Synthetic

biology –

Ethical

Report of the Federal Ethics Committee on Non-Human Biotechnology

considerations



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1 Preliminary remarks

Synthetic biology is the name given to a relatively new field of research, combining elements of molecular biology (gene technology), chemistry, computer science and engineering. Underlying synthetic biology is the idea that organisms can be rebuilt or designed in a controlled manner for specific purposes.

Synthetic biologists work with systems which have functions of living beings. Therefore, in assessing synthetic biology from an ethical perspective, the question of how life is to be defined is of crucial importance. Although this question is also raised by applications of other technologies, it has never been considered to arise as urgently as it does in connection with certain objectives of synthetic biology.

In April 1998, the ECNH was established by the Federal Council as a standing expert advisory committee, charged with monitoring developments in and applications of nonhuman biotechnology and providing ethical assessments. The ECNH comments on ethical aspects of associated scientific and social questions and advises the Federal Council and federal authorities with regard to the adoption of regulations.¹ The ECNH comprises no more than 12 members, who are external experts drawn from various disciplines. The majority of Committee members are ethicists from the fields of philosophy or theology, and the disciplines of biology, molecular biology, genetics, medicine and law are also represented. The members and the chair are appointed ad personam by the Federal Council.² The composition should ensure that various ethical approaches are considered in the Committee's deliberations. The ECNH is supported by a scientific secretariat and, if necessary, can also call in external experts and commission expert reports.

In preparation for this report, the ECNH invited a number of experts to take part in presentations and discussions, and commissioned various studies. To gain an overview of how the concept of life has been used to date in philosophical discourse, the ECNH requested Dr Andreas Brenner of the Philosophy Department at Basel

- In 2003, the ECNH and its mandate were placed on a new legal footing by Art. 23 of the new Federal Act on Non-Human Gene Technology (Gene Technology Act, GTG, SR 814.91).
- 2 Details of the Committee's mandate and current membership, as well as all the opinions and other publications, can be found on the ECNH website: www.ekah.admin.ch.



University to prepare a philosophical study, which was published in 2007³ as part of the ECNH series of contributions to ethics and biotechnology⁴. In 2007, at the request of the ECNH, Dr Anne Eckhardt (risicare GmbH, Zurich) prepared an overview of how the field of synthetic biology is organised and what goals the various actors are pursuing.⁵ In September 2007, Professor Sven Panke of the Institute of Process Engineering at the ETH Zurich provided an introduction to synthetic biology for the ECNH. At the end of 2007, the ECNH commissioned another two studies. Firstly, Professor Giovanni Maio of the Institute of Medical Ethics and History of Medicine at Freiburg University was asked to produce an "ethical map" of synthetic biology. This report, co-authored by Dr Joachim Boldt and Dr Oliver Müller, was published in 2009⁶ as part of the ECNH series. Secondly, ECNH member Dr Bernard Bærtschi of the Institute for **Biomedical Ethics at Geneva Universi**ty was asked to prepare a report on the moral status of synthetic organisms. This report also appeared in 2009⁷ as part of the ECNH series. In the meantime, members of the ECNH discussed

various concepts of life with Professor Beda Stadler of the Bern University Institute of Immunology. The role of epigenetics and causes of epigenetic phenomena were explained to ECNH members by emeritus Professor Frederick Meins of the Friedrich Miescher Institute (FMI) for Biomedical Research in Basel. Professor Joachim Frey of the Bern University Institute of Veterinary Bacteriology – a member of the Federal Expert Commission for Biosafety (FECB) - was interviewed on the use of microorganisms, in particular Mycoplasma spp., as models in synthetic biology. Dr Kurt Hanselmann of swiss i-research & training, a member of the Microbial Ecology Group at Zurich University, gave a presentation on the role of microorganisms, their behaviour and their functions in the ecosystem.

- 3 Andreas Brenner, Leben Eine philosophische Untersuchung, Beiträge zur Ethik und Biotechnologie, Vol. 3, ECNH, Bern, 2007.
- 4 In the "Beiträge zur Ethik und Biotechnologie" series, the ECNH publishes expert reports commissioned by the Committee. These reports provide a basis for the consideration of ethical aspects of biotechnology and serve as working papers for the Committee. The books can be ordered from the publications distribution office of the Federal Office for Buildings and Logistics (FOBL, www. bundespublikationen.ch) or from booksellers. The texts can also be downloaded free of charge from the ECNH website (www.ekah.admin.ch).
- 5 Anne Eckhardt, Synthetische Biologie. Organisation und Ziele, report commissioned by the ECNH, 2008, (http://www.ekah.admin.ch/de/ dokumentation/externe-gutachten/index.html; in German).
- 6 Joachim Boldt, Oliver Müller, Giovanni Maio, Synthetische Biologie – Eine ethisch-philosophische Analyse, Beiträge zur Ethik und Biotechnologie, Vol. 5, ECNH, Bern, 2009.
- 7 Bernard Baertschi, La vie artificielle Le statut moral des êtres vivants artificiels, Beiträge zur Ethik und Biotechnologie, Vol. 6, ECNH, Bern, 2009.



2 The concept of synthetic biology as used by the scientific community

In order to be able to assess synthetic biology, its goals and impacts from an ethical perspective, it is first necessary to clarify the nature of synthetic biology as a subject of scientific research. What is initially striking is the variety of ways in which the term "synthetic biology" is used, not only in everyday but also in scientific language. According to some definitions, the ultimate goal of synthetic biology is restricted to "understanding the minimum requirements for life processes"8; however, other definitions refer to synthetic biology as a means of creating living systems not previously found in nature. For example, cells and their metabolic processes are to be designed and assembled in such a way as to serve new functions. Some researchers also speak of their vision of producing new (or modifying existing) life forms using standardised DNA components, or even of creating life purely from chemical components and DNA blueprints. Steven A. Benner, for instance, writing in Nature in 2003, described this aspiration of synthetic biology as follows:

"To a synthetic biologist, life is a special kind of chemistry, one that combines a frequently encountered property of organic molecules (the ability to undergo spontaneous transformation) with an uncommon property (the ability to direct the synthesis of self-copies), in a way that allows transformed molecular structures themselves to be copied. Any chemical system that combines these properties will be able to undergo Darwinian selection, evolving in structure to replicate more efficiently. In a word, 'life' will have been created."⁹

Even though Steven A. Benner talks about life being created, it is not surprising that he puts the word "life" in inverted commas. One of the key questions for an ethical assessment is, precisely, how the products of synthetic biology are to be characterised. Is life actually created? This depends on a clarification of what life is. As Andreas Brenner points out, scientists often omit to answer this question, although this is not true of the pioneers of synthetic biology. In 2001, also writing in *Nature*, Jack W. Szostak, David P. Bartel and Pier Luigi Luisi ventured

- 8 Cf. www.ethz.ch/news/ethupdate/2007/070619_1/ index.
- 9 Steven A. Benner, Synthetic biology: Act natural. In: *Nature*, Vol. 421, 9 January 2003, p. 118 (cited in A. Brenner, *op. cit.*, p. 158).



a definition, while at the same time acknowledging the major difficulties involved in such an attempt.¹⁰

"We can consider life as a property that emerges from the union of two fundamentally different kinds of replicating systems: the informational genome and the three-dimensional structure in which it resides." ¹¹

A striking feature of definitions of synthetic biology as used by the scientific community itself is that they now mainly avoid the term "life", speaking instead of "biological systems". The emphasis is placed on the technical nature of the discipline. In the European Union's TESSY¹² project, synthetic biology is defined as follows:

"Synthetic biology aims to 1. engineer and study biological systems that do not exist as such in nature, and 2. use this approach for i) achieving better understanding of life processes, ii) generating and assembling functional modular components, iii) developing novel applications or processes."¹³ This definition of synthetic biology is couched in such general terms that it also covers transgenic organisms. To this extent, it does not indicate what differentiates synthetic biology from genetic engineering. The website of the Synthetic Biology 4.0 Conference (held in Hong Kong in October 2008) gives this description of the subject:

"Synthetic Biology is a new approach to engineering biology, with an emphasis on technologies to write DNA. Recent advances make the de novo chemical synthesis of long DNA polymers routine and precise. Foundational work, including the standardization of DNAencoded parts and devices, enables them to be combined to create programs to control cells."¹⁴ 10 Andreas Brenner, op. cit., p. 156.

- 11 Jack W. Szostak, David P. Bartel and Pier Luigi Luisi, Synthesizing life. In: *Nature*, Vol. 409, 18 January 2001, p. 387 (cited in A. Brenner, op. cit., p. 156).
- 12 TESSY: Towards a European Strategy for Synthetic Biology.
- 13 Cf. http://www.tessy-europe.eu/public_docs/ TESSY- Final-Report_D5-3.pdf.
- 14 Cf. Synthetic Biology 4.0 Conference, 10–12 October 2008, Hong Kong University of Science & Technology, http://sb4.biobricks.org/field. (Preparations for the Synthetic Biology 5.0 Conference are now under way: http://syntheticbiology.org/ Conferences.html).



The new features of synthetic biology, as compared with genetic engineering, are defined on the website as follows:

"Synthetic Biology builds on tools that have been developed over the last 30 years. Genetic engineering has focused on the use of molecular biology to build DNA (for example, cloning and PCR) and automated sequencing to read DNA. Synthetic Biology adds the automated synthesis of DNA, the setting of standards and the use of abstraction to simplify the design process."¹⁵

Standardising and automating the production of biological systems thus forms the core of synthetic biology and is a prerequisite for the achievement of its goals, which are defined as:

- "- the design and fabrication of biological components and systems that do not already exist in the natural world,
- the re-design and fabrication of existing biological systems."¹⁶

15 Ibid.

16 Cf. http://syntheticbiology.org/FAQ.html. (This website can be edited by all members of the synthetic biology community.)



3 Synthetic biology: a field involving a variety of goals and methods

Synthetic biology thus focuses on the design and fabrication of biological components and systems that do not already exist in the natural world, and on the re-design and fabrication of existing biological systems. In pursuing these goals, various methods are used. It has become common practice to distinguish essentially three different approaches that come under the heading of synthetic biology.

The first ("top-down") approach is sometimes known as the chassis model. Here, the genome of an existing organism is pared down so that, under laboratory conditions, it is left with only those components which are absolutely essential to sustain the system's life and preserve basic metabolism. Synthetic modules are then to be incorporated into this minimal organism so that it can perform the desired new functions, e.g. producing a specific substance. At present, the application of this model is restricted to bacteria and viruses. Since this approach makes use of existing organisms, which are endowed with new properties, this form of synthetic biology can also be called "extreme genetic engineering".

In the second ("bottom-up") approach, sometimes known as the **Lego model**, defined functional DNA sequences (BioBricks) are assembled so as to create new kinds of organisms. Chemical systems are constructed step by step to exhibit certain biological properties. This model involves a method which does not build on existing organisms and thus goes beyond genetic engineering. It is as also sometimes called "absolute synthetic biology".

As is apparent from the definition of goals given above, a third approach also comes under the heading of synthetic biology – namely, the **synthesis of DNA sequences** (e.g. combining newly designed or existing sequences).



4 Applications of synthetic biology

A number of potential applications of synthetic biology discussed to date¹⁷ are listed below.

- Bioenergy: Cells are to be engineered to transform renewable products into fuels.
- Materials production: Recombinant cells are to be designed to build chemical precursors for the production of plastics or textiles, e.g. spider silk or alternatives to petrochemical products.
- Pharmaceutical production: Pharmaceuticals are to be produced at low cost using synthetic bacteria and yeast – e.g. the antimalarial drug artemisinin and the cholesterol-lowering agent atorvastatin (Lipitor[®]).
- Medicine: Cells are to be programmed for therapeutic purposes. Bacteria and T-cells could be modified to circulate in the body and identify and treat diseased cells and tissues.
- Military uses: Synthetic biology could be exploited for developing or combating new biological weapons.

- Environmental technology: CO₂absorbing bacteria could be used to reduce atmospheric CO₂ levels.
- General-purpose technology: Synthetic biology could facilitate computer simulation and analysis of complex biological networks. In this way, it is hoped, active substances capable of influencing these biological systems could be developed and designed in silico.

The only commercially mature applications that have been realised to date are the production of the antimalarial drug artemisinin and the cholesterollowering agent atorvastatin. This process is an application of the chassis model, i.e. a form of genetic engineering. At present, all the other potential applications can be regarded as visions for the future. For an ethical assessment, however, it is relevant to consider not only what is already being done but also what is planned or hoped for - namely, the ability to produce new organisms in a controlled manner, with controllable functions.

17 Cf. http://sb4.biobricks.org/field or – for an overview of current European synthetic biology projects – www.synbiosafe.eu/index.php? page=other-sb-projects.



5 The aspirations of synthetic biology

Synthetic biology aspires to produce new organisms via a controlled process, with controllable functions. How are these aspirations to be judged from an ethical viewpoint? To answer this question, the individual aspects of the enterprise need to be discussed separately: What is meant by "new living beings"? What does "production" mean? How is "controllability" to be understood?

5.1 New living beings

When the Lego model refers to the production of *new living beings*, how is this to be understood? Like the other synthetic biology approaches, the Lego model makes use of existing molecules. There always remains a connection with what already exists. Accordingly, "new" cannot be taken to mean that the products of the Lego model are created *ex nihilo.*¹⁸

Does "new" rather mean "novel"? What distinguishes synthetic biology from genetic engineering is not the fact that it produces novel living beings, but – in the case of the Lego model – how it does so. Rather than modifying existing living beings, it aims to assemble them from components that are not themselves alive. If one were to argue that living beings of this kind did not previously exist, it would be easy to counter that synthetic biology – with both the chassis and the Lego model – is merely repeating what breeders have been doing for tens of thousands of years, and genetic engineering for the past 50 years – in this case also crossing the species barrier. Dogs such as the dachshund, for example, did not exist until they were bred by humans.

Is "new" supposed to mean that these living beings – as envisioned by certain synthetic biologists – are partly or exclusively created from inorganic matter? This would involve the use of chemical elements or compounds previously assigned to inorganic chemistry. The term "inorganic" denotes chemical substances and reactions that are not of biological origin. Compounds are called "organic" if they contain carbon. As long as Lego model projects continued to be based on existing carbon compounds, they would produce nothing new in this sense. 18 The criticism that the Lego model presumes to "play God" by seeking to create new organisms presupposes the markedly Western/Christian notion of God creating matter out of the void. This conception of creation is not found in other religions, and matter was also considered to be eternal in most ancient Graeco-Roman philosophy.



Novelty would only arise if synthetic organisms were produced, for example, on the basis of silicon instead of carbon compounds.

Finally, "new" can also be taken to mean that here, for the first time, living beings are to be "engineered" in the same way as machines – designed on the drawing board and then assembled.

5.2 Production

The aim of the Lego model is to synthesise (i.e. put together) organisms from molecular components, thereby producing life forms. What does it mean to speak of *producing* or creating living beings?

For some people, this merely means using the techniques of synthetic biology to *establish the conditions required for life*. It has been objected that this use of terminology is not compatible with everyday language: in this context, it is argued, creation can only be taken to mean *creating life as a product*. However, as critics then point out, this conception of production implies that the production of living beings is a purely mechanical, physical process. But this, they argue, fails to capture the essence of life. Furthermore, if synthetic biology situates itself within the engineering tradition which combines technology and art, then this concept of production also involves the element of imaginative, artistic design. If this is associated with the idea of creation, the criticism of synthetic biology is directed not only against the language it uses but also against what it appears to aspire to - the ability to modify and control biological nature in the technological tradition.

5.3 Controllability

Synthetic biology aspires to be able, via a controlled process, and with specific purposes in mind – i.e. in a predictable and controllable manner – to rebuild living beings (chassis model) or to design new ones (Lego model). This may also involve the idea of continuing to be able to control the resultant products. Whether this is possible is of particular relevance with regard to the ethics of risk (cf. Section 7). Initially,



we are only concerned with the idea of being able to produce living beings via a controlled process. How is this aspiration to be judged?

Critics of synthetic biology object that the idea of life being reducible to its constituent parts is based on a mechanistic view. This type of view, they argue, leads to a narrow conception of life. The aspiration to be able essentially to fully control the existence and functions of living beings then not only applies to microorganisms, but is extended to all living beings. According to critics, this reductionist conception of life also means that the primary goal of synthetic biology is not to gain a better understanding of living beings but to be able to exert more control over and thus instrumentalise them.

In response to this criticism, the following counterarguments may be adduced. Firstly, the generation of knowledge is one of the tasks of scientists. The causal connections underlying life are in principle accessible to natural science. Secondly, it could be that functional knowledge is sufficient for the experimental practice of synthetic biology. It would then not even be necessary to know what life is in order to do synthetic biology, nor would this be required for an ethical assessment of its impacts. In response to the objection that synthetic biology aims to instrumentalise living beings, it may be conceded that an improved knowledge of living beings and the technical applicability of knowledge are interlinked. However, this connection does

not require us to refrain from applying such knowledge, but always to exercise responsibly the power associated with technological capability.

5.4 Different ontological conceptions of life

How one answers the question to what extent it is possible or impossible in principle to produce living beings in a controlled manner will depend on what conception of life one's assessment is based on.¹⁹

Divergent ontological conceptions of life are also to be found within the ECNH. These are manifested in different ways of speaking. On the one hand, a "technical" language is used, describing life as a set of functions (organisation, reproduction, metabolism, response to environmental stimuli). Here, what constitutes life can be explained in terms of causal logic. On the other hand, a systems-oriented language is used, favouring a hermeneutical approach. On this view, a description of functions alone provides an inadequate account of life - additional knowledge is required in dealing with living organisms.

These different approaches and the associated senses of life cannot be reconciled. Nor, however, can they simply be left to coexist, for each approach makes the same claim to be able to answer the question of what life is. The ontological view that life can be definitively explained in terms of causal logic sees no plausible reason why anything more than functional 19 Even if, for example, the TESSY definition refers not to *life* but to *biological systems*, it is not irrelevant to discuss the question of what life is. "Biological systems" is an abstract term sometimes used as a synonym for the abstract term "life".



knowledge should be required to adequately assess our dealings with living organisms. This is rejected by proponents of the other viewpoint. They deny that it is possible to grasp what life is solely on the basis of functional knowledge. On this view, knowledge that is only accessible by hermeneutical means is essential for an adequate understanding of the ethically acceptable handling of living organisms.

The ECNH distinguished the following fundamental ontological positions:

- Monism: This is defined as the reduction of the world's processes and phenomena to a single principle (here: ontological naturalism/materialism). What we call life relates to *purely physical/chemical* properties of living beings; life is (or may be) an emergent property of material entities.
- Vitalism: On this view, the foundation of all living beings is a life force (vis vitalis) in the sense of an independent principle, which at the same time accounts for the difference between the animate and the inanimate. According to this doctrine, organisms are not solely explicable in terms of physical/chemical properties. Life comprises at least one property that is essentially unknown.
- Dualism: This is usually defined as the joint or competing existence of two – generally contrasting – principles, substances, forces and/or purposes which are not reducible to one another. Dualism is now also understood – in the sense of "polar

dualism" – as the interrelationship of two such elements.²⁰ On a dualistic view, life can never be reduced to purely material properties, as it always encompasses at least one non-material component.

Scepticism: The sceptic questions

 at a fundamental level – the possibility of giving a true account of the nature of life; nothing whatsoever is to be said on this subject.

A weaker version of scepticism holds that the nature of life cannot be determined at present.

Proponents of a monistic ontology take living beings to be of a purely material nature. For those who hold this position, there is in principle no reason why the Lego model should not succeed in producing life.

Those who subscribe to a vitalistic or dualistic ontology assume that life comprises at least one essentially unknown, non-material property. Proponents of these positions will perhaps doubt whether it is possible to "assemble" living beings from non-living components. On this view, the nature and origins of life are not amenable to the methods of natural science. Accordingly, the aspiration to be able to produce life in a calculated, controlled manner is to be rejected.

Adherents of a sceptical view, holding that one comes up against (possibly temporary) epistemological limits in dealing with living beings, assume that we cannot know what life is. Therefore, no answer can be given to the ontological question concerning 20 Cf. Franz von Kutschera, Jenseits des Materialismus, mentis, Paderborn, 2003.



the nature of life. Sceptics must therefore reserve judgement with regard to the products of synthetic biology.

It should be noted that neither the sceptical view nor the vitalistic or dualistic positions exclude the possibility that the products of the Lego model may be living beings. Whether they are living beings can be ascertained on the basis of certain manifestations of life, such as metabolism, reproduction or spontaneous movement. But even someone who rejects in principle the possibility of the Lego model being successful (on the grounds that the production of living beings is fundamentally beyond our powers) has not thereby provided a justification for prohibiting any efforts in this direction. Other reasons would need to be given for prohibiting the pursuit of this goal, which, though ontologically impossible on this view, could in fact prove to be attainable.

Ultimately, all the ontological positions considered leave open the possibility that the Lego model approach may be successful, with living beings arising as products. The differences between these positions are reflected in different ways of speaking about the controllability or non-controllability of the process and products of synthetic biology. These different viewpoints and ways of speaking affect the discussion of questions concerning the ethics of responsibility.

Within the ECNH, half of the members hold a monistic position, thus representing a **majority**. The **largest minority** takes a vitalistic viewpoint, while a **smaller minority** adopts a sceptical position. A dualistic conception of life is favoured by the **smallest minority**.



6 Moral status of living beings used in or created as products of synthetic biology

The members of the ECNH are in agreement that, if the Lego model is successful, living beings arise as its products. How these living beings arise - via a natural process or in some other way - has no influence on their moral status.²¹ The current focus is on microorganisms, which both models of synthetic biology use or seek to create as products. In the longer term, at least according to certain visions of synthetic biology, attention will be focused on living beings of all kinds. However, the question of the moral status of living beings arises in a particularly problematic form with regard to microorganisms.

6.1 Moral consideration based on inherent value

It may be asked whether a discussion of inherent value is necessary in connection with microorganisms, or whether the ethical discussion could not be restricted to issues concerning the ethics of responsibility. However, the context of constitutional law within which the present discussion is being conducted calls for examination of the question of inherent value. Under Art. 120 of the Swiss Federal Constitution, the "dignity of living beings" is to be taken into account in the handling of animals, plants and other organisms.²²

Do microorganisms have an inherent value, i.e. do they have something that is also called "dignity"? Beings with an inherent value are morally significant in their own right. If one concludes that they do have an inherent value, one then needs to consider what *direct* obligations we have towards these beings.

- 21 On this point, the members concur with Bernard Baertschi, who concludes in his publication "La vie artificielle – Le statut moral des êtres vivants artificiels" (2009) that the origins of living beings do not affect their moral status.
- 22 Federal Constitution, SR 101, Art. 120 Non-Human Gene Technology, www.admin.ch/ch/d/sr/ 101/a120.html.



Whether microorganisms deserve moral consideration based on an inherent value depends on the ethical position adopted. With particular reference to the question of inherent value, the members of the ECNH discussed the most common environmental ethical approaches which are generally dealt with in the literature.

Theocentric position: Theocentrism is a fundamental conception of human knowledge, ethics and nature, in which God (Greek theos) is considered to be the principle, measure and goal of all existence, knowledge and action. On the theocentric view, the value of everything that exists is a result of its being created by God. Like all other living beings, microorganisms have, not an inherent value, but a value bestowed by God. They are to be respected as God's creatures. However, critics describe a value of this kind not as inherent, but as relational. Within a religious ethical system, it may be claimed that God can also create beings with inherent value; however, from the critics' perspective, this yields, not a theocentric position, but anthropo-, patho-, bioor ecocentric positions.

Anthropocentric positions:²³ Anthropocentrism holds that humans alone have a value in their own right. Other living beings only have a relational or instrumental value, not an inherent value. The special status ascribed to humans by anthropocentrism is derived either from their being created in God's image (cf. the theocentric position) or from their (potential) rationality and capacity for abstraction and language. The latter position is more accurately described as ratiocentrism. All living beings that have the same capacities and characteristics as humans belong to the circle of beings with an inherent value. Neither of these positions is relevant to the question of hether microorganisms have an inherent value.

The anthroporelational position is sometimes described as a moderate form of anthropocentrism. On this view, a special role is ascribed to humans because they are the only beings that can assume responsibility for others. Non-human living beings merit moral consideration on account of their relation to humans. A theological version of this position places the entire structure within a theocentric context. Critics argue that here, once again, the value in question is not inherent, but relational: as soon as an inherent value is ascribed in any way to living beings other than humans, the position is to be classified as patho-, bio- or ecocentric.

23 Epistemic anthropocentrism is not considered here. This position emphasises the fact that ethics is a human activity and ethical values are only apprehended by humans. Epistemic anthropocentrism does not determine what value is to be attached to other living beings.



Pathocentric position: Like all other beings, microorganisms have an inherent value if they can in some way perceive damage as harmful for themselves. This position must at least be able to provide evidence that microorganisms can perceive harm as harm.

Biocentric position: Microorganisms are living beings, and all and only living beings have an inherent value. This position must show how living beings differ from the inanimate. While biocentrism may describe viruses as something intermediate between animate and inanimate, it also needs to define the criteria for classifying viruses in this way.

Ecocentric position: This position ascribes an inherent value to living beings, but in particular also to ecosystems and groups of living beings. Here, microorganisms may have an inherent value both as specific individuals and as parts of ecosystems.

Holistic position: On the holistic view, only nature as a whole has an inherent value. Individuals, groups or ecosystems do not have an inherent value. Microorganisms have only an instrumental value, which is only ascribed if – as individuals or groups – they serve a function within the whole.

6.2 Moral consideration of interests irrespective of inherent value

Some ethical systems do without the concepts of "inherent value" and "dignity". Therefore, it is also necessary to discuss the possibility of moral claims being ascribed independently of inherent value or dignity as ontological requirements. If moral claims are to be ascribed, two conditions need to be met: firstly, interests must be present, and secondly it must be possible for these interests to be represented at least in an advocatory manner. However, interests are bound up with the concept of self: they can only meaningfully be ascribed in the presence of some form of self.

6.3 Weighting in an evaluation of interests

With regard to the handling of microorganisms in specific cases, it remains open what precisely follows from those positions which ascribe an inherent value or interests to microorganisms. The consequences will also depend on the weight attached to this value or these interests in an evaluation of interests.

If it is assumed that microorganisms merit consideration on the basis of an inherent value or interests, the question arises how such value or interests are to be weighted in the handling of these beings. This will determine whether and if so what direct obligations arise towards microorganisms. On the question of how the inherent



value or interests of microorganisms are to be weighted, two positions can be distinguished.

The *egalitarian position* maintains that all living beings deserve moral respect and are of equal status. Here, the possibility is conceded that the interests of microorganisms are to be given equal consideration to those of other living beings.

According to the hierarchical position, although all living beings deserve moral respect, they are not all of equal status. Species membership may be taken to be the decisive factor, in which case greater weight is attached to the interests of humans than to those of animals, to the interests of animals than to those of plants, and to the interests of plants than to those of microorganisms. Alternatively, certain capacities and characteristics may be taken to be decisive, but here, too, the moral weighting increases with the degree of similarity to human capacities and characteristics.

The majority of Committee members adopt a hierarchical biocentric position. According to this majority, microorganisms have an inherent value because they are living beings. However, in line with the hierarchical position, the weight attached to this value in an evaluation of interests is negligible. A first minority takes a pathocentric approach. In the view of this minority, there is no evidence that microorganisms can in any way perceive harm as harm, and they have no inherent value or interests of their own. A second, smaller minority subscribes to a hierarchical anthroporelational position: microorganisms deserve moral respect on account of their relation to humans. However, in the view of this minority, the weight attached to microorganisms in an ethical evaluation of interests is likewise negligible.



7 Considerations concerning the ethics of responsibility

As well as direct obligations, it is necessary to examine the *indirect obligations* arising from the production of synthetic organisms. As the producers of synthetic organisms, what responsibility do humans bear for the associated consequences?

7.1 Influencing society's attitude to the treatment of living beings?

Even though the inherent value of microorganisms is either non-existent or so slight as to be of no practical significance in the evaluation of interests, and even though we have little empathy for these beings, they are nonetheless living beings. Is there not a danger – some people fear – that the way in which we think and speak about microorganisms and the way we handle them might prepare the ground for behaviour which has or could have adverse consequences for other living beings, ourselves included? One criticism, endorsed by a minority of Committee members, is that synthetic biology conflicts with fundamental conceptions shaping society's attitudes to technology, culture and nature.24 According to this criticism, synthetic biology helps to promote a mechanistic - and hence reductionist conception of life. This conception, it is claimed, influences and determines not just research, but all areas of life. It is even argued that the influence of this conception will spread irrespective of whether the visions of synthetic biology can ever be realised, as other more holistic - conceptions of life are driven out by this prevailing view.

The way of thinking which underlies synthetic biology, critics argue, is shaped by the engineering sciences. It is the expression of a fundamental attitude which regards living beings as producible, controllable and at our disposal. The dominance of this attitude is attributable to its close association with technological and economic exploitation interests. However, critics believe, this fundamental attitude changes the way we perceive other living beings and our values and 24 On this point, cf. the discussion in J. Boldt et al., op. cit., pp. 55 ff.



relationships vis-à-vis such beings and life in general. Ultimately, it could change humans' conception of themselves and threaten the protection of human dignity.

In response to this criticism, the following counterarguments - endorsed by the majority of Committee members - are adduced. A variety of fundamental conceptions shaping cultural attitudes coexist. Criticism of the mechanistic/reductionist way of thinking relates only to those traditions of thought in which the distinction between living beings and machines is central. To be effective, this line of criticism would need to show why the approach of distinguishing between living beings and machines is correct, while others - which fail to make this distinction - are incorrect. It is also pointed out that "mechanistic" is often used as a pejorative term. This depreciation overlooks the fact that mechanistic constructions may also be highly complex, and inherent value or interests are not ruled out.

To counter the criticism of the instrumentalisation of living beings, it is argued that instrumentalisation is not automatically to be rejected on moral grounds. Even human dignity does not exclude instrumentalisation of human beings, e.g. as workers or family members. It merely provides protection against undue (exclusive or excessive) instrumentalisation. To lend weight to the slippery slope argument, one would need to show that the way in which synthetic biology handles microorganisms actually exerts an adverse influence on our treatment of other living beings, including humans. It would need to be demonstrated whether and to what extent the way of thinking underlying synthetic biology changes our perceptions of other living beings and of humans. And if changes did occur in our perceptions, and in our relations and dealings with other living beings, it would need to be shown why these would be morally undesirable. It would also need to be shown that these changes threatened not only our perception of ourselves but also, as a result, the protection of human dignity.

The members of the ECNH accept that slippery slope arguments are useful for highlighting possible consequences from an ethical perspective at an early stage, so that these can subsequently be monitored. However, they take the view that the concerns raised by critics in this regard do not at present justify a veto on synthetic biology projects.

7.2 Considerations relating to justice

Not only synthetic biology but all technologies and their applications also need to be examined and assessed in relation to justice. There are several dimensions to justice. As already discussed by the ECNH in its report on "Gene Technology and Developing Countries"²⁵, key elements of a just political order include the assurance of fundamental rights, the just distribution of a society's material and non-material goods, and the

25 ECNH, Gene Technology and Developing Countries, Bern, 2004.



existence of procedures guaranteeing individual participation in political decision-making processes. Like all other technologies, synthetic biology is to be assessed by its effects on these dimensions of justice.²⁶ Particular attention should be paid to the effects of this technology on developing and transition countries.

In many respects, the discussion of issues of justice in connection with synthetic biology mirrors the debate on genetic engineering. Rather than singling out specific projects and visions of synthetic biology for ethical assessment, the ECNH focuses here on the criteria that should always be considered in assessing synthetic biology and particular applications thereof in relation to justice.

Effects on food security, food sovereignty and biodiversity: Public debate on synthetic biology has been sparked in particular by efforts to produce energy with the aid of synthetic organisms. On the one hand, it is argued that this technology can make a vital contribution to energy production and also to efforts to combat global warming. On the other hand, concerns are expressed that the land resources required for this type of energy production could further threaten food security, food sovereignty and biodiversity, especially in developing and transition countries.27 The violation of key aspects of justice could not be offset by the application of possible solutions to problems which also affect developing and transition countries (e.g. use of synthetic organisms

for the remediation of contaminated land). Alternative solutions would then need to be sought.

Deepening of the "technological

divide": Critics fear that synthetic biology and its applications will further increase the technological gap between industrial and developing/transition countries. This objection applies to all technological developments. National sovereignty requires that, in response, particularly disadvantaged countries should be supported in building up their technological expertise and capacity, and that technology transfer should be promoted if these countries so wish. This will enable them to handle new technologies appropriately and to conduct context-specific risk research.

Intellectual property protection in synthetic biology: Here, as in the case of patents in the area of gene technology, the ethical acceptability and specific effects of intellectual property protection need to be examined. In this regard, the ECNH refers to its earlier comments included in the Dispatch on the Revision of the Patent Act of 23 November 2005²⁸.

Effects on economic and research policy: By providing start-up funding (supporting public sector research institutes or private companies) or creating a structural framework for the promotion of a particular technology or applications, the state creates faits accomplis and takes advance decisions. These interventions lead to market distortions. While this may be

- 26 The European Molecular Biology Organization (EMBO) Report, Vol. 10, No. S1, August 2009, pp. S1–S53, is concerned with the social questions raised by synthetic biology (www.nature. com/embor/journal/v10/n1s/index.html).
- 27 Public debate is currently focused on projects aiming to produce energy from sugar fermented by synthetic cells and converted into energy. The impacts on developing and transition countries are critically discussed in the ETC group report "Commodifying Nature's Last Straw? Extreme Genetic Engineering and the Post-Petroleum Sugar Economy" (2008).
- 28 Dispatch of 23 November 2005 on the Revision of the Patent Act and on the Federal Decree on the Approval of the Patent Law Treaty and Regulations, pp. 18–20, published in the Federal Gazette (BBI) 2006 1 (in German: www.admin. ch/ch/d/ff/2006/1.pdf; in French: www.admin.ch/ ch/f/ff/2006/1.pdf).



justified in specific cases, the effects of such decisions on other approaches need to be kept in mind in any assessment. State support for technologies with a risk potential should always be combined with appropriate risk research, also taking long-term risks into account.

7.3 Considerations relating to the ethics of risk

The Committee members take the view that the moral status of microorganisms currently used in synthetic biology does not pose an obstacle to their synthetic production. Nor at present, according to the majority view, do slippery slope arguments carry any weight. One dimension of synthetic biology remains to be considered – the ethics of risk.

In many respects, the discussion on the risks of synthetic biology is also reminiscent of early debates on genetic engineering. As with genetic engineering, one of the fundamental objections raised against synthetic biology is that it operates with materials which it is not able to control. In working with living organisms, it is tinkering with unknown quantities (either essentially unknown or too complex to be grasped), which therefore have a significant potential to endanger humans and the environment. In addition, the fact that proponents of synthetic biology have used the image of a young magician in a comic strip published by a scientific journal²⁹ means that the association with Goethe's sorcerer's apprentice (familiar from debates on genetic engineering) is not far off - the sorcerer's apprentice who used his master's spells without understanding their full implications. Here, however, unlike in Goethe's tale - so the critics of synthetic biology fear - no master will return in time to prevent the worst. Proponents, also using arguments familiar from the genetic engineering debate, reply that the composition of products of synthetic biology is relatively simple. Accordingly, the potential risks are claimed to be calculable and manageable. As laboratory creatures, they are said to be dependent on laboratory conditions and not capable of surviving in a natural environment. If synthetic organisms were to be

29 http://www.nature.com/nature/comics/ syntheticbiologycomic/index.html.



released, the associated risks would be low, as they would not be able to compete in a natural ecosystem.

In the view of Committee members, both sides are guilty of exaggeration. The mere hope that all will be well should not be the guiding principle for the handling of potentially dangerous substances and organisms, any more than fears should be allowed to prevent any action whatsoever. It is evident that, even though every technological development builds on what has gone before, what is being created is partly new. Moreover, reference to what is already known does not provide grounds for claiming that something partly new is calculable. Uncertainties remain, and one is therefore confronted with a typical risk situation.

Synthetic biology opens up a wide field of research and applications. Applications of synthetic biology have yet to be specified in much detail, and at the same time developments are proceeding at a rapid pace. The current state of synthetic biology is dominated by visions, uncertainties and a lack of knowledge. Specific data from risk analysis remains scant; for this reason, risk evaluation can only be conducted in approximate terms. Here, therefore, the ECNH largely confines itself to a discussion of the individual steps required in response to a situation of risk, with only peripheral consideration of isolated examples which have been mentioned in the public debate.

In risk management, appropriate risk description and analysis needs to be distinguished from risk evaluation. In addition, duties of care play a significant role both in risk analysis and in risk evaluation.30 The following (general) considerations on how to proceed in risk situations may appear familiar and self-evident to most people. However, experience - especially in the evaluation of projects involving genetically modified organisms in the environment - has shown that it is advisable to consider carefully, and repeatedly, the demands placed on us by risk situations.

30 On the management of risks, cf. the provisions concerning non-human gene technology in the Federal Act on Non-Human Gene Technology (Gene Technology Act, GTG) of 21 March 2003, SR 814.91.



7.3.1 Appropriate risk description and analysis

Risk analysis is a matter for the empirical sciences. It is used to quantify the likelihood of occurrence and the magnitude of the effects of actions. Risk analysis aims to produce probabilistic conclusions, not evaluations. For risk analysis to proceed correctly, appropriate risk description is required.

In synthetic biology, as in biotechnology, a distinction is drawn between biosafety risks and biosecurity risks.³¹ Biosafety risks are defined as risks for humans and the environment which arise unintentionally in the course of the essentially legitimate handling of synthetic organisms. Firstly, risks arise when such organisms are handled in a contained environment (in the laboratory). Here, the risks arising in the context of research and production of synthetic organisms need to be considered. Health risks for researchers and other workers are of central importance. However, it is also necessary to analyse the risks for humans and the environment which arise - in spite of compliance with all safety

regulations – as a result of the accidental release of an organism from the laboratory. At a later stage in the development of synthetic biology, it will be necessary to analyse risks of this kind associated with deliberate experimental – and ultimately commercial – releases of synthetic organisms. In all cases, these risks are to be analysed *ex ante* (i.e. beforehand) so as to permit conclusions concerning the likelihood of their occurrence.

Biosecurity risks are risks arising as a result of illegitimate handling of such organisms (i.e. misuse or inappropriate handling). Examples of risks arising from illegitimate handling include prohibited transport by individuals, e.g. if researchers change jobs and (illegally) take organisms with them to their new laboratory. Risks arising from laboratories that are not professionally run ("garage laboratories") are to be assessed under the heading of biosecurity. Misuse is also discussed under the heading of bioterrorism and sometimes also dual use. The latter term applies to cases where a technology can be used both for civilian and for military or terrorist purposes. Synthetic

31 Cf. also J. Boldt et al., op. cit., pp. 65 ff.



biology makes it possible to produce dangerous viruses or bacteria using relatively simple means. There are fears that this could increase the likelihood of misuse. In 2002, researchers at a US laboratory assembled the poliovirus from commercially produced, freely available DNA sequences. In 2005, another group in the US synthesised the extinct Spanish flu virus. The blueprints for these viruses were published and are thus accessible to all. These examples show that fears concerning misuse are justified, even though it remains easier at present to obtain highly pathogenic organisms (dangerous to humans and the environment) from natural sources. However, with advances in technology and an associated increase in the commercialisation of DNA sequencing, it will become increasingly easy to overcome the financial and technical obstacles to misuse.

Since data availability in risk situations is characterised by gaps and uncertainties, it is also necessary to consider *plausible hypotheses* that differ from the majority view. In addition, constraints on risk analysis arising from gaps in current knowledge need to be admitted. One general criticism frequently levelled at risk analysis and description in synthetic biology projects is that technocratic blinkers give rise to a restricted view of possible risks. It would need to be investigated whether and to what extent such a "reductionist" attitude and approach exists, and leads to an inadequate risk description.

With regard to risk description and analysis, reference should also be made here to the responsibilities of the advisory Federal Expert Commission for Biosafety (FECB) and the competent authorities.

7.3.2 Risk evaluation

Normative risk evaluation is to be distinguished from descriptive risk analysis. Risk evaluation is conducted in accordance with the latest data available, in the knowledge that this is constantly changing. It involves weighting not only the expected effects, but also the remaining gaps in knowledge. It evaluates the probabilities and damage scenarios determined and then



decides what (if any) action is required. In a democratic society, the need for action is determined by collective decisions concerning the probabilities and levels of damage deemed to be acceptable.

In weighting the conclusions of the risk analysis and in assessing the acceptability of risks, it is also important to consider whether there are any alternatives to the chosen course of action. The existence of alternatives is relevant to the weighting because people are more inclined to accept higher risks in order to solve an urgent problem (e.g. satisfaction of basic needs) if no other less risky options are available. Alternatives are to be considered on three different levels:

- Alternatives to the object to which the technology is applied: e.g. hydrogen-producing bacteria as an alternative to synthetically produced algae for biofuel production;
- Alternatives to the method: other technologies for producing energy from renewable resources (solar, wind power, etc.);

 Alternatives to the goal: e.g. technologies for increasing energy efficiency.

7.3.3 Duties of care

Duties of care serve two functions. Firstly, they require the actor, in the light of the current state of knowledge, to be aware of the possible consequences of his actions and the associated damage potential. His responsibility encompasses whatever should have been foreseen given the current state of knowledge. He must anticipate possible consequences and the associated damage potential. He cannot, however, be held liable for what was unforeseeable.

Secondly, duties of care require the actor to take all necessary precautions to prevent the occurrence of the expected damage. How far he has to go to meet this requirement will depend on two factors: the likelihood of occurrence and the magnitude of the damage. The greater the likelihood and the higher the damage, the more stringent are the duty-of-care requirements. He



must seek to ensure that the damage is prevented as far as possible and, if it does occur, is limited as far as possible.

Duties of care also have an influence on risk evaluation. Possible measures to reduce the likelihood of occurrence and the magnitude of damage which are also discussed and in some cases implemented in other areas of technology include systematic monitoring programmes. Such programmes are designed to allow harmful effects on the environment and human health to be detected as early as possible. Another measure is to require a stepby-step approach - progressing from experiments at various safety levels in the laboratory, through restricted and controlled field trials, to the placing of organisms on the market. The rationale for this approach lies in the fact that the knowledge required for appropriate risk evaluation in the case of new technologies has to be generated step by step. If the required data is not available from a risk analysis for a subsequent step, no conclusions can be drawn concerning the likelihood of damage occurring. In the absence of

such conclusions, it is not possible to carry out a risk evaluation. And without a risk evaluation, it is not possible to make a rational decision concerning subsequent steps. It is then not permissible to proceed to the next step, thereby blindly exposing others to risks.

7.3.4 Implications for the handling of synthetic organisms

In the view of the ECNH, while plausible risk scenarios exist, the empirical data on the properties of synthetic organisms is inadequate to allow an appropriate risk assessment to be undertaken. From the perspective of risk ethics, therefore, particular caution needs to be exercised in the handling of synthetic organisms. The precautionary principle is to be applied. Until the empirical data required for an appropriate risk evaluation of release trials is available, synthetic organisms are only to be handled in contained systems, in accordance with the step-by-step principle, and taking into account the particular precautions required for specific organisms.

At present, given the lack of data, it is not possible to judge whether the more specific legal provisions already existing for the handling of genetically modified organisms are also sufficient to regulate the handling of synthetic organisms.



8 Summary

In its report, the ECNH assesses the ethical acceptability of the various goals and methods of synthetic biology, and in particular the aspiration to produce new life forms in a controlled manner using so-called BioBricks. The first part of the report concentrates on the question of what the products of synthetic biology are, and whether and to what extent there are ethical obligations towards these products which would pose an obstacle to the application of synthetic biology. The second part of the report is concerned with questions relating to the ethics of responsibility.

As the report explains, how one answers the question to what extent it is possible or impossible in principle to produce living beings in a controlled manner will depend on what conception of life one's assessment is based on. Various fundamental ontological positions are distinguished. The majority of Committee members adopt a monistic conception of life (i.e. what we call life relates to purely physical/chemical properties of living beings). The other positions – vitalism and dualism, but also scepticism – are adopted by minorities. However, all the ontological positions considered leave open the possibility that the vision of synthetic biology may be successful, with living beings arising as products of its methods.

While certain long-term visions of synthetic biology contemplate the production of organisms of all kinds, the focus at present is on microorganisms, which are used by synthetic biologists or are to be created as products. In the context of Art. 120 of the Swiss Federal Constitution - which calls for the "dignity of living beings" to be taken into account in the handling of animals, plants and other organisms - the question of the inherent value of microorganisms needs to be examined. In the view of the ECNH, the way in which living beings arise - via a natural or an artificial process - has no influence on their moral status. Whether microorganisms have something that may be called an inherent value or "dignity", and therefore deserve moral consideration in their own right, depends on one's approach to environmental ethics. The majority of Committee members adopt a biocentric position:



microorganisms have an inherent value because they are living beings. A first minority takes a pathocentric approach. In the view of this minority, as there is no evidence that microorganisms can in any way perceive harm as harm, they do not belong to the circle of beings meriting moral consideration. A second minority adopts an anthroporelational approach: microorganisms deserve moral respect on account of their relation to humans. However, the members who ascribe an inherent value to microorganisms also accept that, in view of the hierarchical position of microorganisms, the weight attached to their inherent value in an ethical evaluation of interests is negligible. For all members, therefore, no ethical obstacles exist in practice to projects involving microorganisms.

The differences between the ontological positions adopted within the ECNH are reflected in different ways of speaking about the controllability of the process and products of synthetic biology. These in turn affect the discussion of questions concerning the ethics of responsibility. In the public debate, slippery slope arguments are put forward in connection with synthetic biology. The Committee members accept that such arguments are useful for highlighting possible consequences at an early stage, so that they can subsequently be monitored. However, they take the view that the concerns expressed to date do not at present justify a veto on synthetic biology projects.

Nonetheless, like all technologies and their applications, synthetic biology also needs to be measured and assessed in relation to various aspects of justice. In addition, issues of risk ethics need to be examined. The ECNH notes that synthetic biology opens up a wide field of research and applications. However, despite the rapid pace of developments, applications have yet to be specified in much detail. The field is dominated by visions, uncertainties and a lack of knowledge; in short, we are confronted with a typical risk situation. In the view of the ECNH, while plausible risk scenarios exist, the empirical data is inadequate to allow an appropriate risk evaluation to be undertaken. In this report, therefore, the ECNH confines itself principally to recalling the procedure which is to be adopted in risk situations on the basis of ethical requirements (and which is already prescribed by law in other areas of technology). The precautionary principle is to be applied and, in accordance with the step-by-step approach, handling is to be subject to the particular precautions required for specific organisms. At present, in the view of the ECNH, it is not possible - given the lack of data - to judge whether the legal provisions already existing for the handling of genetically modified organisms are also sufficient to regulate the handling of synthetic organisms.



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