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Synthetic biology: Too early for assessments? A review of synthetic biology assessments in Germany

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Synthetic biology is an emerging interdisciplinary domain that focuses on the design of biological parts and systems. Despite its envisaged contribution to tackling various global challenges, there is uncertainty regarding potential impacts, benefits and risks of synthetic biology. Assessments can facilitate policy-making and technology governance as a means to both addressing and potentially decreasing uncertainty. In this respect, public engagement has been recommended to improve the societal accountability of techno-scientific development, as well as been criticised for potentially restricting innovative behaviour. Germany faces a challenging conflict: there is considerable potential to develop synthetic biology but public opinion is generally critical towards genetic modification. This paper reviews the nature and purpose of synthetic biology assessments in Germany and analyses their role in the policy-making processes. Overall, the current state of assessments seems to be characterised by a rather early stage of development and a lack of participatory approaches.

Keywords: synthetic biology; assessment; participation; uncertainty; governance; Germany.

1. Introduction

In the past decade, synthetic biology has gained attention from policy-makers due to its envisaged future technological potential (European Group on Ethics 2009; Presidential Commission for the Study of Bioethical Issues 2010). The German context seems well suited to facilitate synthetic biology's progression. On the one hand, Germany's strong history with respect to its engineering and chemical sectors aligns with synthetic biology's engineering focus and its applicability for chemical production. Indeed, Germany shows considerable activity at the European level with regard to patent applications relevant to synthetic biology (van Doren et al. 2013). On the other hand, there is a lack of clarity regarding Germany's transformation of its available resources into developing synthetic biology. Federal support and formal engagement in the creation of networks and research programmes related to synthetic biology still seems limited. In a German parliamentary inquiry in 2011 (Röspel et al. 2011), federal support of synthetic biology R&D was formally denied by federal representatives (Bundesregierung 2011). In turn, this was criticised by a German non-govermental organisation (NGO) which claimed that federal support was present 'in disguise' by taking advantage of the present confusion with respect to the definition of synthetic biology (Testbiotech 2011). This led to controversy regarding Germany's federal interpretation of synthetic biology and the potential institutional evasion of existing ethics-, environment-, safety- and security-oriented debates.

Although relatively minor, this small political dispute illustrates the degree of uncertainty among policy-makers dealing with this emerging techno-scientific domain. Assessments are able to reduce uncertainty through providing policy-makers with knowledge that could optimise the governance of synthetic biology. Synthetic biology, at least in its current state, is often compared

with genetic modification which initiated radical and critical public opposition in Europe, including Germany. This opposition towards genetic modification highlights the potential importance of regulatory transparency and multi-stakeholder involvement in creating sustainable markets, public acceptance, and legitimate science and technology governance.

As a result, there is a need to reappraise the role of both scientific evidence and the establishment of a legitimate context that can accommodate value-based opinions (Tait 2012). Since many of synthetic biology's expected impacts relate directly to issues concerning safety, security and ethics, it is believed that participatory approaches are required to create a legitimate context for technological development (Schmidt et al. 2009). In addition, it is likely that synthetic biology's broad technological scope and diverse actor involvement (Delgado and Porcar 2013) should be addressed in any legitimate assessment practice. However, despite the perceived necessity of participatory approaches in synthetic biology, upstream engagement is also contested (Bauer 1995; Coates and Coates 2003). Particularly in the context of emerging techno-scientific domains, both technological and non-technological uncertainty may reduce the quality and value of participation within assessment practices.

Against this background, this paper aims to review the state of synthetic biology assessments in Germany.[1] How can the current assessment situation generally be characterised? What role do assessments intend to play? And finally, what kind of methodological approaches have been used? The paper is structured as follows: following a brief description of synthetic biology, we elaborate on the relation between technology governance and knowledge, including the potential value of upstream engagement in assessing synthetic biology. We then introduce and review the current state of synthetic biology assessments in Germany. The paper ends with a discussion of our main findings and suggests additional reflection on different national and international synthetic biology assessment practices, as a potential direction for future research.

2. Synthetic biology, assessments and upstream engagement

2.1 The emergence and governance of synthetic biology

The concept of synthetic biology has evolved since its first public appearance in the early 20th century, when both Leduc (1912) and Loeb (1912) speculated about the possibilities of creating artificial living systems. In the past 100 years, it has aimed to describe the directed improvement of production, formation, and cellular properties through the modification of specific biochemical reactions, as well as the introduction of new ones with the use of recombinant DNA technology (Jarboe et al. 2010; Stephanopoulos and Vallino 1991). Around a decade ago, this concept of bio- or metabolic engineering (Ball 2004) returned to its foundations, when scientists restarted referring to synthetic biology as being related to the synthesis of unnatural molecules (Rawls 2000; Sismour and Benner 2005), unnatural chemical systems (Benner and Sismour 2005), biology-inspired systems (Pleiss 2006) and functions that do not exist in nature (Serrano 2007). Although there is still a lack of consensus regarding synthetic biology's definition, it is currently observed as a meta-discipline of various scientific fields (UK Synthetic Biology Roadmap Coordination Group 2012) with a strong emphasis on the convergence of biology and engineering (Elowitz and Lim 2010) to make the design, construction, and optimisation of biological systems easier and more reliable (Kahl and Endy 2013). Synthetic biology's concepts have driven the involvement of various science and research communities concerned with improving biological understanding, developing enabling technologies or the integration of engineering principles (van Doren and Reiss 2014).

It is believed that synthetic biology could contribute to the development of various sectors, including biomedicine, energy, chemical production (Khalil and Collins 2010) and bioremediation (De Lorenzo 2008). Although envisaged future applications in multiple industrial sectors could benefit both developed (BCC Research 2009) and developing countries (Wellhausen and Mukunda 2009), synthetic biology's progress does not go unchallenged (e.g. see König et al. 2013), as issues related to biosafety (e.g. see De Lorenzo 2010), biosecurity (e.g. see Mukunda et al. 2009),[2] intellectual property rights[3] or ethics[4] may become increasingly critical in the long run. As a consequence, optimising the governance of synthetic biology has been discussed with regard to existing regulation relevance (Carr 2011; European Academies Science Advisory Council 2010), the need for additional synthetic biology specific regulatory forms (Kuzma and Tanji 2010), and precautionary governance that could influence the balance between supervisory control and research freedom (Byers and Casagrande 2010; Parens et al. 2009; Rodemeyer 2009).

In general, science and technology policies aim to develop capabilities for technological innovation and competitiveness based on the perceived critical impact of science and technology on national and industrial competitiveness (Simai et al. 2003). Compared to conventional methods of long-term technology planning (Lundvall 2003), it is believed that dynamic and multi-layered policy approaches are required to manage technology more effectively (Campos and Machado 2000). Historically, science policies have transformed from predominantly facilitating discovery towards a means to both generate application-oriented knowledge (Gibbons et al. 1994) and to represent transdisciplinary societal and

economic interests, purposes and goals (Ihde 2003; Latour 1987). Due to this transition, traditional boundaries between scientific disciplines, between science and technology, between technology and society, between theory and practice, between nature and culture and between facts and values have become blurred (Liebert and Schmidt 2010a).

Due to the increased competitive role of science and technology, in addition to a globalised economy and the increasing scale of social problems and solutions, the context of science and technology has changed (Smits et al. 1995). In addition to a changing context, the understanding of technological change has also evolved. This evolution is driven by alternative conceptions regarding essential innovation process elements, the perceived role of both market and government, and the focus towards social change through the recognized importance of societal acceptance—including the democratisation—of new technologies (Smits et al. 1995). According to the concept of the innovation system (Edquist 1997, 2004; Lundvall 1992), technology policy would need to change from concentrating primarily on generating new technologies and move towards translating technologies into successful products, services and solutions which tackle social problems (Freeman 1995).

2.2 Assessment, uncertainty and the role of upstream engagement

With respect to the changing function of science and technology governance, assessments are instruments which provide valuable input through systematic identification and evaluation of potential secondary consequences—in terms of the impact of science and technology on social, cultural, political, economic and environmental systems and processes (Coates 1975). Regarding the increased political embedding of science and technological development in society, assessments can also support an interactive and communicative process for forming public opinion on societal aspects related to science and technology (Bütschi et al. 2004), including overcoming problems of legitimacy (Black 2008) and technology conflicts (Fleischer et al. 2005). Assessments intend to balance different scientific perspectives, identify neutral positions between stakeholders (Coates and Coates 2003) and identify viable options for technological development and policy (Vig and Paschen 2000). Furthermore, they could provide a means to articulate user demand and enhance communication between users and producers in all phases of the innovation process (Smits et al. 1995).

The scientific output generated by assessments is heavily dependent on available knowledge that can be used as an input for conducting assessments. However, such availability seems problematic in the context of synthetic biology. In this sense, synthetic biology has much in common with the characteristics of emerging technologies in general, being new technologies derived from radical R&D methods (Wood and Brown 1998), but without having short-term commercialisation potential (Adner and Levinthal 2002).[5] In addition to the early technological development phase, emerging technologies are increasingly characterised by complex and interdependent components, widespread application potential (Fleischer et al. 2005) and tend to have a high degree of uncertainty, complexity and limited availability of data.

Despite these challenges, assessments are likely to be an important instrument in optimising the development trajectory of synthetic biology. Such an instrumental role seems especially relevant with regard to the argued diminished control of future technology trajectories parallel to increased technological development, which could potentially lead to system lock-in of undesirable innovations with negative externalities (Collingridge 1980). Although the generalisability of such lock-in processes is still not evident, it has been argued that increased appreciation of the technological and social context of science could overcome the Collingridge dilemma (Liebert and Schmidt 2010a). Especially with regard to synthetic biology, whose expected impacts directly relate to issues concerning safety, security and ethics, it has been argued that participatory approaches and upstream engagement might be required to create a legitimate context for technological development (Schmidt et al. 2009). In addition, synthetic biology's broad technological scope and the involvement of diverse actors (Delgado and Porcar 2013) may need to be addressed and taken into account in any legitimate assessment practice.

In general, the emphasis on expert involvement in assessments has been increasingly criticised. Institutionalised expertise can often be challenged by counter-expertise addressing the uncertainties and ignorance embedded in the knowledge (Knorr-Cetina 1999; Böschen et al. 2010; Hulme 2009; Jasanoff 2005). There is also increased awareness of non-knowing (Beck 2008) escaping the discipline of analysis (Jasanoff 2003). In the context of synthetic biology, it has been argued that scientific secretiveness, expert dominance and negligence of unintended consequences could enhance existing public suspicion (Torgersen 2009).

As a consequence, assessments have increasingly taken on board arguments as to the importance of participatory approaches (e.g. see Guston and Sarewitz 2002; Schot and Rip 1997; Barben et al. 2012). To ensure that science contributes to the common good, it has been argued that more diverse forms of public knowledge and social intelligence should be increasingly valued through opening up innovation processes at an early stage (Wilsdon and Willis 2004). It is believed that upstream engagement could contribute to fundamental issues of technology risks, ownership, beneficiaries and purpose (Wilsdon and Willis 2004). There are several justifications regarding actor interaction in technology assessment. Actor interaction provides more effective articulation of social needs in the face of both

market failures and other limitations of private initiatives (Smits et al. 2010). In addition, it can increase the competitive strength of enterprises through aligning their products with public expectations—thereby improving acceptance and the social embeddedness of knowledge during the early phases of technological development (Smits et al. 2010). Participation provides opportunities to articulate user need, improve producer response and enhances democracy through allowing citizens the opportunity to influence the course of science and technology (Smits et al. 2010). Moreover, those outside the scientific regime can explore scientific weakness through the evaluation of expertise (Collins 2009; Collins and Evans 2002), improve orientation concerning the power/actor dimension (Liebert and Schmidt 2010b), attune technological development to societal needs (Joss and Bellucci 2002), and provide strategic intelligence for decision-making systems regarding science, technology and innovation (Smits et al. 2010).

This argued necessity for early participation to improve future consumer acceptance and public understanding is also present within the sphere of synthetic biology (Torgersen 2009; Schmidt et al. 2009; Gaisser et al. 2008; European Academies Science Advisory Council 2010). In order to complement current regulation and compensate for synthetic biology's rapid development, scientists' awareness and interactive involvement with stakeholders and the public have been argued to be necessary concerning issues of safety, security, ethics and the science–society interface (Ganguli-Mitra et al. 2009; Stemerding et al. 2009). Likewise, due to synthetic biology's interdisciplinary nature and broad spectrum of potential applications, continuous dialogue between different stakeholders—those who could be directly or indirectly impacted by synthetic biology—is likely to be required (Gaisser et al. 2008; European Academies Science Advisory Council 2010). Arguments have been made that public support and understanding of synthetic biology research is needed to support significant scientific advances through funding and regulation (Royal Society 2010).

However, it has also been argued that upstream engagement could potentially hamper the R&D process and block specific strands of research which are irrationally associated with feared or unaccepted impacts (Bauer 1995). Broad public participation might not only be unnecessary, but could also be inappropriate for many topics (Coates and Coates 2003). Technologies prone to skewed benefit distribution also tend to be more intensively scrutinised (Torgersen et al. 2002). In addition, the way in which synthetic biology is framed in public debate could influence the inclusion of deliberated issues, the legitimacy of arguments made during participatory approaches and the conceptualisation of the public in general (Torgersen and Schmidt 2013). It has been argued that standards might be required to determine both the quality and breadth of the evidence included, and the encouragement and accommodation of alternative values in discussions (Tait 2009). It should be presumed that upstream engagement could restrict research activities as well as fail to avoid conflicts and mistakes within technological development (Tait 2009).

Despite the implications of upstream engagement in technological development, the impact of participatory approaches is still unclear. Although scientists have acknowledged the need to anticipate potential risks and public unease (Maurer et al. 2006) through aligning research with public attitudes by means of public consultation negotiating the boundaries of 'socially acceptable science' (Balmer and Martin 2008), they do not feel the need to address broader political and socio-economic issues (Torgersen 2009). Furthermore, although there have been a number of public and private initiatives on national and international level focusing on ethical, legal and social aspects (ELSA), the impact of such programmes in stimulating public dialogue is still unclear. Finally, although a number of 'science-in-society' research projects have been initiated by the European Commission in order to stimulate public dialogue, it is unclear to what extent public participation has influenced the strategic intelligence used for policy advice focused on synthetic biology.

3. Synthetic biology assessments in Germany

Given its substantial innovation (and market) potential, Germany seems ideally placed to explore possibilities and challenges related to the development of synthetic biology. Despite Germany's limited federal engagement with synthetic biology debates, a number of assessments have been (and continue to be) conducted.[6] Taking into account both the appreciation and contestation of participatory approaches in directing the development of synthetic biology, in combination with the potential impact of assessments in science and technology governance, we now provide an overview of German synthetic biology assessments and their role in policy-making processes. We start with a descriptive overview of all completed and ongoing assessments, which is then followed by an analytical reflection on the assessments of synthetic biology that have been completed in Germany.[7]

3.1 A chronologic overview of assessment practices

3.1.1 Completed assessments. The earliest synthetic biology assessment identified is a collaborative statement paper (Deutsche Forschungsgemeinschaft et al. 2009) by the Deutsche Forschungsgemeinschaft (transl.: German Research Foundation), the National Academy of Science and Engineering (acatech), and Germany's Nationale Akademie der Wissenschaften Leopoldina (transl.: National Academy of Sciences Leopoldina)—three

organisations dedicated to the advancement of science and research in society. As the subtitle 'Statement' suggests, the assessment was not commissioned by any external actor but was self-initiated. Being aware of the importance of public dialogue for the success and acceptance of emerging techno-scientific domains, the statement's main purpose was to initiate such a dialogue on synthetic biology, with a focus on potential opportunities and risks.[8] As such, it is explicitly:

> ...directed at representatives of political bodies and the authorities, the public, and last but not least, the scientific community. (Deutsche Forschungsgemeinschaft et al. 2009: 56)

Its recommendations include: the promotion of basic research and academic education in synthetic biology, conducting further ELSA research to explore opportunities and reduce risks, to apply the precautionary principle in situations of high uncertainty, and to conduct ethical evaluations on constructed life forms which are based on synthetic biology. With regard to biosafety and biosecurity, it is stated that existing legislation in Germany is sufficient, although suggestions are made to scientifically monitor developments in synthetic biology. This monitoring was to be carried out by the Zentrale Kommission für die Biologische Sicherheit (ZKBS; transl.: Central Committee on Biological Safety). Methodologically, the assessment was based on an international one-day workshop whose participants included scientists from various disciplines—such as biochemistry, molecular biology, genetics, microbiology, virology and social science—and only few representatives from public institutions and industry. Starting from there, an interdisciplinary working group compiled the statement paper which was, after a review process, finally approved by the executive committees of all three organisations.

A year later, this statement was followed by a report from Testbiotech (Testbiotech 2010), a German NGO committed:

> ...to promote independent research and public debate on the impacts of biotechnology.[9]

This was also a self-initiated assessment with no external client.[10] Stating 'a critical analysis' in its title, the report's main objective was to stimulate public debate on synthetic biology. Another, more implicit, aim was to work towards certain amendments of the German Genetic Technology Act (Gentechnikgesetz). This second goal has not yet been achieved. Although the report covers issues around synthetic biology's potential benefits and risks, its *de facto* focus is on risks, ethical issues and public debate. As for biosafety, the report suggests developing, introducing and working with a new protection concept called 'evolutionary integrity', a principle that should protect an ecosystem's natural dynamic. It is stated that a release of synthetic life forms should be avoided under all circumstances. For the scope of biosecurity, it is claimed that all firms and research institutions should be strictly monitored and controlled. A moratorium on all public funding of synthetic biology is also proposed as long as this emerging techno-scientific domain has not been discussed intensively in the public sphere and new regulations have not come into effect. In terms of its methodology, the Testbiotech assessment was basically carried out by desk research, whereas the final report was subjected to some type of peer-review process. Apart from that, no external actors of any kind were involved.

Following Testbiotech's report, a position paper was published a year later by the Gesellschaft für Chemische Technik und Biotechnologie Dechema (transl.: Society for Chemical Engineering and Biotechnology) (Dechema 2011), that seeks:

> ...to promote and support research and development in chemical technology and biotechnology.[11]

This paper was also self-initiated and authored by a working group on synthetic biology within Dechema. It was intended as a reaction to a perceived lack of support for techno-scientific research and the impression of an overabundance of ethical debates and assessment workshops on synthetic biology that fail to consider the international state-of-the-art.[12] Thus, one objective was to provide a summary of what has already been discussed on an international level. Another objective was to work towards a change of German policy through the promotion of synthetic biology research (instead of further ELSA research). Accordingly, the topic of the position paper is the current state of synthetic biology in Germany. The paper recommends that Germany should become more pragmatic in dealing with synthetic biology, otherwise it will lose connection with the forefront of international development. The media coverage on synthetic biology so far is seen to be fair and well-informed, implying that there are no reasons to fear public outrage. Risks of synthetic biology are hardly addressed, while current regulation is seen to be sufficient. The Dechema paper was written and revised on the basis of internal intelligence, without the involvement of external actors.

In 2012, the Interdisciplinary Research Group 'Gene Technology Report'—an initiative of the Berlin-Brandenburgische Akademie der Wissenschaften (transl.: Berlin-Brandenburg Academy of Sciences and Humanities), which was established in 2001 and strives to monitor the development of genetic engineering in Germany—produced its first publication on synthetic biology (Berlin-Brandenburgische Akademie der Wissenschaft 2012b). In line with the Research Group's general working approach, their assessment was not commissioned by an external actor, but was self-initiated. According to its foreword, its main aim was to increase transparency within public debate on synthetic biology. Being a volume that comprises various articles by different

authors, it covers diverse topics such as: a historical view on synthetic biology, therapeutic perspectives, philosophical and ethical implications, public perception, media coverage and some data on selected indicators (e.g. publications, research funding and public events). However, only the three-page 'key conclusions and recommendations for action' are accounted for by the Research Group itself (Berlin-Brandenburgische Akademie der Wissenschaft 2012a). In these conclusions, synthetic biology is framed as biological engineering with a high potential for applications in environmental protection, energy supply, chemical-technical production and medicine. It is stated that:

> . . . synthetic biology does not presently enjoy majority acceptance in Germany. (Berlin-Brandenburgische Akademie der Wissenschaft 2012a: 41)

Also, to date it does not implicate any new problem areas unknown to biotechnologies in general, although this may change in the future. In particular, the growing field of do-it-yourself research might soon demand closer scrutiny. However, no need for further regulation is presently seen. Apart from the different authors whose articles—as is explicitly stated in the volume's foreword—do not necessarily reflect the view of the Interdisciplinary Research Group, no other actors were involved.

The first synthetic biology assessment in Germany that was not self-initiated, but commissioned by a public authority, was the monitoring report on synthetic biology by the Central Committee on Biological Safety (Zentrale Kommission für die Biologische Sicherheit 2012) – an organisation affiliated to the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (transl.: Federal Office of Consumer Protection and Food Safety). The assessment was initiated by the accountable Federal Ministry of Food, Agriculture and Consumer Protection, following up on a recommendation made in the assessment by the Deutsche Forschungsgemeinschaft et al. (2009). Institutionalised in 1990 by the German Genetic Technology Act (Gentechnikgesetz, GenTG), the ZKBS' main task is to assess the risks of genetically modified organisms and the safety of the corresponding infrastructure and activities. The main objective of the synthetic biology monitoring report follows this mandate. The report covers five research areas: the design of genes and genomes, metabolic engineering, xenobiology, the building of minimal cells and gene circuits. It concludes that research approaches currently applied in Germany do not imply any additional risks (some synthetic biology approaches even tend to increase biosafety) that could not be managed by the active GenTG. However, the report also points to exceptions. For instance, *in vitro* DNA synthesis is perceived not to be covered by the GenTG as long as it is not placed within living organisms. This would also apply to *de novo* synthetic biology organisms lacking comparability to natural life (bottom-up approach). As for the report's methodological approach, both desk research by the committee's office and an interdisciplinary workshop fed into the assessment process. It should also be noted that the ZKBS consists mainly of experts in microbiology, genetics, virology etc., but it also has members representing, among others, the economy, labour unions and environmental protection organisations.

3.1.2 Ongoing assessment efforts. In addition to these five assessments which have been completed and published, we also identified several ongoing German synthetic biology assessments. Although we did not include ongoing assessment efforts in our review, since no final report was available (status as of December 2013), we will briefly mention them here to complete our description of the current situation in Germany.

An interdisciplinary study called 'Engineering life', which officially ended late in 2013, was funded by the ELSA programme of the (Bundesministerium für Bildung und Forschung (BMBF; transl.: Federal Ministry of Education and Research)).[13] It consisted of five rather disciplinary sub-projects focusing on ethical, theological, legal and biological aspects, as well as on risks and opportunities. These projects have already resulted in several academic publications (e.g. Dabrock et al. 2011; Boldt et al. 2012; König et al. 2013). The academic debate in Germany around the ethical issues raised by synthetic biology can undoubtedly be described as advanced. The BMBF has funded another assessment project on synthetic biology titled 'SynBioTA' focusing on both risks and opportunities. Although this project should have been completed in 2013, no publicly available report could be found.[14]

In addition, a classical technology assessment has been commissioned by the German Parliament to its Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (TAB; transl.: Office of Technology Assessment at the German Bundestag). Although it was originally scheduled to be completed in 2013, the overall assessment process is still ongoing.[15] The same holds true for an assessment conducted by the Europäische Akademie (transl.: European Academy of Technology Assessment) in Germany.[16] Another running assessment project titled 'SynGovernance' is currently being carried out by the Institute for Technology Assessment and Systems Analysis (ITAS) on behalf of the synthetic biology initiative of the German Helmholtz Association.[17]

3.2 An analytical reflection on conducted assessments

In order to analyse and compare the purpose of assessments or the roles they aim to play in the political process, we used an approach which was developed in

the European project 'Technology Assessment in Europe: Between Method and Impact' (Decker and Ladikas 2004). The approach has two dimensions: the first dimension depicts the different roles an assessment aims to play, which can be cognitive (raising knowledge), normative (forming attitudes) or pragmatic (initialising actions). The second dimension depicts the extent to which an assessment addresses technological/scientific, societal or policy aspects. Classifying the German assessments that we have reviewed shows that the majority aim to play a cognitive role by raising knowledge about the scientific and technological aspects of synthetic biology. While this is not surprising, it should be noted that the Dechema and Testbiotech assessments also aimed to have both a normative and pragmatic role by forming attitudes (in the sense of political agenda setting and stimulating public debate) and initialising actions (in the sense of aiming for a change in policy-making processes).[18] Certainly, these two assessments strive for quite different directions for technological development. Whereas Dechema (2011) in its assessment promotes applied synthetic biology research, Testbiotech (2010) highlights critical issues related to the release of synthetic life, the need for additional monitoring- and control-based regulation and the establishment of a synthetic biology moratorium in the absence of such regulation. The other three assessments have within their cognitive role an additional focus on raising knowledge about the societal and policy aspects of synthetic biology.

There are a few indications that the reviewed assessments had some impact on political processes in Germany, including references made in the political inquiry by Röspel et al. (2011) to the Deutsche Forschungsgemeinschaft et al. assessment and to a public call[19] by Testbiotech based on its own assessment (2010). In addition, the German government followed up on one of the recommendations by Deutsche Forschungsgemeinschaft et al. (2009) to commission the monitoring by the ZKBS, despite this being an obvious step given ZKBS's general mission. Apart from that, no direct line to decision-making or new regulations could be found, though it must be noted that such need, excepting Testbiotech's assessment, was not claimed by the reviewed assessments.

Regarding the scope of assessments, we observe that issues related to biosafety, biosecurity and the economy are dominant. Apart from the conflicting Dechema and Testbiotech assessments, many of the overall conclusions made by assessments seem to align. However, the often generic approach to synthetic biology taken in assessments seems to have caused unspecific conclusions. With respect to observed assessment purposes, there seems to be limited appraisal of the rich variety of potential synthetic biology applications. This generic approach is correlated with the long-term anticipatory approach regarding the potential future impacts often observed in assessments. Due to the lack of applied structured tools for anticipation, the generally unspecific anticipatory approach taken in synthetic biology assessments is closely related to the conceptual, but limited, level of attention paid to more specific possibilities for the commercialisation of synthetic biology. However, it should be noted that certain assessments (Dechema, Berlin-Brandenburgische Akademie der Wissenschaft and ZKBS) also include rather retrospective perspectives within their assessments, with considerable reflection on synthetic biology's past developments and current state.

With regard to the methodological approaches used, it seems that the German assessments we reviewed try to apply available scientific knowledge—knowledge mainly rooted in the synthetic biology literature—in a transparent manner. Most striking, however, seems the limited role of participatory approaches within assessments, even with respect to ongoing practices in Germany. Stakeholder participation has been limited and there is no evidence of lay participation. Even with regard to scientific expertise, it is remarkable that—with the exception of the Deutsche Forschungsgemeinschaft et al. and ZKBS assessments—only previously defined persons or (expert) groups conducted the assessments. External experts are barely included, either temporarily or permanently. This methodological bias towards literature review and scientific expertise might not be unexpected when one considers synthetic biology's pre-commercial nature and limited available knowledge. Since the majority of synthetic biology developments are still based on fundamental research, it is not unexpected that assessments use the actors involved in these efforts as a main source of understanding and evaluation, in order to determine synthetic biology's unique characteristics and features in comparison to more traditional biotechnology practices. But the argued criticism regarding selective expertise inclusion, counter-expertise and non-knowing (cf. Section 2) is not reflected or structurally addressed in the assessments. Since many assessments stress the importance of public debate on synthetic biology, the limited appreciation of both public and stakeholder participation in German synthetic biology assessments seems surprising.

4. Conclusions

Overall, the current state of synthetic biology assessments in Germany seems to be characterised by its early developmental stage. The first wave of assessments (2009–12) were mainly self-initiated (Deutsche Forschungsgemeinschaft et al., Testbiotech, Dechema, and also Berlin-Brandenburgische Akademie der Wissenschaft) with an important—and often explicit—interest in positioning themselves in emerging debates on synthetic biology. The first assessment that can be traced back to a mandate given by a public authority appeared in 2012 (Zentrale Kommission für die Biologische Sicherheit

2012). This benchmarks a second wave (2012 to the present), which features assessments commissioned directly by the political system. It can only be speculated as to whether or not these subsequent (mainly ongoing) assessments will lead to more impact on political processes than the reviewed (completed) assessments.

The nature of synthetic biology assessments in Germany may seem to fit the immature developmental stage of the techno-scientific domain itself. In terms of the content, however, there seems unused potential to complement the observed generic and abstract assessment approaches with increased differentiation regarding synthetic biology's diverse application domains, time horizons and concrete scenarios. In addition, given the limited availability of knowledge and the uncertainty concerning the potential impacts of synthetic biology, an increase in the assessment of visions, in the reflection on societal discourses and in the contextualisation of debates on synthetic biology has been suggested (Grunwald 2012; Torgersen 2013). Methodologically, the restricted use of participatory approaches in German assessments seems to limit the amount of different perspectives, statements and opinions that could be included within assessment practice. Although the dominant expertise-oriented approach might minimise the amount of uncertainty regarding the evidence base considered, it is also likely to limit an assessment's applicability, legitimacy and scope. Therefore, the potential value of co-development between producers and users of technology-based products in the early phases of technological development is mainly unaddressed in German assessments of synthetic biology. However, taking into consideration the diverse intentions of the assessing organisations, the nature of challenges and uncertainties addressed within assessments and the limited political involvement in commissioning assessments of synthetic biology, a critical judgement regarding the limited use of participatory approaches remains difficult to make.

Although this paper provides an overview regarding the aims, roles and applied methodologies of synthetic biology assessment in Germany, judging the generalisability of our insights remains difficult. The definition of synthetic biology, the perception and determination of its unique features, as well as challenges related to existing or changing visions, may well be rooted in local, institutional and cultural determinants. Therefore, it may be worthwhile to compare the case of Germany with the nature and role of other national and international synthetic biology assessment practices. In Europe, several countries show indications of interest in synthetic biology, from both scientific and public perspectives. In particular, the UK may prove to be an interesting case due to its large public commitment to the development of synthetic biology (UK Synthetic Biology Roadmap Coordination Group 2012) and the initiation of upstream engagement activities (Biological Sciences Research Council and Engineering and Physical Sciences Research Council 2010). Outside Europe, the USA shows considerable R&D involvement, and several Asian countries are also starting to direct increasing resources into the local development of capabilities related to synthetic biology (e.g. see Pei et al. 2011). The comparison of different national and international settings could provide valuable insights regarding the contribution of assessment practices in synthetic biology's evolution, both regarding its techno-scientific progression and public awareness. Such insights could facilitate better understanding of the role of assessments in the governance of synthetic biology.

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Notes

1. The analysis was conducted in the context of a European Commission FP7 project (EST-Frame) on integrated assessment of emerging science and technologies (cf. other papers in this special section of *Science and Public Policy*). It represents one of four techno-scientific case studies that were conducted on the basis of the same research protocol.
2. Biosafety issues relate to confined use of micro-organisms, or potential unintended release thereof. Issues that are being discussed include the survivability and evolvability of novel synthetic organisms and the impact of 'exotic' biological systems based on alternative biochemical structures (Schmidt et al. 2009). Biosecurity issues relate to the potential of a micro-organism or toxin to be used as a weapon or, in more general terms, to malicious misuse of biological systems.
3. See Henkel and Maurer (2007, 2009) for discussions regarding the appropriateness of various intellectual property rights, knowledge dissemination and incentive systems to optimise inter-actor collaboration and innovative behaviour in synthetic biology.
4. The ethical dimension seems to be of considerable importance with respect to synthetic biology's potential to adapt naturally occurring biological systems and to create new unnatural biological systems. A considerable volume of research has reported about synthetic biology's potential impact on issues including global justice, ownership to life and the creation of artificial life (e.g. see Kaebnick 2009; Schmidt et al. 2009).
5. Kwok (2010) provides a discussion with regard to practitioner challenges—and how these challenges might be resolved—that will influence the techno-scientific

progress and future commercialisation activities of synthetic biology.

6. In addition, there have been some public conferences on synthetic biology in Germany. Among the best documented is one organised by the German Ethics Council (Deutscher Ethikrat 2013). The National Academy of Science and Engineering (acatech) has also been active in this regard (e.g. see Pühler et al. 2011). Although, strictly speaking, conferences cannot be considered as proper assessments, they may still play a role in the public discourse and influence other efforts at assessment.
7. In reviewing the assessments, particular focus was placed on: their purpose, their output, the impacts considered, the temporal orientation taken and methodology used. In addition, some interviews were conducted with people who were directly involved in preparing the assessments. Finally, a workshop with several German experts and stakeholders was held to discuss the state of the assessments on synthetic biology in Germany, and also to reflect the German situation on the context of other national and international efforts and developments.
8. Cf. the corresponding press release <http://www.dfg.de/service/presse/pressemitteilungen/2009/pressemitteilung_nr_37a/index.html> accessed 14 May 2014.
9. See Testbiotech's website <http://www.testbiotech.org/en/testbiotech> accessed 14 May 2014.
10. Some of the information given in this paragraph has its source in an interview with one of the report's authors, cf. Note 7.
11. See Dechema's website <http://www.dechema.de/en/About+us/About+the+DECHEMA.html> accessed 14 May 2014.
12. Some of the information given in this paragraph has its source in an interview with one of the paper's authors, cf. Note 7.
13. See the project website <http://www.engineeringlife.de/> accessed 14 May 2014.
14. See the project website <http://www.tecdesign.uni-bremen.de/typo3/index.php?id=485> accessed 14 May 2014.
15. See the project website <http://www.tab-beim-bundestag.de/en/research/u9800.html> accessed 14 May 2014.
16. See the project website <http://www.ea-aw.org/research/overview/synthetic-biology.html> accessed 14 May 2014.
17. See the project website <https://www.itas.kit.edu/english/iut_current_grun12_syngov.php> accessed 14 May 2014.
18. This was explicitly stated in the interviews with some of the authors, cf. Note 7.
19. See <http://www.testbiotech.org/en/signonline> accessed 14 May 2014.

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