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COMECE

OPINION OF THE REFLECTION GROUP ON BIOETHICS ON SYNTHETIC BIOLOGY

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(Translated from French)

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1. A RAPIDLY EXPANDING DOMAIN

"*It is not easy to find a working definition of synthetic biology. It depends on the desired outcomes, either on its applications (or aims) or more in general on the broad concept of basic research and therefore its experimental nature. It may not be possible to find an unequivocal definition and it could change over time as awareness of this discipline increases and becomes more widespread*"[1].

1.1. Designing and making artificial biological systems

Most of the authors who have tried to grapple with this emerging discipline have exercised prudence with regard to work already done on synthetic biology (SB) and with regard to the methods used and recommended. Nevertheless, the European Group on Ethics in Science and New Technologies (EGE), source of the remarks quoted above, went ahead to describe the main pillars of this discipline: the engineering of biological components that do not exist in nature and the re-engineering of existing biological components. According to the EGE, "*Synthetic biology centres on the intentional design of artifical or re-worked biological systems, rather than primary understanding of the biology of exisitng organisms in nature. A definition of synthetic biology should therefore include:*

1. The design of minimal cells/organisms (including minimal genomes);

2. The identification and use of biological 'parts' (toolkit);

3. The construction of totally or partially artificial biological systems"[2].

SB aims to produce artificial biological components and systems and even living organisms which do not exist in nature. At the same time, the available definitions put the emphasis on methodology. The methods formerly used in the diverse biotechnologies appear far too artisanal, tentative and time-consuming. Specialists in synthetic biology seek to build up a veritable "engineering" of living organisms, in a structured manner, using methods stemming from engineering science and practices, particularly mathematical modelling and computer simulation. The object is to complete the rational design and testing of new biological systems before seeking to build them using genetic engineering, synthetic chemistry or other technologies, and then to assess their interest and their impact on health, environment or society.

1 European Group on Ethics in Science and New Technologies in the European Commission (EGE), *Ethics of synthetic biology*, Opinion No. 25, November 2009, 1.3, http://www.coe.int/t/dg3/healthbioethic/COMETH/EGE/20091118%20finalSB%20_2_%20MP.pdf.

2 *Idem.*

1.2. Engineering living organisms

This notion of engineering is frequently used in the available definitions. The European research consortium Synbiology proposes the following wording: "*Synthetic Biology is the engineering of biological components and systems that do not exist in nature and the re-rengineering of existing biological elements ; it is determined on the intentional design of artificial biological systems, rather than on the understanding of natural biology*"[3].

In synthetic biology, several approaches can be considered. The so-called "*top-down*" approach consists in modifying a natural biological system in order to obtain a system that is simpler, easier to understand and manipulate. For example, it is possible to take a bacterium, strip out the majority of its genes and keep only the minimum necessary for it to survive in laboratory conditions. The opposite approach, called "*bottom-up*", consists in making a selection from an existing "inventory" of building blocks with well-defined functions, then assembling them to produce tailor-made biological systems. It is even possible to go further and create "protocells", vesicles with a wall similar to membranes of living cells which are able to absorb specifically selected small molecules and to process them inside, thanks to a simple cellular machinery. Protocells are able to perform a variety of functions, such as detecting and identifying a health defect before any symptoms appear[4].

Having "minimal" cells – only needing an equally minimum number of genes in order to function and easy to manipulate – would enable a rapid leap forward in synthetic biology. In America, a team at the J. Craig Venter Institute has focused on this task. After managing to create an artificial virus, then to construct a bacterial artificial chromosome, at the end of fifteen years of research this team managed in 2010 to synthesise in a laboratory the genome of the *Mycoplasma mycoides* bacterium, formed of 1.08 million base pairs, and to transplant it into another bacterium *Mycoplasma capricolum*, in such a way that the recipient remained viable although completely controlled by the artificial genome. This is actually a new bacterium, currently named *Synthia*. The Institute boasts of having created

3 *Synbiology, An Analysis of Synthetic Biology Research in Europe and North America, Final Report on Analysis of Synthetic Biology Sector*, September 2006, http://www2.spi.pt/synbiology/documents/news/D11%20-%20Final%20Report.pdf. See also the definitions set out in the abovementioned EGE Opinion, Ethics of synthetic biology, Opinion No. 25, 1.3.

4 Cf. Biologie de Synthèse, 4, http://www.biologie-de-synthese.fr/us/biosyn.html. See also EGE, Ethics of synthetic biology, 1.5.

"*the first synthetic bacterial cell*"[5]. It did not take long for this claim to be challenged by scientists who observed that, although the chromosome had been built by synthetic chemistry and put together using biotechnology, the whole (far more complex) cellular machinery was still that of the host bacterium.

1.3. A great many anticipated industrial applications

In the future SB could well have multiple industrial applications in the domains of health, energy, materials, environment and agriculture[6]. Its successful applications already include: a sensitive diagnostic system which enables the monitoring every year of 400,000 patients infected by HIV and hepatitis; a simple system for detecting the presence in drinking water of arsenic, a source of poisoning for millions of people worldwide; the synthesis of artemisinin, a powerful anti-malarial medicine[7].

Artemisinin is a molecule produced naturally by a plant, *Artemisia annua* (sweet wormwood). It has been used in China for over two thousand years for treating malaria and the World Health Organization recommends its use in combination with other drugs. Its manufacture through plant extraction methods no longer keeps pace with demand; moreover, its annual yields fluctuate in quality and quantity. At the beginning of the 2000s, Jay Keasling, of the University of California at Berkeley, USA, carried out research with his colleagues on an alternative manufacturing process. Starting from the plant's genes, he optimised their expression and introduced them into brewer's yeast, thereby managing to build in the yeast a pathway for synthesising a precursor of artemisinin. Later on he improved this path through introducing additional DNA sequences and by making careful adjustments to the yeast. In 2013, after a decade of hard work, this research was crowned with success[8]. They ended by manufacturing sixty tonnes of artificial artemisinin per year, with markedly improved purity and availability, and all this at half the former cost.

5 J. Craig Venter Institute, First Self-Replicating Synthetic Bacterial Cell, http://www.jcvi.org/cms/research/projects/first-self-replicating-synthetic-bacterial-cell/overview/.

6 Horizon 2020 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:347:0104:0173:EN:PDF), the Framework Programme for Research and Innovation of the European Union for the period 2014 – 2020, includes as one of its specific objectives under the pillar "industrial leadership" the objective linked to «leadership in enabling and industrial technologies". Its aim is "*to develop competitive, sustainable, safe and innovative industrial products and processes and contribute as an innovation driver in a number of European sectors, like agriculture, forestry, food, energy, chemical and health as well as the knowledge-based bioeconomy.*" Among these technologies lies biotechnology, which includes synthetic biology.

7 Biologie de synthèse, cited document, 5. Cf. EGE, Ethics of synthetic biology, 1.5.1.

8 F. Képès, "La biologie de synthèse. Vers une ingénierie du vivant", *Pour la science,* n° 440, June 2014, p. 28-35.

Synthetic biology raises great expectations. "*With regard to possible applications of SB, they touch upon a great many domains: health (prevention, diagnosis and treatments), energy, chemistry, environment, agriculture, industrial processes. That is why scientists see in SB this century's industrial revolution and a means of contributing solutions to the very important challenges that confront humanity today: climate change, energy crisis, environmental remediation, fight against diseases such as cancer, neuro-degenerative diseases, disabilities and malaria […] With regard to the feasibility of certain SB applications, some people (like the authors of the Royal Academy of Engineering) are making predictions of an industrial development over a period varying between 5 and 25 years. Others, more cautious, refuse to make any forecasts, invoking even the risk – as was the case for gene therapies – of overhyped promises*"[9].

Many unknown factors remain, concerning not only the feasibility of current projects or those in the pipeline, but also what decisions will be taken at the outcome of the risk assessment, whether objections based on ethical, philosophical and religious grounds will be taken into consideration and how the general public will react in the various countries concerned.

9 Parliamentary Office for Evaluation of Scientific and Technological Options Presentation, OPECST, France, *Les enjeux de la biologie de synthèse*, p. 199-200, http://www.assemblee-nationale.fr/13/pdf/rap-off/i4354.pdf (free translation).

2. OBJECTIONS IN PRINCIPLE OR A CALL TO RESPONSIBILITY?

Operating in this way on living organisms, artificially building new biological functions and even organisms which do not exist in nature, thereby giving rise to new forms of life – are we not on a collision course with objections of principle?

2.1. A rebellion against the sovereignty of God?

Can mankind indeed alter the universe which has been entrusted to it, can it make new forms of life appear? Is it not jeopardising the universe? Above all, is it not a manifestation of excess and of an unacceptable pretension? Is it not usurping the place of the Creator? Will the expression *Playing God* turn out to be justified?

Some people report that Craig Venter, following the success of his *Synthia* project, had boasted that he had managed "*to have 'created life', thus provoking a comparison with God and inviting a risk of rejection for either religious reasons or simply through a justified reaction to an unacceptable degree of megalomania and exaggeration from an ethical point of view*"[10].

Such claims have been vigorously contested. In his paper on ethical questions posed by synthetic biology, Patrick Heavey[11] quotes Richard Land, president of the Southern Evangelical Seminary and a celebrity whose authority is recognised by the Baptists in the American South: "*We see altering life forms, creating new life forms, as a revolt against the sovereignty of God and a attempt to be God*"[12].

2.2. An arbitrary manipulation of life?

Clearly Craig Venter has not created life. The label of overweening megalomania would be attached to anybody who regarded himself as a creator in the strong sense that this term has in a religious context. Craig Venter has obtained a new life form, but to do that he has only exploited, after long and costly efforts, the natural properties of a bacterium which certainly did not owe its existence to him!

Indeed, does mankind have any right to modify life on Earth? Ever since men started interfering with plant and animal species, this question has engendered a

10 *Idem*, 4, A.2, p. 175 (free translation).

11 Patrick Heavey, *Ethical issues in synthetic biology*, School of Law, University of Manchester, 2012, Chapter 10, p. 278.

12 Quoted by Ted Peters, *Playing God? Genetic Determinism and Human Freedom*, New York, NY, Routledge, 2003, p. 118.

great deal of controversy. In the eyes of the Catholic Church, mankind must not "*make arbitrary use of the earth, subjecting it without restraint to his will, as though it did not have its own requisites and a prior God-given purpose, which man can indeed develop but must not betray. When he acts in this way, instead of carrying out his role as a co-operator with God in the work of creation, man sets himself up in place of God and thus ends up provoking a rebellion on the part of nature, which is more tyrannized than governed by him*"[13].

2.3. An urgent appeal for responsibility

These warnings do not prevent a healthy Christian vision of Creation from including "*a positive judgment on the acceptability of human intervention in nature, which also includes other living beings, and at the same time makes a strong appeal for responsibility. In effect, nature is not a sacred or divine reality that man must leave alone. Rather, it is a gift offered by the Creator to the human community, entrusted to the intelligence and moral responsibility of men and women. For this reason the human person does not commit an illicit act when, out of respect for the order, beauty and usefulness of individual living beings and their function in the ecosystem, he intervenes by modifying some of their characteristics or properties*"[14]. "*Many recent discoveries have brought undeniable benefits to humanity. Indeed, they demonstrate the nobility of the human vocation to participate responsibly in God's creative action in the world*"[15]. The human person is therefore invited to behave as God's associate, meaning that he reaches a heightened sense of his responsibility at the moment when he is altering the world that has been entrusted to him.

"*As with every human behaviour, it is also necessary to evaluate accurately the real benefits as well as the possible consequences in terms of risks. In the realm of technological-scientific interventions that have forceful and widespread impact on living organisms, with the possibility of significant long-term repercussions, it is unacceptable to act lightly or irresponsibly*"[16].

"*The complexity of the ecological question is evident to all. There are, however, certain underlying principles which, while respecting the legitimate autonomy and the specific competence of those involved, can direct research towards adequate and*

13 Pontifical Council for Justice and Peace, *Compendium of the Social Doctrine of the Church*, §460, http://www.vatican.va/roman_curia/pontifical_councils/justpeace/documents/rc_pc_justpeace_doc_20060526_compendio-dott-soc_en.html#Lenvironnement,%20un%20bien%20collectif.

14 *Compendium of the Social Doctrine of the Church*, §473.

15 John-Paul II, *Message for World Day for Peace,* 1 January 1990, §6. This passage is quoted by Pope Francis in his Encyclical '*Laudato Si*', 24 May 2015.

16 *Compendium of the Social Doctrine of the Church*, §473.

lasting solutions. These principles are essential to the building of a peaceful society; no peaceful society can afford to neglect either respect for life or the fact that there is an integrity to creation"[17].

Therefore it is vital to take whatever precautions are necessary to prevent the development of new techniques from endangering either human health or environmental quality.

"*Responsibility for the environment, the common heritage of mankind, extends not only to present needs but also to those of the future….This is a responsibility that present generations have towards those of the future*"[18]. Protection of biodiversity is particularly important as it "*must be handled with a sense of responsibility and adequately protected, because it constitutes an extraordinary richness for all of humanity*"[19]. Besides, biodiversity protection is the main objective of the Cartagena Protocol on biosafety and the protection of "*human health and the environment from the possible adverse effects of the products of modern biotechnology*"[20].

Going further, "*modern biotechnologies have powerful social, economic and political impact locally, nationally and internationally. They need to be evaluated according to the ethical criteria that must always guide human activities and relations in the social, economic and political spheres. Above all the criteria of justice and solidarity must be taken into account*"[21] to facilitate fair trade, encourage the dissemination of scientific knowledge and the transfer of technology to developing countries[22].

17 John-Paul II, cited message, §7.

18 Compendium of the Social Doctrine of the Church, §467.

19 *Idem*, §466.

20 *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, Montreal, 2000, Introduction, https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

21 *Compendium of the Social Doctrine of the Church*, §474.

22 Specifically, in regard to genetic modifications, Pope Francis states in his Encyclical '*Laudato Si*' (§ 133 and § 134) that «*it is difficult to make a general judgement about genetic modification (GM), whether vegetable or animal, medical or agricultural, since these vary greatly among themselves and call for specific considerations. The risks involved are not always due to the techniques used, but rather to their improper or excessive application (…) Although no conclusive proof exists that GM cereals may be harmful to human beings, and in some regions their use has brought about economic growth which has helped to resolve problems, there remain a number of significant difficulties which should not be underestimated. In many places, following the introduction of these crops, productive land is concentrated in the hands of a few owners (…) The expansion of these crops has the effect of destroying the complex network of ecosystems, diminishing the diversity of production and affecting regional economies, now and in the future. In various countries, we see an expansion of oligopolies for the production of cereals and other products needed for their cultivation. This dependency would be aggravated were the production of infertile seeds to be considered; the effect would be to force farmers to purchase them from larger producers*», http://w2.vatican.va/content/francesco/en/encyclicals/documents/papa-francesco_20150524_enciclica-laudato-si.html.

3. AN ESSENTIAL FRAMEWORK FOR PRACTICES

The abovementioned remarks, made over ten years ago, refer to the manipulation of living organisms by biotechnological means, in particular by genetic engineering. They are also completely relevant to the field of synthetic biology as it can be considered as the rationally prepared implementation – using available data, tested by computer and coordinated with declared objectives – of different biotechnologies associated with chemical and biochemical techniques.

The volume of knowledge already collected, the engineering methods used in SB and the scale of funding which has been allocated to it in several Member States, all amount to an emerging discipline with huge potential for development that will probably result in the acquisition of immense power of manipulation of living organisms.This is why in these times it raises enormous interest among a number of leaders in industrial and political circles. For the same reasons, recommendations need to be drawn up and precise rules enacted. It is still hard to predict the power of SB to transform the universe, or even the the risks that it might incur and the issues it could raise in future.

3.1. Safety and security

It is essential to ensure that, after completion of the requisite impact studies, SB research and its industrial applications should be carried out in a "*safe*"[23] manner such that neither human health nor the environment will be harmed. This requirement covers the protection of workers' health and the rules for caution with regard to the containment of live forms modified or assembled by using SB, and with regard to their possible dissemination in the environment[24] with its consequences for humanity and "*for specific ecological settings as well as with potential risks and benefits for the whole biosphere*"[25], including the marketing of products obtained as a result of the process.

In addition there are precautions to be taken in the area of "*biosecurity*"[26]. A great many biological manipulations are in fact within the reach of amateurs or

23 EGE, *Ethics of synthetic biology,* Opinion No. 25, 4.2.

24 *Idem*, 4.2.1.

25 *Ibidem*, 4.4.

26 *Ibidem*, 4.3.

"*biohackers*"[27] carrying out experiments "*in their garage labs*"[28]. SB resources could moreover be used for malicious purposes and even become weapons in bioterrorist hands.

Every society can only try as it might to arm itself against unwise and irresponsible behaviour in the areas of health and ecology, and also against the attacks of people who have a real desire to cause harm. That means that there should be some detailed reflection about what governance should be provided for synthetic biology, what legislation should be passed in each Member State and at EU level[29] and also international level, what monitoring of activities should be set up and also what constant risk assessment should be carried out by competent authorities, what forms of control should be enforced, what declarations should be demanded and what permits should be applied for prior to taking action[30]. This requires that the European Union and each Member State should examine their procedures for risk assessment for human health and the environment, and define what is needed for either authorising or banning SB research and industrial manufacture[31]. On their side "*the relevant science communities should be encouraged to establish ethical, preferably global, guidelines*"[32].

While freedom of research forms part of the fundamental rights formally recognised by the European Union[33], the EU has also undertaken to ensure that "*a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*"[34]. Neither the possible interests of private individuals nor those of industrial companies, nor even the interests of science, should be allowed to hold the upper hand but should be subordinated to the demands of the common good[35].

27 *Ibidem*.

28 Cf. CNAM, Biologie de garage, Do it Yourself biology (DIYbio), biohackers, http://biologie-synthese.cnam.fr/pratiques-non-institutionnelles/etats-des-lieux-des-pratiques-non-institutionnelles-487242.kjsp, (free translation).

29 The applicable EU regulatory framework is not unified and includes the pieces of legislation which govern the various applications of synthetic biology, including the legislation concerning genetically modified organisms; medicinal products; medical devices and in vitro diagnostic medical devices; gene therapy; clinical trials; cosmetic products; chemicals, among others.

30 EGE, *Ethics of synthetic biology*, Opinion No. 25, 4.4.

31 *Idem*, 4,2.

32 *Ibidem*, 4.4.

33 *Charter of Fundamental Rights of the European Union*, Article 13.

34 *Idem*, Article 35.

35 *Compendium of the Social Doctrine of the Church*, §164-167.

3.2. International trade and justice

It is quite possible that synthetic biology may experience a huge surge, that it will generate many industrial businesses, that it will contribute to the prosperity of any country already possessing some know-how in this field, which might well be the case for the countries of the European Union.

"*The [European Group on Ethics] welcomes this possibility; insofar as principles of the EU Charter of Funamental Rights and main EU fundamental values are not negatively affected by this technological sector and the trade of its products. The ECE therefore has concerns about the possible risks of a technology divide within the EU and between developed and less developed countries*"[36].

This prospect of economic growth as a result of the development of synthetic biology research and its industrial applications is not in itself open to criticism. It is even to be hoped that this discipline would expand in the countries that have already set up precise rules for SB and comply with them, thereby gaining at international level the authority enabling them to advocate a controlled expansion of biotech industries. The EGE is right to raise, at the same time, the question of how countries may work together on this fairly and how to disseminate information and know-how without digging even deeper the ditch that separates developed from developing countries.

"*It is necessary to break down the barriers and monopolies which leave so many countries on the margins of development, and to provide all individuals and nations with the basic conditions which will enable them to share in development*"[37].

3.3. Patents

It is inevitable in our highly competitive world that the development of any new discipline, the invention of new tools, the manufacture of new products or of already known products using innovative processes, the acquisition of renewed savoir-faire, will bring up the issue of patenting inventions. "*Indeed, particularly in the area of biotechnologies, research and development call for major investments. Legal protection of inventions by means of patents is therefore of great importance. A factor in the promotion of research is to permit the authors*

36 EGE, *Ethics of synthetic biology*, Opinion No. 25, 4.5.2.

37 John-Paul II, Encyclical *Centesimus annus*, 1991, quoted in *Compendium of the Social Doctrine of the Church*, §179.

of these inventions to benefit from them by guaranteeing to them intellectual property rights for a specified duration; It also contributes to the dissemination of scientific knowledge because, to be patented, any invention must be described sufficiently so as to be capable of being reproduced; Generally speaking, all of this contributes to a justification for the granting of patents, except where serious requirements of an ethical or social nature stand in the way. Thus manor interests relating to the common good can, in certain circumstances, lead to limiting or even suspending such intellectual property rights"[38]. This also raises a great many questions, especially the definition of what can be patented.

"*European Directive 98/44/EC of 6 July 1998 on the legal protecting of biotechnological inventions introduces the notion of 'biological material'. It defines it as 'any material containing genetic information and capable of reproducing itself or being reproduced in a biological system'*[39]*. 'Traditional' patents relate to inventions with an industrial application which are based on a knowledge of inert matter. New questions arise when patents related to biological materials as defined above. When this biological matter is capable of reproducing itself, one can speak of 'living matter' with more or less problematic status*"[40].

In the domain of SB, one can well wonder what would be a suitable basis for applying for a new patent. Could this be on the "*invention*" of the processes put in place to design, test and build a biological system? Could it be based on the inert biological components? Or on the basis of the "*living matter*"? In the latter two cases, it would not just be a matter of intellectual property but rather "*the appropriation of elements of biological organisms by specific industrial actors*"[41] or even the claim of a copyright on the living matter itself? That would be met by stiff opposition.

Moreover, how broad should be the scope recognised for such a patent? The European Patent Office tends to grant a very broad scope, resulting in a large number of functions of a biological organism coming within the scope of a patent, which can raise barriers to the development of scientific research and the transfer of know-how to third world countries.

38 COMECE Bioethics Reflection Group, "Patentability of human stem cells". In: *Science et éthique*, COMECE, 2008, p. 29, www.comece.eu/dl/ppmuJKJOMOkJqx4KJK/20080601PUBIOVOL1_EN.pdf.

39 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, Article 2.

40 COMECE Bioethics Reflection Group, cited Opinion, p. 29-30.

41 EGE, *Ethics of synthetic biology*, Opinion No. 25, 4.5.1.

3.4. Public information and dialogue between science and society

The scale of the potential applications of synthetic biology and the questions raised by its development call for a serene and responsible democratic debate, weighing up the benefits expected from this possible industrial revolution against the risks to be avoided. In Europe, this debate has scarcely got off the ground. Opinions have not yet crystallised into entrenched positions argued with passionate zeal. So it seems there is still time to attempt to deliver to the public the balanced information to which it is entitled and to try to get a dialogue going between the scientific community, political leaders and ordinary citizens.

On the subject of "*biological innovation*", Pope Francis recently wrote: "*Certainly, these issues require constant attention and a concern for their ethical implications. A broad, responsible scientific and social debate needs to take place, one capable of considering all the available information and of calling things by their name. It sometimes happens that complete information is not put on the table; a selection is made on the basis of particular interests, be they politico-economic or ideological. This makes it difficult to reach a balanced and prudent judgement on different questions, one which takes into account all the pertinent variables. Discussions are needed in which all those directly or indirectly affected (farmers, consumers, civil authorities, scientists, seed producers, people living near fumigated fields, and others) can make known their problems and concerns, and have access to adequate and reliable information in order to make decisions for the common good, present and future*"[42].

Here is a clear statement of what is needed to establish a climate of confidence, so essential for a healthy approach to the issues raised.

3.5. Application to human beings

Insofar as it evolves, synthetic biology will obviously have profound repercussions on human beings and their life styles. However, we can expect that questions will emerge very soon about the direct application on the human body of inventions regarding the most diverse biological systems. As was mentioned earlier in this paper, we already have the rollout of a sensitive diagnostic system capable of monitoring every year hundreds of thousands of patients suffering from viral diseases.

The topic is not new. For a quater of a century already, research studies have been

42 Pope Francis, Encyclical 'Laudato Si', 24 May 2015, §135, http://w2.vatican.va/content/francesco/en/encyclicals/documents/papa-francesco_20150524_enciclica-laudato-si.html.

officially carried out with the aim of altering the human genome. That activity has enabled children to be cured who would otherwise not have been able to survive except under extremely difficult conditions[43]. Until a very recent date, doctors used to observe a clear rule. While it may have seemed feasible, having taken all necessary precautions, to attempt to modify the genome of cells taken from the bodies of people suffering from serious genetic illnesses, it was absolutely out of the question to effect on a human being any genetic modifications that could be transmitted to future generations[44]. In medical terms, that translates as: "yes, with reservations, to somatic gene therapy, but no to germinal gene therapy". Any attempts to perform "germinal therapy" would in fact have required the prior development of extensive research using human embryos, and their unforeseen consequences might then have been passed on from generation to generation.

This rule serves as both a benchmark and a warning. It can also be used as a guideline in the ethical and legal debate. It can only be hoped that while synthetic biology is being developed, some governance will be introduced that will take care to observe full respect for the human being and his dignity. This would require resisting any dreams of "enhanced humanity"[45], yet might still lead, whenever apparently reasonable, to utilising inventions emanating from synthetic biology in order to find cures for illnesses and disabilities.

43 Cf . M. Cavazzana-Calvo et al., "Gene Therapy of Human Severe Combined Immunodeficiency (SCID)-X1 Disease", *Science*, 28 April 2000,Vol. 288, No. 5466, p. 669-672.

44 Cf. Article 13 of the Convention for the protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention for Human Rights and Biomedicine, 1997, https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168007cf98.

45 Cf. COMECE Bioethics Reflection Group, "Human Enhancement by technological means". In: Science & Ethics, Vol. 2, COMECE, 2012, p. 49-58, http://www.comece.eu/dl/NMntJKJOlknJqx4KJK/20120301PUBIOVOL2_EN.pdf.

CONCLUSION

Synthetic biology is a domain of research, and even of practical applications, in rapid expansion. There is no doubt that it is destined to be developed on a large scale; quite probably it will become a powerful tool for understanding and processing living organisms. This new knowledge and power give rise not just to great expectations (some of which are over-hyped) but also to the very real fear that they might be abused to the detriment of humankind and our environment.

Let us hope that humanity will attain wisdom while using these kinds of technology. It is crucial to carry out in-depth studies on them and to take care that they should be utilised in a way that does not endanger both human health and the environment. Their wrongful use should be prevented and care should be taken to maintain a fair collaboration between industrialised and developing countries. Scientists are therefore invited to develop an ethical debate which could conclude with the recognition of the need for some form of self-limitation, as already happened in the history of bioresearch[46]. That does not detract in any way from the need to set up some form of governance able to define adequate rules and to exercise some reasonable and efficient control. Likewise the need to inform the public which is fully entitled to participate in the debates and in the decision-making. We can only hope that real dialogue will be established between scientists, public authorities and society.

Contriving to manufacture new biological components and systems is not "*playing God*" as long as we are careful to respect a Creation that has been "*entrusted to the intelligence and moral responsibility of men and women*"[47] and as long as we always allow ourselves to be guided by the search for the common good of humanity.

46 Cf. *Biologie de synthèse* (cited in note 4), 9, Repères chronologiques, 1975, Conférence d'Asilomar.

47 *Compendium of the Social Doctrine of the Church*, §473.

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