Synthetic Biology –

an Atlantic expedition

From Brussels to Washington: a search for the differences between the ethical approach towards synthetic biology from the EU and the USA

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Date: 30-08-2012

Subject: Master thesis

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Preface

This thesis is the 'final chapter' of the master *Applied Ethics* to which I was enrolled in 2011-2012 on the University of Utrecht. It is meant as an extensive exercise for the student to present his or her academic skills, knowledge about (in this case) the use of ethical tools and deepen his or her insights about a certain subject by focusing on various aspects of it.

Although I firstly wanted to construct a thesis on possible moral obligations for consumers (could there be such an obligation and if so, how could it look like?) in order to address the ever-growing want for numerous products in western society and the correlating (environmental and sociological) damage this causes, this subject never 'lifted off' and this fact, in combination with a failed internship at a political party due to different insights of what my function should be, made that I still had no subject for my master thesis in the April of 2012.

Luckily, however, student-coordinator Mariëtte van der Hoven passed me an email from my now-supervisor Frans Brom in which the latter asked for students who were interested in studying, analyzing and comparing two reports on the ethical aspects of synthetic biology from, of course, an ethical perspective. Not only because I needed a subject, but also due to the clarity of this proposal and my affinity with the ethical aspects of new and emerging technologies, I gracefully took my chance and started this project.

But it was, however, certainly no easy road. In light of the talented individuals who wrote the reports one easily feels like a mosquito, not sure whether any of your words truly make sense or if you even clearly understood the texts. Furthermore, ethical deliberation is a very complex phenomenon and it is difficult to make a selection of its relevant aspects.

Nonetheless, due to the help and trust of various persons I dare to say that this thesis is successfully completed. As usual, though justly, I would like to thank my supervisor **Frans Brom** for presenting a very clear issue in the first place and trusting me with completing this task. Thanks are also in order for my co-supervisor (second reader), **Bernice Bovenkerk**, for reading my thesis on a very short notice and thereby making my graduation possible. **Marcel Verweij** and **Mariëtte van der Hoven** deserve big thanks as well for fully supporting me in the stressful graduation period. Special thanks go out to **Daphne Smets** for debating the topic and general encouragements, **Hans en Anita Nieuwenhuijsen** for always being of great understanding and support and, finally, **Niek Nieuwenhuijsen**, who was always willing to supplement my sometimes absent self-discipline.

Abstract

Synthetic biology is a very promising emerging technology, though it raises various questions, mostly of an ethical nature. Which risk-level is acceptable in light of the numerous benefits synthetic biology might offer humanity? How should we divide those risks and benefits? And should we even alter and construct life on such a still not very-well understood fundamental scale? In both the European Union and the United States of America reports concerning such ethical aspects of synthetic biology are written, respectively by the European Group of Ethics (EGE, 2009) and the Presidential Commission for the Study of Bioethical Issues (PCSBI, 2010). This thesis compares those two reports by presenting the relevant moral content and an analysis or ethical reconstruction to explicate both similarities and differences. It concludes that there are three morally relevant differences. Firstly, the European emphasis on a more principled approach versus the domination of pragmatic arguments on US-side. Secondly, a more conservative attitude from the EGE due to the application of the *precautionary principle* against a strong emphasis from the PCSBI on *public beneficence* and thirdly, a mainly governmental responsibility to keep watch (on the benefits and risks) of synthetic biology according the EGE against more trust in individual responsibility by the PCSBI.

Keywords: synthetic biology, ethical commissions, European Group of Ethics, Presidential Commission for the Study of Bioethical Issues, public beneficence, responsible stewardship, precautionary principle

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Introduction

In the summer of 1999, the German philosopher Peter Sloterdijk (1947) published, first as a lecture (the *Elmauer Rede*) and thereafter as a letter, his essay *Regeln für den Menschenpark* (Rules for the Human Zoo). This short but sensational work[1] was the beginning of a huge and fierce debate concerning the future of bio-ethics, for according to critics the essay consisted of many controversies regarding the position of human beings in the bio-ethical debate, or better stated: human beings as part of a fully modifiable Zoo in which they can adjust even themselves. Let us explore this further.

Sloterdijk aims to provide a contemporary response to Heidegger's *Über den Humanismus* (1949), in which the German philosopher Martin Heidegger (1889-1976), according to the interpretation of Sloterdijk, explained why humanism as a movement was done for. Humanism, originating from the time of the Old Greeks, aims for nothing less than an anthropocentric taming of mankind by the forging of philosophical and political friendships through writing and reading, eventually resulting in the (dangerous) variants "Christianity, Marxism and Existentialism" (Sloterdijk, 2007, p. 27 – translated from Dutch) who utterly fail in asking the most fundamental question concerning the truest and deepest nature of humanity due to misplaced anthropocentricism (idem).

Sloterdijk continues his essay by invoking Friedrich Nietzsche (1844-1900) and Plato (427-347 B.C.), of which the first, in the shape of Zarathustra, complains that humans are "merely one thing: successful growers who succeeded to change the wild human into the last human" (p. 36) and the second pleads for society as a Zoo that is kept and regulated by the wise (p. 41, 45).

With Sloterdijk's alliance with Heidegger regarding the rejection of humanism, the reference to Nietzsche's complaints of human beings as quite pathetic and fully tamed creatures "who mostly desire, in their ignorance, that no one hurts them" (p. 36), and Plato's suggestion that the wisest should 'grow' the rest, Sloterdijk hits more than a few sensible strings, resulting in a huge, hot, mainly bio-ethical debate in 1999 and thereafter. One of the aims Sloterdijk hoped to achieve with this work, however, was a true starting of thinking about an (ethical) codex concerning bio-technology, for this field of science develops very rapidly and makes humanity face questions it never encountered before.

How do we respond to the reduction of a human being to a genetic sequence of A's, C's, G's and T's? How do we respond to the non-humanistic, extreme unequal division of

[1] That is to say; his lecture and letter were mainly *made* sensational by the media, who switched from producing information "to the production of sensation" (Sloterdijk, 2009, p. 47) and polarized the different sides of the debate. The discussion that broke loose in both the continental and analytical philosophy (and beyond) concerning bio-ethics could, however, not be missed.

those who grow and those who are grown; the wise, almost divine bio-engineers versus 'the commons'? How do we respond to the well-intended scientific fight against diseases and malformations on a genetic scale, which could also be named an (undesirable?) fight against natural coincidence (not to speak of: selection)? In other words: how do we respond to the obvious, never before in this form presented shift from phenomenological human *subject* to merely bio-physical human *object*?

These are only a handful of the heavy-burdened questions that cross our path now and in the near future. The here above roughly sketched analysis of Peter Sloterdijk's *Regeln für den Menschenpark*, however disputed on many grounds by many authors[2], visualizes the radical change of being human in a time where this human being can itself be radically changed. The fundamental character of this issue should remind all of humanity every day, hour and minute how much work there yet is to be done in order to create better understanding of the (meta)physical, existential and especially moral dimensions of bio-engineering: the (re)creation of ourselves. And this is where *synthetic biology* kicks in.

Research Question

The central theme of this thesis is a relative new field of science: synthetic biology. Professionals working in this field are, roughly speaking, mostly concerned with a) implementing synthetic genomes in a living, genome-free cell and/or b) creating fully synthetic living cells/organisms from chemical elements (European Group of Ethics, 2009, p. 19). This scientific field advances, like so many fields, very rapidly and is both reason for excitement and concern for societies and governments.

These potentially positive and/or negative characteristic are the reason why the European Group of Ethics (in Science and New Technologies – EGE) published an extensive document on the ethics of synthetic biology in November 2009 (EGE, 2009) on request of the EU-president José Manuel Barrosso. Something similar happened about a year later in the United States of America. In response to the announcement of a "milestone in the emerging field of cellular and genetic research known as synthetic biology"[3] (PCSBI, 2010, p. vi), US-president Barack Obama explained that the replacement of natural genetic material in a bacterial cell with a synthetic set of genes "raises the prospect of important benefits" but at the same time "raises genuine concerns" (idem). Both commissions (EGE and the

[2] Although it is certainly interesting to reconstruct this debate and hear the various sides, this is beyond the scope of this thesis. Shortly naming the contents of the essay and the fact that many reacted upon it, is I believe enough illustration for the final and indelible marking of the future of bio-ethics in the global intelligentsia's agenda.

[3] With this 'milestone' the president meant the extraordinary developments (placing synthetic DNA-material into an empty (organic) cell) in the J. Craig Venter Institute in May 2010.

Presidential Commission for the Study of Bioethical Issues – PCSBI) were burdened with mapping the ethical aspects of synthetic biology.

The outcome of this mapping is bundled in two reports, published, as said, in 2009 (EGE) and 2010 (PCSBI). The aim of this thesis, then, is to analyze and compare the two reports in order to gain a better understanding of the shared and not-shared moral values, suggestions and recommendations of those two 'players', for it may be obvious that these attitudes and following regulations have a serious impact on the global attitude towards synthetic biology. An analysis and comparison of these documents offers us, if clearly executed, more insight in the various moral aspects of this intriguing field of science. This thesis aims to do exactly that. The research question, then, is:

How do the reports on the ethics of synthetic biology from both the European Group of Ethics and the Presidential Commission for the Study of Bioethical Issues differ in an ethical sense?

To answer this question, the following three elements should be addressed:

1. **A presentation** of the reports: what do they look like? That is to say, why were they written, what is their content and what are the most important findings in an ethical sense?
2. **An ethical reconstruction** of the reports, based on the reversal use of a roadmap for ethical reflection (Bolt, Verweij and Van Delden, 2007): which moral dilemmas arise from synthetic biology? Which values are deemed most important and why? Which responsibilities exists and for whom? And which recommendations follow from these deliberations? Furthermore, with the help of a paper from moral philosopher Will Kymlica (1993), a zoom-out seems rightfully required to complete the reconstruction: which 'view' is held by respectively the EGE and PCSBI? Do they depart from a certain, pre-defined moral position with corresponding (strong) recommendations or are the commissions merely observers trying to map, structure and open up the debate concerning the ethical aspects of synthetic biology?
3. **The actual comparison**: which similarities and differences arise when taking into account the actual reports (*raison d'etre*, structure, form) and their ethical reconstructions?

Although contextual information concerning the reports (authors and their personal opinions, political background, extensive analysis of origin of request for the reports, preferred legal

systems etc.) could provide answers on *why* a certain moral attitude or approach is chosen, this study only limitedly focuses on these backgrounds, for not the 'why' but the 'how' (much do they agree/differ in an ethical sense) question is the central one. This study, then, could be of assistance for other possible research on why these visions differ (and agree). This will, inter alia, be mentioned again as a recommendation (see: Conclusion and further recommendations).

Structure

This thesis, besides the introduction and conclusion, consists out of three chapters. **Chapter one** has a methodological character and is devoted to a) giving a working definition of what is understood by ethics and ethical commissions, b) introducing the roadmap or action plan for ethical reflection and discussion (Bolt et al., 2007) and how such a plan can help reconstructing the moral core(s) of the reports and c) introducing, with the help of moral philosopher Will Kymlicka, a meta-analysis ('zoom-out') in which various theories about possible approaches of ethical commissions come to the fore. The **second chapter** puts all this in practice by a) presenting the form and morally relevant content of the reports, b) reconstructing this content by applying the earlier mentioned roadmap and c) applying the meta-analysis of Kymlicka. Finally, the **third chapter** assembles the similarities and differences based on the various findings in chapter two.

1. Ethics, ethicists and ethical reconstruction[4]

The first chapter of this thesis is mainly introductory: what do we understand by ethics and ethical commissions? How can we deliberate on ethical subjects without losing each other due to different insights? And which 'bigger' approaches could ethical commissions, like the European Group of Ethics (EGE) and the Presidential Commission for the Study of Bioethical Issues (PCSBI), take towards ethical issues?

Although certain parts of this chapter will be simplistic and not useful for readers who are already trusted with ethical content, the comprehension of how, eventually, the research question is answered requires certain elementary knowledge about ethics in general and ethics in practice particularly and thus such introduction is needed at least for readers unknown with ethical content. Furthermore, it is the goal of this chapter to explain which methods and tools are used to analyze and compare the both reports. Finally, clear (working) definitions hopefully decrease the chance of confusions and misunderstandings about this thesis.

There are three sections in this chapter. Section 1.1 provides a working definition of ethics and ethical commissions, section 1.2 explains a roadmap/action plan developed by Bolt et al. (2007) to reflect on and discuss about ethical issues and how this method can be of use in analyzing the reports on the ethical aspects of synthetic biology (SB), while section 1.3 zooms out and centralizes the question which underlying theories ethical commissions (could) use as a starting point, hereby assisted by an article of moral philosopher Will Kymlicka (1993).

1.1 What the *bleep* is ethics?

In daily life, when someone states that a certain activity, event or person is unethical, this individual probably means that it is, in one way or the other, *not right*. This 'not right'-idea can be an intuitive gut-feeling ("Torturing someone is wrong!"), a rational deliberation ("If everyone would steal stuff in the supermarket, the markets would simply cease to exist.") or, and this is the most common kind, a combination of both. But what does it *mean* when something is (not) right? When is something right or wrong? How does one know what to do? Or, to put it bolder: how does one live a good life?

It is this very question that occupies the minds of philosophers for at least the last two-and-a-half millennia and it is this very question that characterizes the core of what is

[4] This title is borrowed from the title of the course 'Ethics, ethicists and ethical expertise' that could be followed in the master Applied Ethics (University of Utrecht, 2011-2012).

understood by ethics. However, the field of ethics is mostly divided into three centers: value ethics, normative ethics and meta-ethics (Shafer-Landau, 2010). The earlier mentioned example of when something is considered unethical belongs to *normative ethics*, for it explicitly judges the right- or wrongness of an act (or the entity performing this act). But this judgment is, consciously or unconsciously, always based on certain moral assumptions that are the outcome of following a certain moral theory (or combination of theories) that again can be judged. This latter form of judging is called *meta-ethics*.

The two most important theories in the meta-ethical spectrum, each to be found on the outsides of this spectrum and to be divided into numerous other theories, are *consequentialism* and *non-consequentialism*. The first claims that only the outcome of a certain act matters, while the latter holds on to certain rules and/or principles that should always be respected, no matter the outcome. It is not difficult to see why both meta-theories are problematic: always only considering the outcomes, for example promoting the most happiness for the greatest number, could easily result in a lack of respect for individual rights, while always respecting certain principles will make the actor blind for possible horrific consequences. Well known and popular moral theories that struggle with such shortcomings are *utilitarianism* and *deontological ethics*, in which the former judges an act as right when the outcome results in a maximum amount of happiness for the maximum amount of individuals, while the latter departs from certain fundamental and universal moral obligations one has.[5]

It is now made more clear what normative ethics entails ("Is this a right act to perform?") and what happens on a higher level, in meta-ethics ("Is this the right moral theory to follow?"). Although those two levels of ethics will play an important role in the analyzing of the two reports on the ethics of SB, the role of the first named sub-field, value ethics, must also not be underestimated. The earlier mentioned question "How does one live a good life?" is central in this sub-field, for the question logically requires a search for what 'the good' is and thus which values are important. How should one deal with living organisms? Is it alright to develop new organisms and if so, who bears the responsibility for these creatures? The broadest question, however, would be: does humanity, ultimately, wants to live in a world where nature, including human physiology, is under complete control of human beings? Is that a *good* world? It may be clear that this question will not be answered in this thesis, nor will it ever be answered fully or correctly. But ethics is the only field that engages in asking these kinds of very necessary questions and provides a mapping of the most important elements herein.

[5] Numerous variations on these theories exist, but for this thesis it is not necessary to do so.

Although, as said, most human beings practice ethics everyday by wondering how they should treat others or which acts they should (not) perform, ethics is also professionalized by moral philosophers, ethicists and ethical commissions or committees.[6] Roughly spoken one could state that the first group discusses ethical questions and theories on a meta-level (what *is* ethics, ethical theory and ethical deliberation exactly?), while the second and the third group are burdened with more practical moral dilemmas: what do we think of abortion? Should we legalize euthanasia? What moral status do animals have, if any?

In the article *Do's and Dont's for Ethics Committtees: Practical Lessons Learned in the Netherlands* (Verweij, Brom and Huibers, 2000), the authors note that ethical commissions "are normally multidisciplinary groups" who "discuss moral problems" that are, however, "not their own: they concern actions of persons who are not the members of the committee" (ibidem, p. 344-45). Furthermore, there are, inter alia, health ethical commissions, government ethics commissions (the category in which the EGE and PCSBI fall) or, more concrete, euthanasia committees, "(a)ll of them aim to contribute to morally justified and responsible actions and policies" (p. 345): how they could do this both in practice and on a meta-level will be discussed in the next two sections.

1.2 Reflection, discussion and reconstruction

How can human beings in general and ethical commissions in particular debate carefully, respectfully and systematically about ethical subjects (such as the ethical aspects of SB)? And can we reconstruct already existing deliberations (reports) by applying such methods on them? Those are the two central questions in this section.

One method/roadmap/action-plan[7] of reflecting and deliberating on moral problems is found in the work of Bolt, Verweij and Van Delden (Ethiek in praktijk[8], 2007) and is meant as a tool to a) structure and guard the process of deliberation and b) keep the used values and arguments on which the conclusion is based transparent (p. 17). The authors emphasize that the following method is not the only one, however, it covers at least the most fundamental elements of ethical deliberation and because of the magnitude of both reports it will be, as we will see, a sufficient tool. On page 18 of the work we find the following scheme (figure 1.1), in Dutch, which will be translated in English thereafter (figure 1.2) in order to enable readers to check for translational errors or ambiguities:

[6] 'Commissions' and 'committees' are used interchangeably.
[7] These are the translations of the Dutch word 'stappenplan' and will be used interchangeably in this thesis.
[8] As Dutch readers will notice, this book is written in Dutch and in order to prevent unnecessary translations or translational errors quotes will be restricted to a minimum, however, the actual method is wholly cited in figure 1.1.

Het stappenplan

Fase I Verkenning

1. Welke vragen roept deze casus op?

Fase II Explicitering

2. Wat is de morele vraag?
3. Welke handelingsmogelijkheden staan op het eerste gezicht open?
4. Welke feitelijke informatie ontbreekt op dit moment?

Fase III Analyse

5. Wie zijn bij de morele vraag betrokken en wat is het perspectief van ieder van de betrokkenen?
6. Welke argumenten zijn relevant voor de beantwoording van de morele vraag?

Fase IV Afweging

7. Wat is het gewicht van deze argumenten in deze casus?
8. Welke handelingsmogelijkheid verdient op grond van deze afweging de voorkeur?

Fase V Aanpak

9. Welke concrete stappen vloeien hieruit voort?

Figure 1.1

Method/roadmap/action-plan

Phase I Exploration

1. Which questions arise from this case?

Phase II Expliciting

2. What is the moral question?
3. Which possible acts are available on first sight?
4. Which factual information is lacking at the moment?

Phase III Analysis

5. Who are involved in the moral question and what is the perspective of each of them?
6. Which arguments are relevant for answering the moral question?

Phase IV Deliberation

7. What is the weight of each of these arguments in this case?
8. Which possible act, based on this deliberation, should be preferred?

Phase V Approach

9. Which concrete steps follow from this deliberation?

Figure 1.2

This scheme seems quite self-evident, for it is logical to start with the exploration of the topic: what, really, is the case? And what, then, is the real *moral* question here? Who has which moves to make? What arguments could there be for acting as such? And how weak or strong are these arguments? The authors do warn, however, for various traps: because ethical issues are often quite heavy (think about abortion and euthanasia) in an emotional sense, emotional reactions are quite common in the first phase. This could, however, cloud the real issue and keep commission members in their own, personal sphere (p. 20). Other traps are hiding behind ignorance because the case is too difficult - we do not have all the information yet, but one will never have the disposal over *all* the ins and outs of a case – (p.

24) or the constant repetition of arguments in order to make them weigh heavier (p. 29). Those traps, however, are merely examples of what happens when one (or: a group) goes *off-road*, ethically speaking: such a trip does not contribute to a clear presentation, discussion or possible moral stance of a certain problem.

Using a certain roadmap does not 'solve' complex moral problems, but good use makes those problems more discussable and enhances the very discussion. In a same sense is it possible to apply such a method *afterwards* in order to find out how a deliberation went, to reconstruct a 'moral event'. What problems did the commission notice? Which moral questions arose? What relevant information lacked and how did this influence their judgment? Which values were important? Who should bear which (amount of) responsibility? Although, as we will see in the reconstruction of the next chapter, it is not necessary to follow the previously presented method extremely strict, it does cover the most important elements in moral deliberations and the exposing of these elements from both reports is a necessary requirement to say something useful about how they differ in an ethical sense.

Before turning to the next chapter, however, it is important to take a step further away and question which theories might be the underground on which ethical commissions operate.

1.3 The theory behind ethical commissions

In the article *Moral Philosophy and Public Policy: the Case of NRT's* (1993) moral philosopher Will Kymlicka questions the relation between moral philosophy and governmental commissions. Which contribution can moral philosophers or ethicists deliver towards such commissions? Before continuing it seems wise to elaborate the difference between ethical commissions and governmental commissions: the first explicitly deliberates on obviously moral issues (is this biomedical research sound? Should we euthanize a certain patient who requested it? etc.), while the latter advises governments by adopting a certain public policy. In the case of the reports on the ethical aspects of SB, however, both commissions are obviously governmental, but the content of the reports is mainly 'ethical', that is to say: deliberation took place over which attitude governments should adopt towards SB in light of the various relevant ethical aspects. In other words, there can be a great overlap between the different kind of commissions and although both reports are focused on policy (what should the government do?) their ethical content makes an ethical analysis possible.[9]

[9] That is to say, other forms of analysis (legal, political) are also possible and probably even desirable, but this thesis focuses on the ethical analysis.

That being said, let us return to the article of Kymlicka. According to him, "two main views" (p. 2) are possible, "one of which is ambitious, the other more modest" (idem). With this, Kymlicka means that commissioners either want to promote a certain moral theory, thereby generating a certain direction in which the deliberation and thus policy is steered, or merely doing a 'check-up' in or about the deliberation: is the argumentation coherent? Are the arguments correct in light with earlier adopted values? Moral philosophy, thus, as a technical field that checks whether deliberations are going smoothly.

Remember that, although Kymlicka explicitly talks about the role of *moral philosophers* in commissions, his remarks are relevant for the directions commissions as a whole are taking as well, for a) many commissions (like the EGE and PCSBI) already contain moral philosophers in the form of (bio)ethicists and b) as mentioned before, a certain theoretical underground needs to be apparent for health care/(bio)ethical/governmental commissions: are we searching for the appliance of a certain moral theory to ensure that our recommendations follow from that theory or should we distance ourselves more and only guide the deliberation?

Towards both approaches, however, Kymlicka is skeptical. To promote a certain moral theory, he claims, one should at least be able to state "a) what is distinctive to each theory?, b) which theory is most adequate?, c) what practical conclusions does each theory have for NRT's?[10]" (p. 3). But these questions are very hard, if not impossible, to answer. Concerning the distinctiveness, many proponents of certain moral theories are conceived otherwise by colleagues and "(f)or any given pair of theories, we can find some people who believed that the two theories are identical, or at least consistent" (p. 4). In other words, Kymlicka claims that the ambiguity concerning moral theories does not make them suitable for direct moral deliberation, if only because many philosophers "try to combine the more attractive elements of different theories into a new hybrid theory" (p. 5) – recall the overlap between the earlier mentioned (section 1.1) consequentialism and non-consequentialism. But maybe even more relevant is the fact that these confusions are not intriguing for public policy makers: "(t)hey do not have the time or inclination to sort it out" (idem).

But even *if* commissioners would manage to agree on what is understood by, for example, deontology and utilitarianism (see section 1.1), the evaluation on deciding which theory is most adequate is probably even more problematic, for "(m)oral philosophers have not yet discovered a knockdown argument for or against these different moral theories" (p. 6). That is to say, each moral theory has its own weaknesses, but the strengths are even

[10] With NRT's, *new reproductive technologies* are mentioned, however, one could easily change the question in 'What practical conclusions does each theory have for the ethical aspects of synthetic biology?'

more important, for each theory defends certain moral aspects human beings find important. If act A deceases the amount of suffering in the world, one should undertake that act, however, the same act might require a devastating violation of certain basic human rights - consider the bombing of a rebelled village to prevent the bloody and violent rebel to pass over to the rest of the country while innocent children are still in that village.[11] Thus, evaluating complete moral theories is extremely difficult and should not be the task of a governmental commission.

Kymlicka continues, however, positively by hypothesizing that *if* there would be agreement on a definition and use of a single moral theory, the third question would still be an obstruction: how do we *apply* these theories towards practical conclusions? Again, a lot of disagreement is found. Various important "general concepts of "agreement", "utility", "care"" (p. 6) are open for numerous interpretations. Is, for example, the maximizing of utility (in a utilitarian tradition) a "subjective preference, or are there objective standards by which we can judge some interests to be more important or urgent" (idem)? The real application is another point of lengthy discussion and no commission can and should spend their time on this.

But what about that *other* view, "philosophers as technicians" (p. 8)? Although the above mentioned attitude of commissions (promoting and applying a certain moral theory) is "too ambitious, this (other view, -NN) is far too modest" (p. 9). Kymlicka argues that "arguments can be clear and consistent, and yet be morally bankrupt" (idem). In other words, when a commission would only offer some considerations, check whether the deliberation was structured and if the arguments are sound, the "moral point of view" (p. 10) is missing, the moral element is completely stripped away, while "showing concern for people's lives and interests" (p. 11) should be considered a very important element of moral deliberations.

The third and by Kymlicka presented approach or view of what a (ethical/governmental) commission should do contains two steps. Firstly, listing how the moral issue "affects the various stakeholders" and secondly, which "guiding principles" are relevant. Notice how this resembles the already mentioned roadmap in the previous section, however, thinking in principles instead of applying moral theories is, as we will see in the next chapter, very much the way the reports on the ethical aspects of SB are constructed. This is why the naming of different approaches by Kimlicka is useful in analyzing the both reports: to which extend are they departing from a certain (hybrid) moral theory, if even? Or

[11] Roughly spoken, this is actually the justification the Syrian government gives for their actions when writing this thesis.

should they be seen as mere technical reports who just map the discussion? This is what the next chapter and especially sub-sections 2.1.3 and 2.2.3 will discuss.

2. The Group and the Commission: an analysis

This chapter is divided into two sections. Both sections will be the ethical analysis of respectively the report on the ethics of synthetic biology (SB) of the European Group of Ethics (EGE – the Group) and that of the Presidential Commission for the Study of Bioethical Issues (PCSBI – the Commission). Because the structure of the analysis for both reports (and thus for sections 2.1 and 2.2) is identical it will be explained hereunder.

In the first sub-sections (2.1.1/2.2.1) a general picture of the reports (authors, motivation, structure etc.) will be sketched, followed by a summary of the relevant moral findings of the report (2.1.2/2.2.2). Based on the roadmap introduced in the previous chapter, an ethical reconstruction of the reports (moral question? Values? Arguments? Responsibilities?) will be made in the third sub-sections (2.1.3/2.2.3), including a zoom-out: which theory forms the underground on which the commissions operated?

For readers who are already familiar with the content of these reports it could be unnecessary to read the first two sub-sections (2.1.1/2.2.1 and 2.1.2/2.2.2) of the first two sections, for these are nothing more than notifications and summaries of the reports. Those summaries are, however, a necessary requirement for the independence of this analysis, for individuals who did not read the reports must be able to understand what they entail and furthermore, the ability to refer internally to certain relevant aspects is important for the readability and academic validity of this work.

2.1 The ethics of synthetic biology: the Group

2.1.1 Contextual sketch

The report on the ethics of SB from the Group is presented in November 2009 and is part of a larger publication sequence called *Opinion*. Prior to *Opinion No. 25*, the report on the ethics of SB, reports were presented about, for example, the ethics of modern development in agricultural technologies (2008, no. 24), the ethical aspects of cloning animals for food supply (2008, no. 23) and the ethical aspects of nanomedicine (2007, no. 21).[12] Although those are all independent publications, referring to other reports occurs regularly in order to elaborate on certain moral standpoints that are given more thought and deliberation in certain reports due to their relevance to the subject. As written in the statement and mandate of the European Group of Ethics in Science and New Technologies, the Opinions are

[12] As found on http://ec.europa.eu/bepa/european-group-ethics/publications/opinions/index_en.htm, visited on 28-07-2012.

requested and unrequested advisements on "ethical questions relating to science and new technologies"[13] for the European Commission.

In the case of the ethics on SB the report was requested on May 28, 2008 by President José Manuel Barrosso, who asked "to issue an Opinion on the ethical, legal and social implications that may derive from synthetic biology" to fill the gap of work that exists "on the ethical, legal and social implications that derive from this specific use of biotechnology" (European Group of Ethics, 2009, p. 11). The Group accepted this request with stating that "an ethical, legal and political governance of synthetic biology is needed in the EU and worldwide to ensure that the interests of society are respected" (idem).

The report consists out of 104 pages of which a total of 26 pages are respectively French and German translations of the recommendations of the report. It is constructed out of a chapter concerning the scientific aspects (historical overview of SB, searching for a definition, conceptual basis of SB etc.), a chapter concerning the legal, governance and policy aspects (current legal framework (EU and global), governance of SB, public involvement etc.), a chapter on the ethical aspects of SB and finally a chapter with a total of 24 recommendations on which attitude the Commission should take towards SB.

Finally, the chief editor of the report, Maurizio Salvi, is also head of the secretary of the Group and studied a Bachelor-degree in both Modern Literature and Philosophy, post-graduated in Bioethics and holds a PhD on Health Sciences (University of Maastricht) and a European PhD in Biotechnology (European Association for Higher Education in Biotechnology).[14]

2.1.2 Moral core of report

The way in which the Group approaches the ethical aspects concerning SB can roughly be divided into two areas: a *principled* and a *pragmatic* approach. The first approach is mainly concerned with the fact that there are certain rules, rights and/or principles that always bear a certain value and cannot be ignored, while the second approach is from a practical, consequentialist nature that acknowledges the actual consequences of certain acts, events or developments. This sub-section will first bring to the fore the more principled view of the Group, just as in the report, followed by the pragmatic and concrete ethical implications that are a consequence of SB. The last paragraph presents the concrete recommendations.

[13] As found on http://ec.europa.eu/bepa/european-group-ethics/welcome/mandate-2011-2016/index_en.htm, visited on 28-07-2012.
[14] As found on http://ec.europa.eu/bepa/european-group-ethics/docs/secretariat/cv_m_salvi_en.pdf, visited on 28-07-2012.

The principled approach

The Group starts with naming the European Union's fundamental ethical framework as a set of (fundamental) principles that are regarded as guidance in determining a) what could be found as morally problematic in the field of SB and b) how to hold onto important principles while the field continues to develop. According to the Group, the fundamental ethical framework centralizes around the term human dignity, for the possession of this dignity brings "certain immutable moral obligations" (EGE, 2009, p.39) towards the carrier and must be seen not only as a fundamental right in itself, "but constitutes the real basis of fundamental rights." (idem)

This shows immediately how vague and difficult the notion of human dignity is: is it something that every human being just possesses, no questions asked, or does one have the *right* to be acknowledged this possession? And is there even a difference between those two options? The Group acknowledges this problem, but settles with various plausible interpretations. So can it be seen as a 'moral shield' that protects humans from violence of others, as an idea that dignity entails being autonomous in decision-making and guarantees individual freedom, a more Kantian approach in which moral responsibility is emphasized and finally, in extension of the former, an emphasis of "the need for individuals to consider the general effects their actions have on others, including other human beings, animals and the environment" (idem).

By stating that the notion of human dignity, although open to several interpretations, is a central moral construct that should always be humming on the background, the Group continues by naming three important fundamental ethical issues concerning SB: "(…) a conceptual analysis of life and nature; an analysis of procedural principles that aim to secure the freedom and autonomy of citizens with regard to the development of synthetic biology (…); an analysis of substantial principles, depending on the different fields an applications" (p. 39-40). The two last issues are brought to the fore in the more pragmatic approach and thus will be discussed in the next sub-paragraph. But the 'conceptual analysis of life and nature' is not and hence will be discussed now.

The Group divides this short analysis into two parts. Firstly, a short conception of what we understand by life and which ethical consequences follow from that conception and secondly, a discussion on the position of humanity in its relation with its surroundings (nature). According to the Group, the fact that SB is pre-eminently the discipline in which "the *natural* and the *artificial*" (p. 40), both classically referring to "life and non-life" (idem), mangle and intertwine due to the artificial production of natural entities, could be morally problematic. They do not, however, take a stance in the discussion between the advocates

of the ethical legitimacy of fabricating life versus the opponents of this activity. Instead, they pull the discussion towards human beings and the way in which SB could change our perception of 'life'. On the one side there is *zoe*, the Greek reference to all biological, objective, 'cold' life processes, while *bios* applies to "life in its social and cultural dimension" (p. 41). In the ethical debate concerning SB, this distinction and the emphasis on 'bios' is deemed important, for it shows that *at least* human life is more than merely biological processes. The human body "should not be reduced to the concept of life proper to biosciences and biotechnology since it is also an expression of our social and cultural life deserving particular care and respect, which are at the core of the concept of human dignity" (idem).

Turning to the relation between human beings and nature, the Group approaches the ethical concerns with the framework of ecological ethics, thereby distinguishing between the sub-fields anthropocentric, biocentric and eco-centric ethics. The anthropocentric approach grants merely instrumental value towards natural phenomenon and only limits an activity (such as creating synthetic orgasms) when it could hurt human beings (now or in the future). The biocentric approach is not worked out by the Group, but the eco-centric approach puts forward the far broader question "in what kind of world we may wish to live in" (idem). Given the contemporary status of our environment and humanities severe exploitation of it, the eco-centric approach sees SB mainly as an artificial way to make our environment healthy again. This does not mean that everything is allowed to take 'ultimate control' over our surroundings, but merely that our surroundings should be our central concern, if only because human beings are part of these surroundings.

There always seems to be, however, a certain anthropocentric bias and in the next sub-paragraph we will map the direct and indirect consequences and related ethical concerns of SB upon humanity.

The pragmatic approach

What are, or could be, the (in)direct ethically relevant consequences of the scientific field we call SB? To answer this question, the Group divides its concerns over four fields: biosafety, biosecurity, justice and intellectual property (EGE, 2009), which will each be examined hereunder.

Biosafety. The most intriguing (and gracefully used by Hollywood) scenario concerning the synthetic creation of life is that of a Frankenstein or Godzilla: what if humanity, intentionally or accidently, creates a horrible monster that destroys 'life as we know it'? Such a monster could be, although quite unimaginable, the enormous classical

dragon that throws trains around and eats nuclear power plants, but something closer to the truth is a synthetic bacteria that ruins ecosystems or a evolved synthetic 'super-virus' that brings illness and death on a massive scale.

The Group states that both human health and environmental protection are the most important values in risk assessments concerning the use of synthetically produced products. Furthermore, the fact that the consequences of such products, both on human health and the environment, are so hard to predict, makes that the Group underlines the use of a *precautionary principle* which "requires a) that there are serious and irreversible risks, b) a shift of the burden of proof from those potentially exposed to the hazards of a new technology to those who want to introduce it" (EGE, 2009, p. 42). This principle could also be used to promote SB, for there are numerous contemporary threats that qualify being 'serious and irreversible risks' (for example global pollution) to which SB could be a solution. Finally, and this correlates narrowly to the next field, the Group believes that freedom of research "cannot be invoked if serious or irreversible risks to human health or the environment may occur" (p. 43). In other words: it is more important that certain synthetic life forms are bound to the lab (by ensuring that they cannot survive when released) than that researchers have the freedom to experiment with them 'in the open'.

Biosecurity. If we stick to the value of scientific freedom, the Group acknowledges that some rightly worry that many scientific activities in the field of SB could "alert would-be bio-terrorists to possibilities and provides them with explicit instructions for producing biological weapons" (p. 44). This misuse of knowledge and technology about biotechnology, of which SB is part, is what the Group calls a breach of biosecurity and due to the potentially harmful consequences such breaches should not be taken lightly. Especially in an era where knowledge is easily digitalized, "anyone with a laptop computer can access public DNA sequence databases via the Internet, access free DNA design software, and place an order for synthesized DNA for delivery" (idem). Therefore, both freedom of science and freedom of (sharing/distributing) information could be rendered less important than ensuring that no vital 'bio-info' falls into wrong hands.

Justice. The concept of justice is, according to the Group, explained in two ways, both resulting from the theory of distributive justice (by philosopher John Rawls in his *Theory of Justice* (1972)). The first way is quite evident and must be seen as the equal division of advantages and risks of SB, both on national and global scale. The second way, however, is justice as a means "of the State in protecting and advancing human rights" (p. 45). This practical (just and honest division) and more principal (a just relation between a protecting state and its citizens) approach to justice is "key to the ethics of SB" (idem).

Intellectual property. The right to protect one's ideas from (commercial) use by others is very common (and according to some a prerequisite) in the scientific world and is mostly done in the form of patenting. Being 'just another' field of science, SB is also familiar with this kind of protection. However, according to the Group the patenting system could be morally problematic, for "several experts on the ethics of patenting biological inventions have advocated that some discoveries or inventions should never result in commercialization for profit" (p. 46, source: Bovenberg, 2006). Especially processes "the use of which offend human dignity" and "cloning human beings" (idem) could never be patented (nor commercially exploitable).

The Group distinguishes, however, three categories concerning inventions done in the field of SB. Firstly, an invention "which is common to all humankind" (idem) such as the human genome project or the mapping of the genetics of crops, for "no country is self-sufficient in plant genetic resources; all depend on genetic diversity in crops from other countries and regions" (idem, quoted from The International Treaty on Plant Genetic Resources). Secondly, an invention that "should be placed in the public domain for all to use and exploit" (idem). The difference between the first and second category is that inventions in the first category should never be "directly exploited for commercial gain" (idem), for this would be contrary to morality, while inventions in the second category could be exploited (though not patented). In the third category, however, the invention "may, at the inventor's discretion, be protected through an intellectual property rights system to encourage innovation" (idem). The question whether or not an invention from the field of SB may be a) commercially exploited and/or b) patented depends, then, on the possible violation(s) of human dignity and the possible generality of knowledge so that it belongs to humankind.

Recommendations

The 24 recommendations put forward by the Group are divided into seven main-categories (all again divided into sub-categories): safety, biosecurity, governance, intellectual property, the dialogue between science and society and research. Because the most important (moral) concerns are already mentioned in the two sub-paragraphs above and all recommendations can be easily looked up (EGE, 2009, chapter 4) it is sufficient to shortly mention the emphasis per main-category. Furthermore, the sequence of the categories is, of course, another way for the Group of revealing the importance of certain elements.

Safety. The Group recommends *conditional* use of SB, mainly because it is worried that the current risk assessment procedures are not sufficient to analyze and assess 'GMO's' (genetically modified organisms), for "SB will produce organisms with multiple traits from

multiple organisms, and therefore it may be difficult to predict their properties" (EGE, 2009, p. 49). Therefore new risk assessments need to be made (by the European Commission) and funding of research (of SB) should only occur when this 'upgrade' of assessments is fulfilled and, of course, applied. Furthermore, there should be a "Code of Conduct" (idem) for the researchers, prepared by the Commission, in which certain safety-issues are assured (for example: that GMO's cannot survive outside the lab).

Other areas where SB is active and safety plays a leading role are the environment as a whole, the energy- and chemical industry and in biomedicine and biopharmaceuticals. With regards to environmental issues, the Group recommends that the *precautionary principle* is applied (see 2.1.2, Consequential issues, bio-safety), while the use of SB in the energy- and (sustainable) chemical industry should be "complementary to the EU renewable energy plan" (p. 50). Concerning biomedicine, the Group claims that products from SB "are still far from being available to patients" (p. 51). Therefore the "existing regulatory framework is generally adequate to regulate the use of SB" (idem) and thus the Group states merely that "specific ethics considerations" should be made, in addition to current ethical and legal frameworks, to stay put on the developments in biomedicine and biopharmaceuticals with regards to the role of SB.

Biosecurity. There are three direct security-risks concerning SB that need to be addressed. First, the dangers concerning warfare with severe (and altered with synthetic biological processes) bioweapons designed by nations. The usage of these weapons by governments "must be within current national and international regulatory frameworks" (p. 51). Furthermore, governments must find the balance between being transparent towards their people about possession of such weapons and the protective function of those weapons for society, which is very difficult for the second risk: (bio)terrorism. Again, any form of misuse needs to be addressed to minimize the risk of terroristic activities with dangerous products that are a (direct or indirect) result of SB. And third, in line with the former, the risk that products from SB leave "recognized institutions" (idem) so that they disappear from the radar.

Besides this analysis, the Group emphasizes the moral difficulty of the dual use of SB, both as welcome medicine and deadly weapon, by legit military forces from nations. It is almost impossible to foresee the (un)intended consequences of SB (both military and civil), so the Group argues simply that applications of SB "must not contravene the fundamental rights and ethics frameworks outlined in the opinion" (p. 52).

Regulation is key in the recommendations that follow. It is important that the European Commission ensures that there is a centralized database in which all "DNA

synthesizers would be registered by competent authorities" (idem), so that suspicious sequences (for example bases for dangerous viruses) are detected early and competent authorities (on EU-level) can undertake action. In a more general sense the Group is asking the Commission to create a clear definition of a "comprehensive security and ethics framework for synthetic biology" (idem).

Governance. In line with the above, the section 'Governance' pleads for the creation and application of sufficient governance tools in order to regulate all developments concerning SB. Various questions, however, remain: the earlier mentioned tension between encouraging transparency (and intellectual freedom) and preventing misuse, the very many levels on which developments concerning SB take place (how to take all of them into account?) and the way in which the EU-regulation can be exemplifying for the rest of the world. Or, in other words, can EU-regulation become somehow universal?

The Group therefore recommends the European Commission to put into place a "robust governance framework for synthetic biology" that addresses "relevant stakeholders" and "clearly indicates their responsibilities", the encouragement of "ethical, preferably global" guidelines for the relevant science communities and the proposal that the EU "takes up the question of governance of synthetic biology in relevant global fora" (p. 53).

Intellectual property. Although the Group acknowledges the importance of patenting in order to stimulate further research and intellectual endeavors, it also acknowledges the moral problems regarding the patenting of "genetic material or biological methods" (idem). Therefore, the Group recommends, in line with the EU Patent Directive (98/44/EC)[15], that the Group functions "as the body to assess ethical implications related to patents" (p. 54), in particular in relation to a class of inventions that are potentially commercially exploitable. Furthermore, the Group deems it important that the debate concerning "the most appropriate ways to ensure the public access to the results of synthetic biology" is quickly launched in order to form public opinions concerning the tension between intellectual property and transparency.

Intellectual property is also related to questions concerning global justice - how does one deal with the protection of intellectual and economic endeavors in developed countries while developing countries could also benefit largely from those inventions? The Group states that "(a)ctions to avoid a greater technological divide should then be taken" (idem) and if trials concerning SB take place in "developing and emerging countries the same ethical standards as are required within the EU must be implemented" (idem); this should also be

[15] This directive appoints the EGE as the "body to assess ethical implications related to patents" (EGE, 2010, p. 54).

the case for import-export products of SB. Finally, the Group recommends that when meetings concerning SB take place on an international level, including the WTO, "the ethical issues associated to the technology should always be addressed" (idem).

Science and society dialogue. Public support for SB, and for scientific endeavors in general, is very important to increase both productivity (by more available funds, for example) and self-awareness due to more contact with society. Therefore, the Group recommends that the EU "takes actions to promote public debates", creates "fora, seminars and courses" and emphasizes "responsible reporting on synthetic biology" (p. 55) to ensure that unrealistic, science-fictional scenarios (with correlating risks and benefits) do not become common ideas under laymen.

Research. Finally, the Group emphasizes the importance of interdisciplinary research within the field of SB to ensure strong awareness (ethically, legally, socially etc.) under scientists. Funding from the EU should be(come) available for such research, just as for basic research in SB, for this is "not necessarily connected to market and industrial interests and is therefore dependent on public financing" (idem). Basis research, however, (both in SB and elsewhere) is deemed important for its core role in the development of SB and "the role the EU research may play in global governance of synthetic biology" (idem).

2.1.3 Ethical reconstruction

In line with the method introduced in section 1.2 and the various underlying theories concerning the working of ethical commission in section 1.3, this sub-section will analyze the most important ethical elements of the EGE-report.

Phase I: Exploration

General questions. Emerging technologies like synthetic biology offer interesting prospects in various ways – renewable and sustainable fuels, cheaper medicine, but also better understanding of biological processes. Nonetheless, this field of science is accompanied by worrisome questions concerning human dignity and the value of life, together with various risks that come along with this fundamental form of genetic engineering. As a governmental commission, the EGE is burdened with the question which policy or policies the European Union (concrete: the European Commission) should undertake to properly handle this upcoming field of science.

Phase II: Explicating

Moral question. The moral question is this: how does a government find a balance between reaping the benefits and decreasing possible risks deriving from this relatively new

technology, while continuously holding in mind the bigger 'moral picture' that is drawn by means of the very nature of the technology – severely manipulating and even creating life? Furthermore, the Group wonders how those benefits and risks could be justly distributed, especially in a globalist sense.

Possible actions. Although the potential possibilities for a government like the European Commission are a political and legal matter, it is fair to say that its influence towards scientific projects in the EU is significant due to the fact that many scientific activities take place on a European level. Hence, when asking which actions are possible, the Group could advise the Commission to design either very strict laws and conditional funding's with regards to SB or give a *carte blanche* (possibly even with funding) to this field of science to do what it wants to do. It may be obvious that those extremes are evidently not ideal and that many more options in the middle are possible.

Lacking factual information. The Group is very well informed and spends 13 pages on explaining what is to be understood by SB, however, the established fact that it is a quickly emerging field reveals how difficult it is to keep up-to-date and thus, in that sense, viable factual information that could be of significant moral importance is always missing. Keeping in mind that the Group recommends close reviewing of the various progresses in the field, however, shows a decreasing chance in truly missing viable information that could lead to other recommendations.

Phase III: Analysis

Involvement. Roughly three groups are involved concerning SB: naturally the scientific community, governmental agencies functioning as fund or auditor and the general public. The first group, as the Group acknowledges by naming the importance of intellectual and academic freedom, is both looking for practical implementations of SB as well as gaining fundamental knowledge concerning biological systems; it is easy to see how the other two groups could also benefit from this, however, it is equally easy to see how governmental agencies are promoting order and the minimizing of risks in their jurisdiction and thus, pre-assumed by the Group, should be critical towards new inventions. The general public should not be seen only as a concrete group (citizens of the EU), but also as human beings in general, who are not only looking for the gaining of benefits and the minimizing of risks, but also for the protection of human dignity and a respectful approach towards ourselves and our environment.

Arguments/principles. According to the Group, the most important arguments for morally responsible governance follow from the principled approach: governmental agencies

should, in cooperation with scientific communities and civilians, constantly debate about how far we intent do go with manipulating and creating life. Technology and science are not merely means, but ends in themselves that need to be justified. Working within the current ethical framework of the EU is of extreme importance, thereby constantly guarding human dignity and holding in mind the precautionary principle: the burden of proof that certain inventions (of SB) are safe is on inventors and governmental auditors/observers. This is, however, a bridge towards more pragmatic arguments: the products and research-methods should be safe, constant oversight decreases the chance of malicious use (bio-security) and so on.

Phase IV: Deliberation

Weighing arguments/principles. As stated above, the fundamental questions concerning the identity of SB, as well as other emerging technologies, can hardly be overestimated. The Group prioritizes the importance of respecting human dignity, both in relation to the risks and possible accidents that could be the result of SB as well as the potential for SB to manipulate living organism and human tissue on a fundamental level. In other words, human beings deserve protection from the possible dangers of emerging (bio)technologies, both pragmatically (dangerous viruses, ecological disasters etc.) and principally (manipulation of human (fetal) cells, DNA-altering etc.). The latter is further explained with the earlier mentioned distinction between 'zoe' and 'bios', respectively life as natural phenomenon and life "in its social and cultural dimension" (EGE, 2009, p. 41) and as a set of experiences. Modern biotechnologies mapped numerous, if not all, 'parts' of the human body which might make a reduction of it to merely cells and DNA-sequences tempting, however, the Group strongly emphasizes the importance of always bearing in mind the intrinsic value of human being.

The in chapter one mentioned 'value-ethics' is relevant in revealing another important value for the Group: how do we want to relate to the notion of life if we are getting closer to not only manipulating but even creating it? This relates to the notion and pre-assumption of human beings as autonomous, moral agents who are capable of choosing what they want to do with themselves and their environment, but also which responsibilities they could have. It is, however, not as if the Group provides direct answers or moral judgments about such issues – they merely raise the questions to raise *awareness*.

But when turning to the pragmatic level of the ethical aspects of SB, it is obvious that safety and security are the foremost important principles the Group embraces. Although the promises of SB are certainly acknowledged, the general impression of the report is quite

conservative, that is to say: better safe than sorry. This is probably best embodied in the precautionary principle that the Group uses, in which the advocates of new technology resulting from SB should demonstrate its safety before it can be introduced. This attitude, in combination with recommendations for strict governmental oversights, including continuous risk-assessment, and the quest for constant awareness and reflection while the field of SB further develops, makes it plausible to state that a certain level of restraint and strong governance are highly valued by the Group.

This does of course not mean that SB is a 'moral bad'; instead and as said, the Group certainly acknowledges the enormous potential of this field of science, but the benefits may not be enjoyed at all costs and risks must be decreased as much as possible with governmental aid. Furthermore, other values relating to this are the recommendation for funding (more) basic and interdisciplinary research in the field of SB in order to a) strengthen the knowledge of SB on a more fundamental level and (thus) the global economic position of the EU and b) create more awareness under scientists for the ethical and social implications of SB.

If we were to make a short and raw hierarchical list of the preferred values of the Group, it could be ranked as follows:

- **Awareness** – continuous moral deliberation about emerging technologies like SB;
- **Safety** – including security and enforced with various governmental tools;
- **Justice** – a correct dividing of benefits and risks, both on EU-level and globally;
- **Intellectual property/research** – the encouraging of scientific endeavors with help of patenting, but to a limit set by the Group.

It may be obvious that it is very difficult to construct a 'perfect' list in which every important (moral) value is included and positioned, not only because ethical deliberations and relating values are no natural phenomenon that can simply be picked, but also because every topic has its own priorities. In the case of the ethical aspects of SB, the value of research seems rather low-placed, but this is of course, in general, not the case: it is almost impossible to overestimate the influence and importance of research for all of humanity, however, in the report this is already established – otherwise there would not even be a report on only one facet of research: synthetic biology.

Other values come therefore to the fore: how many risks do we want to take to know more about the world around us? How safe is this newly developed product for human, animal and environment? As said, this paragraph attempted to demonstrate that the general

tone of the report of the Group tends to an ongoing (moral) debate, both politically, scientifically and publically about our awareness of the implications, practical and principal, of emerging technologies like SB and that stringent safety protocols and sufficient governmental oversight must be in place and reviewed over time.

Phase V: Approach

Concrete actions. The recommendations mentioned in 2.1.2 provide sufficient information on which practical steps the Group thinks should be taken.

Responsibilities

Who are or is responsible for the execution of the prioritized values and following recommendations of the Group? This is, of course, first of all the governmental body called the European Commission, to which the report is directed and by whom it is requested. The European Commission should promote, by various measures, safety and security, the international debate concerning SB, a just division of benefits and risks, both on EU and global scale, a safe intellectual and academic environment with constant debate concerning emerging technologies and the dialogue between policymakers, scientists and the public. Those latter two are the other identified parties, just as mentioned in the third phase of the roadmap ('involvement'), with certain responsibilities – the scientific community should create constant awareness of the ethical and social implications of emerging technologies like SB, while this same awareness and critical thought is asked from the European community as a whole. The Group clearly indicates, however, that the government (in this case: the European Commission) is mostly responsible for making the other responsibilities possible.

Theoretical underground

The way in which the Groups approaches the ethical aspects of SB is *pluralistic*, which resembles the 'third way approach' Kymlicka suggested (see section 1.3). This means that various equally important principles are selected in order to reflect on the issue, as we have seen in the writings above. It also means that there is not one moral theory the Group appeals to, although, as said, the principles with a more principled character (that is: the universal respect for, inter alia, human dignity) are very dominant and explain the emphasis on quite conservative principles as safety and security.

2.2 The ethics of synthetic biology: the Commission

2.2.1 Contextual sketch

The Presidential Commission for the Study of Bioethical Issues (PCSBI) "is an advisory panel of the nation's leader in medicine, science, ethics, religion, law and engineering."[16] The Commission reports directly to the President of the United States of America who can turn directly to the Commission as well. This report was such a direct request of the President, which was a result of a significant breakthrough in the field of synthetic biology (SB) by the J. Craig Venter Institute (see Introduction, note 3). This breakthrough seemed to bring humanity closer to the holy grail of bio-engineering: creating life from scratch, with numerous benefits in prospect. At the same time, however, "it raises genuine concerns and so we must consider carefully the implications of this research" (PCSBI, 2010, p. iv). The report concerning the ethical aspects of SB is the consideration.

The report consists out a total of 179 pages. After the correspondence between the President and the Commission, the report presents an executive summary (17 pages) in which the analysis and recommendations (chapter 5) are summarized, the first chapter in which the Commission introduces the subject, the second chapter in which the ins and outs of SB (on a theoretical level) are explained, the third chapter about the applications, benefits and risks of SB, the fourth chapter devoted to governmental oversight on emerging technologies and, finally, the fifth chapter in which the ethical aspects of SB are analyzed and recommendations are presented.

Chair of the PCSBI is Amy Gutman, who was directly named as such by President Barack Obama in November 24th, 2009.[17] Gutman has a long and impressive curriculum vitae, but for here it suffices to state that she is also the H. Brown Distinguished Professor of Political Science in the School of Arts and Sciences of Penn, received her doctorate in Political Science from Harvard University and is known for being "a forceful advocate for increasing access to higher education, for integrating knowledge across multiple disciplines to address complex problems, and for championing civic engagement with communities both domestically and globally."[18]

[16] As found on http://bioethics.gov/cms/about, visited on 08-08-2012.
[17] As found on http://bioethics.gov/cms/amy-gutmann, visited on 08-08-2012.
[18] Idem.

2.2.2 Moral core of report

As mentioned before, the report was requested directly by the President, who asked the Commission to construct recommendations for the Federal Government to "ensure that America reaps the benefits of this developing field of science while identifying appropriate ethical boundaries and minimizing identified risks" (PCSBI, 2010, p. iv). The Commission departed from these three elements (benefits, risks and ethical boundaries) and thereby identified five basic ethical principles as guidelines for their analysis and recommendations. These principles are, in this order, public beneficence, responsible stewardship, intellectual freedom and responsibility, democratic deliberation and justice and fairness (ibidem, p. 112). The remainder of this sub-section will be the mentioning of those principles, accompanied by a short argumentation from the Commission and the final recommendation(s) relating to them.

Public Beneficence

Synthetic biology (SB), together with other emerging fields of science, bares many expectations. The techniques derived from it could provide, inter alia, an alternative for conventional energy sources, affordable medicine and safer and more sustainable food production. These benefits could affect everyone (both citizens of the United States as well as globally) in a positive way and thus making them possible belongs to the principle of public beneficence: to act in such a way that "maximize(s) public benefits and minimize(s) public harm" (p. 113). Public policy, then, should highly prioritize "(t)he development of strategies that will allow the field to continue to grow" (idem).

Although the "intermingling of academic and commercial research" (p. 114), which means that public and private investments in one way or the other collaborate, seems quite successful[19] according to the Commission, an increasing and/or reviewing of public funding is recommendable because the latter "promotes transparency and accountability" (p. 115) and makes research possible that is not commercially viable, such as research that is "exploring the normative and conceptual issues" (idem) related to SB. The Commission recommends therefore that a central body "such as the Executive Office of the President" (idem) reviews the way funding is divided, with special attention to interdisciplinary research that assesses the risks and "ethical and social issues raised by synthetic biology" (idem). Just as some

[19] As an example, the Commission presents the way the synthetically created medicine *artemisinin* is created – in a cooperation of both private and public funds. The medicine is an anti-malaria drug and can now be produced profoundly cheaper than before the invention in the field of SB.

other recommendations done by the commission that will pass by later on, this reviewing "should be completed within 18 months and the results made public" (idem).

The next recommendation done by the Commission concerns the relation of SB with other promising, emerging fields of science and the scarce resources (public funding) those fields compete for. The Commission states that "advancing the public good should be the primary determinant" (p. 118) when it comes to the division of public funding. This might very well be SB due its huge potential, but if other fields of science seem more promising, public funding should be rerouted. The Commission believes that this is an ongoing evaluation that should be done by, inter alia, the National Institutes of Health and the Department of Energy. In illustrating the importance of the just division of public funds, the Commission presents the example of the National Institutes of Health that "created several programs (for the innovation of new drugs - NN) that specifically support creative, highly innovative research approaches that might otherwise be too novel or too risky to receive funding" (p. 117). Many fabricators of drugs prioritize research of medicine of which they know that it will be profitable, while those new medicine are only a little bit better. However, public policy should promote and reward research that truly contributes to the public good, both in the US and internationally.[20]

Finally, the Commission identifies the tension between acting on the principle of public beneficence on the one hand and providing sufficient intellectual freedom on the other. This latter component can be obstructive when important inventions are patented, but also "encourage(s) innovation and investment by providing incentive to inventors" (p. 120). Patenting inventions that are a result of SB is, however, controversial; not only are the components subjected to patenting often (synthetic) organisms or DNA-sequences (can one patent 'living' things?), they are also mainly "standardized, modular parts (and) access to those standard components could be especially critical to the development of the field" (p. 121).

Therefore the Commission recommends that the Executive Office of the President investigates "whether current research licensing and sharing practices are sufficient to ensure that basic research results involving synthetic biology are available to promote innovation, and, if not, whether additional policies or practices are needed" (p. 122), ideally "completed within 18 months and the results made public" (idem). Finding the balance

[20] It would be interesting to find out whether this is merely the Commissions opinion or a broader shared vision among private firms, politicians and scientists in the US – the philosopher Thomas Pogge has published extensively about this subject, arguing that the current patenting system of medicines makes it impossible for the poorest on this planet to buy medicine and that the incentives for the producers are wrong – marginal enhancements to already existing (though sellable) medicines instead of inventing new, truly necessary medicines. See 'Relevant literature' (under References) for more information.

between protecting individual freedom and the need to share information with regards to public beneficence is difficult and therefore relevant policies and regulations should be closely monitored.

Responsible Stewardship

This principle is mainly concerned with the question how human beings can be "responsible stewards of natures, the earth's bounty, human health and well-being" (p. 123). In relation to SB, and other emerging technologies that can severely influence environment and/or society, this means that the benefits and risks of this new field of science must be assessed with the idea in mind that human beings are responsible stewards of this planet.

The Commission identifies two important positions in such stewardship. On the one hand there is the *precautionary principle* in which the advocate of a new technology is responsible for demonstrating its safety before it can be acceptable: according to the Commission, the European Union operates this principle on a statutory level (p. 124). On the other hand there is the *proactionary principle* in which new technologies should be considered beneficial and safe "unless and until shown to be otherwise" (idem).

The Commission, however, "proposes a middle ground – an ongoing system of *prudent vigilance*" (idem) in which careful and constant monitoring is embedded, because the Commission believes that there are already many competent "oversight mechanisms and bodies" in place who monitor emerging technologies and SB, although its potential, "does not raise radically new concerns or risks" (idem) compared to, for example, "molecular biology and nanotechnology" (idem).

Together with the fact that the Commission notices "increasing attention to this new field" (p. 126) by presenting a list with various revisions, reviews and reports of federal bodies (idem), the already apparent oversight bodies do not need extension. "Rather, the Commission urges the Executive Office of the President, in consultation with relevant federal agencies, to develop a clear, defined and coordinated approach to synthetic biology research and development across the government" (p. 127)[21]. Oversight and coordination from the government are key in the first recommendation concerning responsible stewardship.

By extension, the second recommendation (fifth in total) emphasizes the difficulty of risk assessment and the fact that "policy makers should develop policies that acknowledge uncertainty about both risks and potential benefits" (p. 128). Therefore the Commission states that an "interagency process" should be engaged in which various risk assessment

[21] It seems legit to quote this part of the fourth recommendation completely, for many other recommendations will refer to this one.

activities, including gaps due to new developments in SB, should be discussed. Although continuous monitoring is meant here, a first review "should be completed within 18 months and the results made public" (idem).

All those government-based measures are, however, in the end insufficient. Instead, the scientific society should itself be very critical on the risks of SB. The Commission notices that this already is the case and that "(i)ndividual scientists were among the first to raise concerns about the possible risks posed by synthetic biology research" (idem). This internal sharpness and criticism is, as part of responsible stewardship (of the scientific community), "both reassuring and essential" (idem).

Furthermore, the Commission recommends the use of certain safeguards to prevent synthetic organisms from surviving in places where they not belong (and could damage other micro-organisms and/or the environment as a whole). These safety measures should be reviewed continuously by the Executive Office of the President (as part of the first recommendation made in this paragraph and the fourth in total). If, however, field release of "research organisms or commercial products involving synthetic biology technology" (p. 131) is desirable, the correlating risks of such an event should be assessed in the same way as described in previous recommendations and "under the National Environmental Policy Act or other applicable law" (idem).

The scientific endeavors of SB have a highly international character. "From student competitions to commercial gene synthesis companies, the synthetic biology community is an interactive global network" (p. 132). This fact, combined with the global risks (spreads of viruses, for example) that could appear due to the impact of technologies derived from SB, makes that the Commissions finds it important that several federal departments, in line with the earlier mentioned coordinated approach led by the Executive Office of the President, "continue and expand efforts to collaborate with international governments" (idem) and other international organs like the World Health Organization.

Two recommendations under the principle of responsible stewardship remain: ethics education and the ongoing evaluation of (moral) objections. The recommendation to develop "appropriate and meaningful training requirements and models" (p. 134) of ethics education relates to the earlier mentioned quest for the reviewing of public funding for interdisciplinary (ethical, social, cultural) research related to the consequences of SB (and other emerging technologies, for that matter). In line with the importance of the just called critical attitude, both towards safety and moral issues, of the scientific society, the Commission recommends that the Executive Office of the President (in consultation with other, relevant parties) convenes a panel to consider the earlier mentioned training models.

The last recommendation relating to responsible stewardship states that ongoing, continuous evaluation of moral objections needs to occur "as research in the field advances in novel directions" (p. 140). The Commission comes to this recommendation through various moral objections against SB that are, according to the Commission, eventually not failing "to respect the proper relationship between humans and nature" (p. 139), but who need to be taken seriously anyway - especially with emerging and growing sciences like SB. The objections are divided into those with an intrinsic nature and those resulting from certain (expected) consequences of SB. The more intrinsic arguments hold that SB and equal sciences are "a grandiosity about human powers" (p. 135), resulting in a lack of respect for nature and the mystery of life. Others state specifically that SB is a bridge too far because it is about the *creation* of life instead the modification of it (like molecular biology), especially because the organisms created are specifically made for a certain function – a feature that explains the commonly used metaphors in SB, "BioBricks, living machines, hardware and software" (p. 136), and the possible "weakening of society's respect" (idem). More consequentialist arguments came to the forth in already discussed concerns about "biodiversity, ecosystems, and food and energy supplies worldwide" (p. 137), in which a skeptical attitude towards the capabilities of science and society to safeguard the possible risks resulting from SB is central. An ongoing, continuous debate concerning the ethical aspects of SB is therefore recommended.

Intellectual Freedom and Responsibility

According to the Commission, the intellectual and academic freedom of inquiry is a human right. This means that the field of SB, just as any other form of research, governments or even scientists (by self-regulation) should only be limited in gaining knowledge "when the perceived risk is too great to proceed without limit" (p. 144). As written earlier, the Commission believes in a responsibility of both the academic community and 'do-it-yourself' (DIY) amateur-scientists to keep a close watch on the possible risks of SB. The way in which this responsibility is bared, however, should be evaluated and re-evaluated periodically by checking "the effectiveness of current research oversight mechanisms and determine what, if any, additional steps should be taken to foster accountability at the institutional level without unduly limiting intellectual freedom" (p. 145).

It is understandable that the creation of a "culture of responsibility" is easier realized in an institutionalized setting than in the non-institutionalized DIY-sphere. Although the Commission believes that "the risks posed by synthetic biology activities in both setting appear to be appropriately managed" (p. 147) and that various governmental organized

"programs and workshops (…) bring together these groups" (idem), it also believes that developments in the field and more possibilities for amateurs in the near future makes continuous risk-assessment necessary "as part of the coordinated approach urged in Recommendation 4" (idem) and executed by, for example, the Department of Homeland Security and the Federal Bureau of Investigation. The first update of these risks "should be completed within 18 months and the results made public to the extent permitted by law" (idem).

The last recommendation of the Commission under this principle relates to the difficulty of freedom and responsibility in an international sense. The balancing of granting "completely free exchange of data and materials" (p. 149) to enhance the global position (and correlating scientific and economic benefits) of the U.S. with regards to SB and limiting the exchange to decrease risks of malevolent use of information is difficult to find. The Commission, however, is clear in stating that if "significant unmanaged security or safety concerns" (p. 150) are identified due to the following of the previous recommendation, the government should not doubt to apply mandatory measures "for all researchers, including those in both institutional and non-institutional settings, regardless of funding sources" (idem). Furthermore, revising the export controls by limiting information or material, for instance by scanning synthetic double-stranded DNA for being potentially harmful (viruses), belongs to the possibilities, however, such controls "should not unduly restrain the free exchange of information and materials among members of the international scientific community" (idem).

Democratic Deliberation

Where scientists, policymakers and other professionals who are somehow connected to the field of SB are often mentioned in the previous paragraphs, the principle of democratic deliberation centralizes the desired role and position of the 'common man'. According to the Commission it is both "critical" and "essential" (p. 151) that the public participates "in discussion(s) and deliberation(s) about emerging technologies such as synthetic biology" (idem). These ongoing discussions between professionals, policymakers and the public are deemed important to develop policies regarding SB at best, especially because it is a young field, so "there is a unique opportunity to shape its development in ways most likely to promote the public good while assuring safety and security" (p. 152). The Commission recommends and highly encourages such exchanges and beliefs that "scientists and policy makers (…) should respectfully take into account all perspectives relevant to synthetic biology" (p. 154).

To be certain that such debates are fruitful, however, the Commission makes clear that media in general and science journalist in particular have a responsibility to inform the public rightly about issues regarding SB. Especially naming advancements in the field 'playing (for) God', as happened frequently after the widely covered achievements of the J. Craig Venter Institute[22], are considered "unhelpful at best, misleading at worst" (p. 156) due to the "provocative nature" (idem) of such words. Therefore the Commission recommends that "a mechanism should be created (…) to fact-check the variety of claims relevant to advances in synthetic biology" (idem), hopefully contributing to a more informed population.

The last recommendation in this paragraph is about public education in general. The Commission underscores the importance of "scientific literacy" (p. 157) – the ability to grasp "scientific concepts and processes required for personal decision making, participation in civic and cultural affairs, and economic productivity" (idem, quoted from the National Academy of Sciences) and pleads for the expansion of educational activities concerning SB, but also all other fields of science. Concretely, the Commission recommends that the Executive Office of the President, hereby referring to the coordinated approach in recommendation 4, "should identify and widely disseminate strategies to promote overall scientific and ethical literacy" (p. 158). Finally, in line with the earlier named promotion of exchanges between inter alia laymen and professionals, collaborations between professional and 'do-it-yourself' communities, as well as the mere existence of such "do-it-together" (p. 159)-communities, are highly encourages by the Commission.

Justice and Fairness

How does one fairly distribute the benefits and risks in society, both nationally and internationally, which are a result of SB? This is the central question for the Commission in the last discussed principle 'justice and fairness', inter alia derived from the ideas of philosopher John Rawls and his "distributive justice" (p. 161), which refers to "the equitable allocation of goods and evils in a society" (idem). With holding the examples of semi-synthetic artemisinin (cheap anti-malaria drug) and synthetic biofuels in mind, the Commission argues that it is of "great value" to reach "those individuals and communities who would most benefit from them" (idem).

The first recommendation (number 17 in total) within this principle, however, is about the burden of risks, and then in particular the risks following from research in the field of SB. The Commission urges that the Executive Office of the President, in line with the earlier named coordinated approach, evaluates the "current requirements and alternative models to

[22] See note 3 in 'Introduction'.

identify mechanisms that ensure that the risks of research (…) are not unfairly or unnecessarily distributed" (p. 164), with the help of relevant professionals in the field. This evaluation, like certain others in previous recommendations, "should be completed within 18 months and the results made public" (idem).

The last recommendation (no. 18) within the principle of justice and fairness, as well as in the whole report, argues that "manufacturers and others seeking to use synthetic biology for commercial activities" (idem) should ensure that the benefits and risks are equally divided, thereby assisted by the Executive Office of the President who should "consider developing guidance materials and voluntary recommendations to assist manufacturers as appropriate" (p. 165).

2.2.3 Ethical reconstruction

In line with the method introduced in section 1.2 and the various underlying theories concerning the working of ethical commission in section 1.3, this sub-section will analyze the most important ethical elements of the PCSBI-report.[23]

Phase I: Exploration

General questions. What are the potential benefits of emerging technologies like SB? Which possible risks relate to SB? And how far could it bring us? The potential of this technology and the correlating benefits are often emphasized by the Commission, together with the question: how can we maximally reap those benefits?

Phase II: Explicating

Moral question. In the letter to the President, with the report attached, the Commission states that it examined, as requested, "the implications of the emerging science of synthetic biology" (PCSBI, 2010, p. v) and that it "offers recommendations to ensure that America reaps the benefits of this developing field within appropriate ethical boundaries" (idem). The moral problem, then, could be best derived from this solution: which ethically responsible actions should governmental agencies undertake to maximize benefits from the field of SB while a) minimizing, in a general sense, the risks and b) respect "appropriate ethical boundaries" (idem)?

Possible actions. As described in sub-section 2.2.2, under the principle Responsible Stewardship, two extreme actions could be undertaken by a government: applying a precautionary principle in which the advocate of a new technology is responsible for

[23] Due to the similarity of the subject various sentences hereunder will sound familiar due to the fact that the same goes for the earlier discussed EGE-report.

demonstrating its safety before it can be acceptable or applying the *proactionary principle* in which new technologies should be considered beneficial and safe "unless and until shown to be otherwise" (idem). As also described, the Commission discards both options and instead chooses for *prudent vigilance*, however, the possible actions of the federal government towards emerging technologies like SB are to be found between the just named 'extremes'.

Lacking factual information. Through the quickly developing, ever-changing and emerging nature of the technology, it is impossible to be constantly updated on the subject, however, due to numerous (public) deliberations and hearings the Commission organized it is plausible to state that there was no information available that would radically change the Commissions attitude.

Phase III: Analyzing

Involvement. Three parties play a central role: the government, the scientific community and the general public. According to the Commission, their perspectives and wants do not differ dramatically, although intellectual and academic freedom might sometimes clash with safety-measures to decrease the risks of malicious use of SB. Nonetheless, the Commission assumes that the government, scientific community and general public are all helped with the maximizing of public beneficence due to new inventions based on SB.

Phase IV: Deliberation

Weighing arguments/principles. The value that receives most attention and is frequently mentioned throughout the report is *public beneficence*. The human community should always strive "to maximize public benefits and minimize public harm" (p. 113), which, according to the Commission, also "encompasses a duty for society and its government to promote individual activities and institutional practices (…) that have great potential to improve well-being" (idem). No exception is made for the U.S.-government; the Commission recommends reviewing scientific funding in order to promote that scientific research that is most promising; the Commission beliefs SB could be such form of research. Together with the recommendation to switch to the production of (synthetic) medicine that truly benefit the community (see note 19) and the promotion for the individual right to enquiry (which, again, could be beneficial), the Commission instruments various other values in the name of public beneficence.

This does not mean, however, that every risk might be taken if there is the slightest chance of increased welfare. Instead, the Commission is aware of the potential economic and ecological risks of SB and asks for acting with *prudent vigilance*. Or, in other words, a

middle ground between a precautionary principle (inventor must proof 'innocence' of product) and a proactive principle ("let science rip" (p. 124)) in which everyone somehow connected with (emerging) technologies, both professional and laymen, take their responsibility in judging whether the possible benefits outweigh the risks. This must be seen in light of *responsible stewardship* – human beings as the keepers of the earth, with a duty to care "not only for human well-being today but also and importantly for future generations and the environment" (p. 123).

Beware, this does of course not mean that the government has a passive role. The gained benefits and probable risks need to be divided justly and those benefits should "reach those individuals and communities who would most benefit of them" (p. 162) – this is a task for the government. Finally, the way in which the public is committed to (discussing about) emerging technologies, democratic deliberation about scientific projects, is also considered to be important. If a hierarchical list with the relevant values would be constructed, it could be as follows:

- **Public beneficence** – acting so as to maximize the public benefits;
- **Responsible stewardship** – although the environment is a goal in itself, this stewardship is mainly based upon anthropocentrism;
- **Intellectual responsibility** – mainly the responsibility professionals in the field should take, including moral deliberation, in turn for intellectual freedom;
- **Justice** – the equal division of benefits and risks across society *and* beyond;
- **Democratic deliberation** – the voice of the public and the participation of it in discussions concerning emerging technologies like SB.

Although the Commission spends around six pages and one recommendation on 'ongoing moral deliberation', to which a non-consequentialist, principal moral approach is preceded, this awareness plays mostly a role in the consequentialist risk area (are we researching in a right way) instead of the principal area (should we do research on such a fundamental level anyway?). It is, however, part of responsible stewardship and this value is deemed quite important.

Phase V: Approach

The concrete steps that should be undertaken are to be found in sub-section 2.2.2, where a total of 18 recommendations are mentioned. Many of those recommendations are requests for further research and reviewing that should be conducted in a coordinated approach by the Executive Office of the President.

Responsibilities

As already stated, three parties are relevant here: the government, the professionals (scientists et al.) and the general public. Although many recommendations are directed towards the government and a serious set of tasks lie ahead ('within 18 months and the results made public'), it are often recommendations that aim to conduct further reviewing or promoting activities of other parties, for instance the scientific community or the 'do-it-yourself'-community (enthusiasts amateurs working with SB-technology). Especially the central role the Commission reserves for the own responsibility of scientists is strong, but the emphasis on democratic deliberation (every citizen should pay attention and bear some responsibility) also shows a direct preference for individual responsibility, thereby supported and partly controlled by the government.

Theoretical underground

The Commission chose a pluralistic approach in this report: selecting several relevant principles that are deemed to be important in the aspect of SB. Thereby it resembles the 'third approach' discussed by Kymlicka, however, the strong emphasis on the maximizing of public beneficence, not only as a principle itself but as an echo throughout the whole report, could be noted as the promoting of an unspecified form of utilitarianism.

3. Apples and pears?

Based on the findings in the previous chapter, this short but important chapter discusses both similarities and differences between the reports on the ethical aspects of synthetic biology (SB) from respectively the European Group of Ethics (EGE, 2009) and the Presidential Commission for the Study on Bioethical Issues (PCSBI, 2010). The comparison will be done quite simplistic on a contextual level (section 3.1) and more detailed on a level of content (section 3.2).

3.1 Contextual

Similarities

The reports are both written by governmental commissions, who were each requested to research the ethical aspects of SB by a governmental agency (respectively the President of the European Commission and the President of the United States of America). The structure of the reports is very much alike: both spend a whole chapter on what SB is, the political and legal aspects, the ethical aspects and a chapter concerning the recommendations.

Differences

An important difference concerning the recommendations, however, is the fact that the Group spends an *entire* chapter solely to the recommendations, while the Commission presents their most important principles at once with the recommendations. The most important differences, however, is the fact that the Commission spends a special chapter on the 'Applications, Benefits and Risks' of SB, while the Group barely emphasizes the benefits of SB, but instead begins their ethical analysis with the 'General moral aspects', spelling out their principled concerns.

3.2 Content

Similarities

Both reports have a pluralistic nature, that is to say: they present several principles c.q. values that are each and in themselves important, however, they also both prefer a certain value in such a way that the promoting of a certain underlying theory might be suggested. For the EGE this is the strong emphasis on a principled approach, while the PCSBI tends towards utilitarianism due to the promotion of the value of public beneficence. Nonetheless, a lot of their pragmatic principals overlap: the importance of involvement of the general public (democratic deliberation), the need for (and the right to) intellectual and academic freedom and a just division of the benefits and risks resulting from SB. Finally, both

commissions ask the exact same question: how to increase benefits, decrease risks, all "within appropriate ethical boundaries" (PCSBI, 2009, p. v).

Differences

But that, however, is where the similarities stop. Three relevant differences can be mentioned. Firstly, and this is the greatest difference between the Group and the Commission, the fact that the former devotes, as already argued in the contextual differences, far more attention towards the principled approach and the questioning of the very nature of technology, while the Commission is mainly concerned with the pragmatic issues and regards technology as a means to gain benefits. This is exemplified by the fact that the Group embraces the *precautionary principle* with regards to SB, in which inventors and scientists firstly need to demonstrate the safety of products from SB before it can be used. The Commission, however, centralizes around the principle of *prudent vigilance*, in which there is more freedom for scientific endeavors, although scientists do bear more responsibility.

Secondly, relating to this first difference, there is a sharp discrepancy between the emphasis of the EGE on safety and security, while the PCBSI is mainly concerned with the public benefits the field of SB could bring. The sharpness lies in the fact that the EGE is quite conservative with regards to how to proceed, while the PCBSI is progressive and does not want to miss the potential benefits deriving from (products of) SB. Let it be evident that this does not mean that everything is permitted, but that one could say, in a general sense, that the PCBSI is more welcoming towards emerging technologies like SB due to its potential benefits, while the EGE is more reserved.

The third and final difference is to be found in responsibility. While the Group is focusing mainly on the question how to govern scientific as well as amateur activities concerning SB, the Commission strongly emphasizes the importance of intellectual responsibility, especially amongst the scientific community, but also from the general public, which should try to stay connected with discussions concerning the ethical aspects of emerging technologies like SB. After all, science and technology are in service of the public beneficence.

Conclusion

Summary

This thesis started with formulating the following research question: how do the reports on the ethics of synthetic biology from both the European Group of Ethics (EGE) and the Presidential Commission for the Study of Bioethical Issues (PCSBI) differ in an ethical sense? In other words, after reading this thesis one should have an idea of what the differences are between these two reports - that is the goal of this thesis.

To reach this goal the **Introduction** starts by sketching the context in which the emerging of biotechnologies like genetical modification and synthetic biology (SB) take place: the controlling and manufacturability of living organisms, human beings included, means a drastic change in the way humanity sees itself and although SB is very promising in offering solutions both in and outside human bodies, various ethical concerns exist. Therefore two reports were written on this subject, one by the EGE (requested by the European Commission) and on by the PCSBI (requested by the American President). In order to compare those reports, three steps must be taken. Firstly, one much sketch the content of both reports, secondly, one must find a method to ethically reconstruct them (extracting core values, arguments, principles etc.) and thirdly, one must compare those reconstructions.

The **First Chapter**, however, first shortly explains what is understood by ethics and ethical commissions (1.1) in order to better understand the method used to systematically reconstruct ethical deliberations (1.2), based on Bolt et al. (2007): exploration of the problem, explicate the moral question, analysis of who are involved and what their wants are, mapping the relevant arguments, values and principles, weighing them (which are most important?) and checking which recommendations followed. Finally (1.3), the chapter concurs with a paper from Kymlicka (1993), who argues that ethical and governmental commissions should follow a pluralistic path in which various relevant principles are selected. The introduction of this paper is necessary to analyze the reports (and thus the commissions) on their theoretical underground: what is their aim?

In the **Second Chapter** both reports are described in a total (2.1.1/2.2.1) and ethical (2.1.2/2.2.2) fashion to a) form a better picture on what the reports are about and b) offer consistency and independence of this thesis. Based on these descriptions the reports are subjected to the earlier mentioned method (2.1.3/2.2.3), which shows that the EGE-report is emphasizing a principled and conservative approach with a significant responsibility for the government agencies (EU), while the PCSBI-report is more pragmatic, focuses on the

numerous benefits that could derive from SB and how gaining these benefits should be promoted by both commercial and non-commercial (for instance public funding) institutions. Thereby, both individual scientists and scientific communities as a whole bare a responsibility to ensure proper ethical deliberation concerning the field of SB.

Finally, **the Third Chapter** compares the reports on a contextual level (structure, form – 3.1) and on the level of content (3.2) between the two reports, leading to the following answering of the research question.

Answering the research question

The reports differ on three major points. First, the report of the PCSBI has a highly pragmatic character, while the EGE-report is emphasizing the general ethical aspects, which are more of a principled character. This means that the American report selects practical principles that help determining how maximum public benefit can be gained while minimizing the risks, where the European report questions not only the fruits of this technology but also this technology *itself*: are we willing to go as far as SB could take us? And if so, how can we do this as safe as possible? Yes, in the PCSBI-report ongoing moral evaluation is also mentioned, but its role is significantly smaller than in the EGE-report.

Second, when focusing on the pragmatic approaches of both reports, the EGE emphasizes safety and security, while the PCSBI attaches most value on public beneficence. This means that the EGE has a more conservative attitude towards SB due to both its potential risks and the just called principled deliberations.

Third, the division of responsibilities differs. The EGE keeps the recommendations and relating actions close to governmental agencies and states that most responsibility lies with the policymakers, while the PCSBI strongly invokes the intellectual and academic responsibilities of scientists and the moral obligation for laymen to keep somehow deliberating on SB and other emerging technologies.

Recommendations and remarks

Various remarks could be made on this thesis. First the question whether it is truly necessary to go into the very nature of ethics, instead of directly and more explicitly defining what is meant with an ethical commission (or committee). The difficulty, however, is that this thesis should, in my opinion, be readable for everyone and thus talking about comparing ethical reports requires a short introduction on what ethics is. In other words, the quality of this thesis might be improved if it aimed more directly on the ontological status of ethical (and governmental) commission, but the readability might suffer from it.

Secondly, the method and meta-analysis. Why Bolt (2007)? And why Kymlicka (1993)? Although better methods might exists, for example a specialized method for comparing different ethical reports, I did not find any and the roadmap seems to be a good check-list to extract the most important moral deliberations of the reports. The article of Kymlicka was presented to me by my supervisor, Frans Brom, as a means to transcend the one-on-one comparison and look for the theory *behind* the ways commissions operate. I found the article very useful and could see how Kymlicka's theory could be applied on those reports, however, a more critical attitude towards this work, including a short literature-survey on which scholars reacted on him, might not have been wrong. Then again: there is only so much you can do.

This brings me to the 'how' and 'why' issue mentioned in the introduction. Although this thesis provides an answer on *how* the reports differ, no explanation is given. It seems therefore recommendable to, in extension to this research, write a political or sociological (or both) analysis in which those differences can be explained. Furthermore, a legal analysis would certainly be no luxury, for it would map and clarify the current policies and legal systems, creating a better understanding of how the EU and the USA see the emerging field of synthetic biology.

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