to remedy the possible risks of certain practices. The document cites, as one of the approaches to the engineering of terminator genes (suicide gene) that can be introduced in the organism preventing them from reproducing or surviving outside laboratories or in another controlled environment due to the unique chemical conditions, which they would not find in the natural environment (WHITE HOUSE, 2010, p. 63).

The energy sector represents one of the most anticipated uses of synthetic biology. There is the possibility of a significant use of natural resources to produce biomass for fuel raw material. Ribeiro states that seen in this way there is still a risk that the whole of nature, the ecosystem itself and living beings in general, may be categorized as "biomass", that is, a universal raw material that can be processed through biology synthesis, exponentially increasing the exploitation of planetary biomass (2013, p. 52).

It should also be noted that these developed organisms may represent unusual and unprecedented risks, considering that their potential, to reproduce and evolve, is not well established. The report concludes that "Additional data are needed to assess how well biologically engineered safeguards, such as "kill switches" that activate after a defined number of generations, will work." (WHITE HOUSE, 2010, p.67-68). Regarding agriculture, the report finds safety concerns to be similar to those raised about genetic engineering itself. Among these risks are included the damage to humans, plants or animals that may come from uncontrolled environmental leaks, new or resistant pests that are difficult to control, and increased resistance and growth of invasive species, among others (WHITE HOUSE, 2010, p. 70).

Finally, there is a concern with biosafety in general. In this regard, the report, on the one hand, states that there is a great attention on the part of society to the risks related to biosafety and to the double use of emerging technologies, however, synthetic biology can develop techniques that increase biosafety allowing researchers to identify agents dangerous biological substances, developed synthetic or semi-synthetic. He mentions that, in a similar way as it was done at the J. Craig Venter Institute, one can "mark the bacteria that was synthesized with traceable information in the genetic code" (WHITE HOUSE, 2010, p.71). In addition to this measure, others such as "suicide genes" or technologies that inhibit the growth or survival of the organism outside the containment environment can be effective means to combat the threats of biosafety. Despite these perspectives, the uncertainties remain that these strategies are indeed effective. The report verbatim states that "Concerns about dual use or intentional misuse of synthetic biology to do harm are among the most prominent critiques of this emerging technology" (WHITE HOUSE, 2010, p.71). The risk that the synthetic biology technique could be used in the wrong hands is real, and it can be used to create harmful organisms aimed at bioterrorism. The report cites as a recent example the reconstruction of viruses using the recombinant DNA technique, such as the infectious polio virus, the mycoplasma genome and the 1918 strain of the influenza virus.

If, on the one hand, the prospects for advancement in the areas of social welfare, fuel, health and food present an encouraging scenario, on the other hand, there are still many issues that are not completely clear, safe and defined in relation to the risks that accompany them. Camara et al, points out that:

> one cannot fail to consider that contradiction and change of opinion is characteristic and expected in the strategic dimension of the political game. There are several actors involved and factors behind a political decision, therefore, decisions vary during the search for coalitions to establish alliances (2013, p.272).

The possibility of use in bioterrorism cannot be minimized. There are several radical groups with enough financial resources to finance sophisticated laboratories for the development of biological weapons. It is possible to observe more and more popularization, in the academic environment itself, in which competitions are held to create new organisms. In this way, biosafety must be greater the more accessible and complete the development of synthetic biology is.

Threat and hope Risks

Society lives a constant paradox, there is a concern for the future, for ecology and consumerism, but what drives the present are the immediate economic interests that take precedence over attention to future generations (LIPOVETSKY, 2004, p.69). In general, there is a risk of prioritizing technological optimism, ignoring the risks and threats present in it, both for the present and for future generations. The ideal of a possible sacrifice of the present in view of the future, needs to be understood and practiced in our times.

The technological utopia demands daily overcoming in view of its achievements, and with that, it ignores risks and threats, as well as the most elementary questions of its activity: who is interested in all this process of interference in life? What gains will humanity have with such achievements? What are the real human needs in our times?

For situations in which the possible risks are not yet so evident, due to the unpredictability of the consequences, the in dubio pro malo proposed by Jonas (2013, p. 76-77) seems to point us a way to avoid with the threat come to fruition. The methodological option of fear heuristics and comparative jonasians futurology, prioritizing the negative diagnosis before the positive (JONAS, 2006, p. 70), wants to emphasize not success, but failure, so that it does not become materialize. This negative methodology proposed by Jonas, wants to prevent the expectations presented by the utopia of progress obscuring our ability to see the threats present in it. This is not a pessimistic position, but a position taken independently of the possible promises announced. In practice, it is about giving space and voice to the virtue of prudence, so necessary for the techno-scientific development of current times that it has become capable of unimaginable achievements, but which also creates a scenario of uncertainty and insecurity. Jacobi and Giatti affirm that the virtue of prudence has become indispensable in our times because the process of "development is not capable of dialoguing with possible side effects, nor with issues of a global-local nature full of profound inequities, not even skilled in consider a transgenerational and lasting perspective "(2015, p. 1).

Although it is not possible to guarantee a risk-free guarantee in the scientific process, risks cannot be taken in order to achieve certain benefits. Therefore, when dealing with new and complex situations in research, but with unpredictable consequences, the jonasian rule in dubio pro malo, must prevail over technological optimism, because the bets in these areas of knowledge can be extremely risky (PORTUGAL & ESPANHA, 2011, p.17).

The benefits and expectations of synthetic biology are widespread. These promises, in turn, demand that this model or way of thinking of the utopia of progress must be prioritized, and with that, humanity is driven to increase its production and consumption. More affirms that in the speeches the supporters of bioengineers, they present the development as capable of solving, in a magical way, the problems that were left by yesterday's technologies with tomorrow's technologies (2013, p.15), thus authorizing to continue the march of progress.

This human capacity to manipulate, and, consequently, interfere in the natural course of the evolution of living beings, including the human being himself, "makes recombinant DNA technology a technology that is both popular and controversial" (COELHO, et al., 2013 p. 262), and this is a general perception when it comes to the development of biotechnology. The ambiguity present in technoscience, and, in our reflection, in synthetic biology, cannot be ignored when analyzing hopes and threats.

The risk of unpredictability and excess power

Although the techno-scientific capacity of our times grows incessantly each day, however, our capacity for predictability about development and research results does not increase. On the contrary, it seems that the mark of this progress lies much more in unpredictability than in certainty. The short-term prognoses of technological civilization are not sufficient for long-term issues, hence the need for ethics (JONAS, 2006, p.73). Consequently, it is necessary to deal with the paradox of the unpredictability of scientific development, since the prediction of future scientific and technological development is limited by rational scientific and technological knowledge of the present. The appearance of new techniques or scientific discoveries may radically alter the previous prediction regarding that technique. Thus, there is a relativism in the prediction of science and therefore the constant need to review its procedures and forecasts. Jonas states:

> (...) in any case, the required extrapolation demands a greater degree of science than that which already exists in the technological extrapoldum; and, considering that it represents each time the optimum of the existing science, the required knowledge is always, necessarily, knowledge not yet available at the moment and never available as previous knowledge; at most, only as retrospective knowledge (2006, p.73).

There is a limitation in the predictability that technology itself can produce, so caution is required in seeking the development and applications of synthetic biology. The Report of the Bioethics Committee of Portugal and Spain shows that research should be carried out with due caution, and therefore recommends that research with synthetic biology be carried out evaluating case by case, and step by step within this research (PORTUGAL & SPAIN, 2011, p.18). Here again, the heuristics of fear prevails, due to the difficulty of predictability, even more when dealing with organisms that may interact with other organisms if dispersed in nature, generating a quantity of risks that effectively cannot be "measured" in the laboratory.

The risks present in the techno-scientific capacity, that can threaten humanity, occur because technological advance has not been accompanied by the development of human responsibility. Jonas states that the responsibility of the human being is proportional to the power he possesses. Therefore, it is necessary that the human being acts so that his actions and decisions do not compromise the authenticity of life in the future (JONAS, 2006).

> When, then, the new nature of our actions demands a new ethic of far-reaching responsibility, commensurate with the breadth of our

> power, then it also demands, in the name of that responsibility, a new kind of humility - a humility not like that of the past, as a result of littleness, but of the excessive greatness of our power, for there is an excess of our power to do over our power to predict and over our power to grant value and judge (JONAS, 2006, p. 63).

Faced with the relation of responsibility and power, one may question: what is the risk that can be taken in order to achieve certain benefits? Is it possible to advance technically and scientifically without endangering human dignity and that of life as a whole? How to achieve this? How to reconcile the goals of homo faber with the wisdom of homo sapiens? To what is the scientist committed? To humanity? To the interests of industry and the economy? To progress? Although these questions are extremely complex and require the participation of different actors in their answers, the analogy made by Jonas in dealing with the subject seems to help in the direction that should be proceed. He states that "the doctor is always obliged to the patient and to no one else" (JONAS, 2013, p. 146). In other words, the interests of third parties, be they industry, the economy, politics, cannot be prioritized when the advances of techno-science are at stake.

The possibilities of synthetic biology are not limited to creating synthetic DNA for new organisms, because there is the possibility of inference in human DNA. In the document The Principles for the Supervision of Synthetic Biology developed by Friends of the Earth U.S. and International Center for Technology Assessment (CTA) and ETC Group asserts:

> the use of synthetic biology to modify the human genetic composition, whether of the human genome or epigenome, or even the human microbiome, must be prohibited. The convergence of synthetic biology with other technologies, such as gene transfer through viral vectors, nanomaterials or stem cells, makes the possibility of altering the human genome even more disturbing. Any change in the human genome through synthetic biology - particularly an inherited genetic change - is too risky and has ethical repercussions (CTA, s/d, p.5).

The synthetic biology beckons with the possibility of creating new genetic codes, of manipulation and creation of improved organisms aimed at human need. Recently scientists from the scripps research institute reported that they have developed new semi-synthetic bacteria by adding two synthetic bases (called X and Y) to the four natural ones (A, T, C, G) in their genetic codes. The novelty of this procedure is that the new pair remained stable replicating in the cell divisions, potentially increasing the storage of DNA information from semi-synthetic organisms (ZHANG, et al., 2017). The use of synthetic biology is enhanced by the ease that the development of the CRISPR (clustered regularly interspaced short palindromic repeats) genetic manipulation tool can provide in genome editing. In this technique, an enzyme, for example, Cas9 (a nuclease) has the potential to cut both tapes of the double helix of DNA, making room for insertion of a new sequence, or replacement of previous DNA sequence. This tool has been described as "molecular scissors" for its ability to make previously improbable genetic engineering by the exercise of “cutting and sticking” to the genome of any organism. Editing is based on the process of homologous recombination of the synthetic sequence with the sequence one wishes to edit in the genome. The enzyme Cas9 acts, through the break in the double tape, as inducer of the recombination process (LIANG et al., 2016; RODRIGUES et al., 2017).

In order to make the use of the CRISPR technique even more efficient, can be also counted on the use of artificial intelligence software, developed by Microsoft researchers, which aims to minimize eventual effects outside the desired target in the genetic edition project (LISTGARTEN, 2018, p. 38-47). The off-target cutting effects are pointed out in the literature as the main source of risk in the use of the technique, because the imprecise repair of the double tape induces random mutations (BRUMER et al., 2019). Although according to Nohama and Simão-Silva (2018) the ethical issues related to genetic editing can be addressed in three focal points: the issues inherent to the research and development process; the problems inherent to the CRISPR technique and the problems related to the use, that can be made of the products generated by the technique. The latter being the line of questions in common with synthetic biology.

In the face of these achievements and human dilemmas in the use of techno-science, Lewis warns us that what can strengthen is also what can weaken, which reinforces the ambivalent character of techno-science. Lewis affirms:

> The conquest of nature by man, if the dreams of a few planners come true, would mean that a few hundred men would be ruling the destinies of billions and billions. There is nor can there be any addition to man’s power. Every new power conquered by man is likewise a power over man. Each advance makes him weaker, at the same time as it makes him stronger. In each victory, man is both the general who triumphs and the slave who follows the chariot of victors (2005, p.56).

Faced with this scenario of excessive human power with the use of techno-science and the unpredictability of results, reflection on the freedom of research and human responsibility is becoming increasingly necessary, so that humans do not start idolizing what could harm them. The effort according to Rojas Hernández (2017) is in the same way to establish the minimum foundations to guide the entire development process.

Final considerations

Science has chosen to follow the cartesian dualism that no longer considers life in its totality, it has treated the organism in a mechanistic way, defining its actions only through chemical/physical processes, in order to ignore any ontology that is not linked to materiality. The ease this vision has provided for science is evident. To treat the genetic code as a program, a software, that can make the hardware, the organism, act in the way it can be programmed is really tempting. However, the organism cannot be reduced to just this kind of dualistic view.

If the above analogy is used, which is so dear to synthetic biology, it should be noted that unlike the computer that executes the code that is imputed to it, in which can be easily differentiate the software from the hardware, the living organism absorbs its code, and in this junction the total control cannot longer be taken because the hardware can modify the software in the absence of its programmer, and, this altered code can be transferred to future generations.

Only life can know life, says Jonas (2004), and with this life reveals its character of unpredictability and spontaneity. To think that it is possible to master all the processes and procedures of life is a human failure, and not trying to foresee all the consequences, for the present time and for future generations, is a serious and risky mistake.

Human life is deeply linked to the maintenance of nature, because humans are part and fruit of nature, so the possible transformations made in the life of nature, has in the short and long term, strong impacts on human life.

The technological power of synthetic biology and the unpredictability of its results demands that the virtue of prudence take on a prominent position, since the threats no longer derive from inability to accomplish, but from power and pride. Therefore, responsibility is much more in the political-collective sphere than in the individual, and therefore the practice of government regulators' responsibility is needed. In other words, it is a matter of adding the responsibility of the scientist (and those who can finance research) as well as the sphere of the political legislator. In this aspect it is important to highlight the need for the synthetic biology theme to be discussed and legislated in Brazil.

Although general rules based on the precautionary principle and responsibility are sought to guide biosafety legislation in relation to synthetic biology research, each new product must also be individually analyzed to identify its impacts and its threats and risks. Thus, transparency and honesty must be essential in the research development process, because society must be aware of the steps being taken. Without democratization of information and knowledge, the process of autonomy and clarification will not be effective.

When the conclusion of this reflection is come, it is possible to state that the recommendations for companies and research laboratories in synthetic biology present in the bioethics reports of the White House and the Bioethics Committee of Portugal and Spain are extremely relevant because they state that research in synthetic biology should be guided by the following principles: 1] public beneficence, [2] responsible administration, [3] intellectual freedom and responsibility, [4] democratic deliberation, [5] precautionary principle, [6] traceability principle, [7] and "step by step" and "case by case" principles.

Although the defense of these principles already represents a significant step in orientation with research in synthetic biology, it is possible to identify other fundamental principles to guarantee human dignity, diversity and respect for nature and the preservation of what can be called natural life. Therefore, it was taken the liberty of adding other principles to the above-mentioned documents, which have an approach to the universe of bioethics: [8] non-maleficence to the public: care with synthetic biology should not be evaluated only by looking at public beneficence, which may suggest a concern only with the care of providing good for society, but also the aspect of non-maleficence, that is, synthetic biology cannot promote problems for society; [9] justice and proportional distribution of risks: the most vulnerable sectors of society should have greater protection from governments and legislation, and the sectors that benefit most from synthetic biology techniques should be held accountable in case of accidents and unexpected results; [10] government responsibility: the public institutions responsible for the release and inspection of research and products developed from synthetic biology are held responsible and liable to legal and administrative actions for the consequences of the use of the technique; [11] risk maximization: priority should be given to the maximization of risk and problems that may arise from accidents, and the undesirable development of genetically synthesized organisms or the possibility of double use; [12] reversibility principle: reversible actions have preference over irreversible actions. For each risk or possibility of accidents identified there must be a plan that can safely reverse the action to the previous stage. The addition of these principles to the report of the White House and the Bioethics Committee of Portugal and Spain can ensure more ethical, legal and technical security in the process of developing research in synthetic biology.

With the creation of new types of materials, synthetic biology will be able to revolutionize all human life, assuring many benefits and achievements. However, if the possibilities of success, the risks can be ignored, so it is necessary to reconcile the increase in human power with the practice of responsibility. If wisdom, as Potter said, is the capacity to know how to use knowledge, that is what is needed to guide research in synthetic biology.

If on the one hand there is no "progress without shadows" as Morin states (2010, p. 29) because all progress risks degradation, and therefore progress represents one of the uncertain faces of the future, on the other hand, the commitment of techno-science must be to the dignity of biosphere life.

Although synthetic biology is recent, the subject has already been debated by bioethics in its different areas of knowledge, because the results of research in synthetic biology are promoting strong impact on life, diversity, ecology, sustainability, biodirect, especially when the creation of new forms of life are referred, not yet existing in nature. It is, therefore, a new possibility that brings unpredictable consequences beyond the academic and scientific world. If "science is too serious a process to be left in the hands of scientists alone", as Morin (2013, p. 133) states, then it is necessary to promote dialogue, debate, reflection, access to information for the entire society and in the different areas of knowledge. For this, the interdisciplinary character of bioethics represents a privileged tools.

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SciELO

BIOLOGIA SINTÉTICA E MANIPULAÇÃO GENÉTICA: Riscos, promessas e responsabilidades

Roberto Rohregger
Anor Sganzerla
Daiane Priscila Simão-Silva

São Paulo. Vol. 23, 2020
Artigo Original

Resumo: Fruto do avanço biotecnológico, a biologia sintética tem sido aplicada desde o melhoramento de alimentos até a criação de novos organismos. Este artigo investiga, sob uma perspectiva bioética, a respeito dos benefícios, riscos e ameaças à vida, decorrentes da produção, manipulação e, principalmente da criação de DNA's sintetizados inexistentes na natureza. Os relatórios de bioética da Casa Branca e do Comitê de Bioética de Portugal e Espanha contribuíram para discussão. O progresso da tecnociência, sem a devida capacidade ética de avaliação, pode produzir resultados que comprometem o desenvolvimento social, a preservação ambiental, a dignidade humana e a vida da biosfera no futuro. Nesse sentido, as conquistas da biologia sintética, tem se demonstrado ambivalentes, porque as esperanças se misturam com as ameaças, com resultados imprevisíveis à diversidade da vida da biosfera, o que torna a prudência a virtude por excelência.

Palavras-chave: Biologia Sintética; Bioética; Responsabilidade; Prudência

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Resumen: Fruto del avance biotecnológico, la biología sintética se ha aplicado desde la mejora de los alimentos hasta la creación de nuevos organismos. Este artículo investiga, desde una perspectiva bioética, acerca de los beneficios, riesgos y amenazas a la vida, derivados de la producción, manipulación y, principalmente, de la creación de ADN sintetizados inexistentes em la naturaleza. Informes de bioética de la Casa Blanca y el Comité de Bioética de España y Portugal contribuyeron a la discusión. El progreso de la tecnociencia, sin la debida capacidad ética de avaluación, puede producir resultados que comprometen el desarrollo social, la dignidad humana y la vida de la biosfera en el futuro. En ese sentido, las conquistas de la biología sintética se han demostrado ambivalentes, porque las esperanzas se mezclan con las amenazas, con resultados imprevisibles a la diversidad de la vida de la biosfera, lo que hace la prudencia la virtud por excelencia.

Palabras-clave: Biología Sintética; Bioética; Responsabilidad; Prudencia

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