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AMERICAN INSTITUTE FOR CONTEMPORARY GERMAN STUDIES
AT JOHNS HOPKINS UNIVERSITY

AICGS Transatlantic Perspectives

June 2011

Vigilance vs. Precaution: Diverging Directions in U.S. and European Technology Governance?

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How has the emergence of synthetic biology affected scientific regulatory principles in both the U.S. and Europe?

What risks remain in the future of techno-science, and how should policymakers approach the ethical cost/benefit analysis of this expanding discipline?

On 20 May 2010 Craig Venter, famous for being the first to sequence the human genome, announced a major milestone in the emerging field of synthetic biology: the creation of the first synthetic life or, more precisely, a self-replicating bacterial cell with entirely chemically constructed DNA. On the same day, President Barack Obama requested his recently created bioethics council, the Presidential Commission for the Study of Bioethical Issues (PCSBI), to assess the ethical and social implications of synthetic biology. This new research area was suddenly the center of public attention. The president gave the commission six months to study the challenges proposed by synthetic biology and to develop policy recommendations about the next steps the federal government should take to maximize the benefits and minimize the harms of the emerging technoscience.

The PCSBI published the results of their deliberations on 16 December 2010. Scientists, ethicists, and policymakers alike awaited the commission's report with high expectations. Obama had just dismissed President George W. Bush's Council of Bioethics and it was obvious that the new commission would not continue the conservative and very precautious approach on biotechnology of its predecessor.

After the publication of the commission's report, "New Directions – The Ethics of Synthetic Biology and Emerging Technologies," voices from civil society claimed that Obama's commission had opted for an approach that was far too laissez-faire and was not doing justice to the threats synthetic biology poses to biosafety and biosecurity. They were worried that the PCSBI had explicitly turned away from the Precautionary Principle (an important norm in environmental policy and an integral part of EU policy design) and replaced it through the new concept of "Prudent Vigilance." The aspiration of the report to serve as a guideline not only for synthetic biology, but for emerging technologies in general, aggravated the concerns further—especially in Europe. What is the source of these concerns?

Emerging Technologies and the Unknown

Emerging technologies always pass through cycles of hopes, fears, and disappointments. Only when a technology leaves the laboratory and enters the marketplace will it slowly become clear what expectations can pass the reality check. Biotechnology (which now, as synthetic biology arrives, is often labeled "traditional" biotechnology) has not lived up to the high hopes it once generated. In the past several years, scientists realized that naturally occurring biological systems proved to be more complex and difficult to manipulate than expected.

Synthetic biology, however, promises to leapfrog the problem inherent to "traditional" biotechnology. In building biological systems "from scratch," bioengineers strive to create artificial cells, genomes, and DNA-based devices that should perform exactly the desired

functions and work similar to tools or factories. Hence, the hopes are high again. The outcomes of synthetic biology are expected to lead to cleaner energy, better pollution control, improved agricultural products, and unprecedented medical developments.

At the same time, the field gives rise to great fears. Unlike synthetically produced chemicals, synthetic biology products may be much more difficult to control, because of their capacity to reproduce and evolve. Some potential risks are already known: If scientists engineer a smallpox virus, it could be fatal if it is released (by accident or consciously used as a biological weapon). Other dangers are unknown, but can be specified: we know that some viruses can mutate quickly, but we cannot predict how synthetic viruses will evolve. However, the greatest fear is invoked by the "unknown unknowns" (an epistemological concept made famous by Donald Rumsfeld): risks that we currently cannot even speculate about but do, despite our non-knowledge, nevertheless exist or might be created as a result of synthetic biology research in the future.

But the notions of known and unknown risks can also be turned upside down. Proponents of synthetic biology argue that besides the known *benefits* of the field, there are also benefits to consider that are unknown today and can only be detected if synthetic biology research is pushed rather than restricted.

The divergent expectations that synthetic biology evokes are not surprising. All recent emerging technologies (like "traditional" genetic engineering, robotics, or nanotechnology) gave rise to great hopes and fears, because their future implications are very difficult to predict. This is one of the reasons why emerging technologies pose unprecedented challenges for the governance of innovation: their regulation cannot be based on scientific facts alone—political decisions must be made *before* scientific certainty has been reached.

The Governance of Technological Innovations between Precaution and Laissez-faire

A widely accepted way to deal with the uncertainty surrounding emerging technologies is through policies guided by the Precautionary Principle. This principle, originating from the German *Vorsorgeprinzip*, states that if an action (like scientific research and technological development) is suspected to pose a severe harm to the public or to the environment, and a scientific consensus regarding the probability of the harm—or even the cause and effect relationship between action and harm—is absent, the burden of proof should be shifted to those taking the action; they must present evidence that the action is *not* harmful. The Precautionary Principle is an important guide in EU policy design. It provides the basis for the regulation of deliberate release and commercialization of genetically modified organisms. Therefore, it is not surprising that the Precautionary Principle plays a key role in the report of the European Group on Ethics in Science and New Technologies (EGE) on synthetic biology that was released a year before the U.S. report.

But the strict regulation of new technologies, which the Precautionary Principle seems to imply, has also provoked strong criticism. Opponents of the precautionary approach worry that the principle can result in a slowing down of technoscientific progress. They claim that innovations like the railway, the airplane, electrification, antibiotics, open-heart surgeries, or organ transplantations would never have been developed, or at least would have never been widely diffused, if governments had adhered to the Precautionary Principle in the past.

They also suggest that the Precautionary Principle ignores the risks of postponing or inhibiting innovation, for instance "natural" risks (infections that would be fatal if certain medicines would not have been invented); the risks of regulatory actions themselves, which—just like technological in-

novations—could also have unexpected side effects; and finally, the economic opportunity costs if a technology is not developed (or worse: is developed in another country). Therefore, proponents of emerging technologies often call for a laissez-faire approach that should be more innovation-friendly and shift the burden of proof to those who propose restrictive measures.

Prudent Vigilance – A New Guide for Science Governance?

This laissez-faire stance is not the position of Obama's new commission. As the commission's chair Amy Gutmann said, the PCSBI has neither recommended to "let science rip" nor has it embraced the Precautionary Principle. Instead, the commission made the case for an evolutionary approach to technology governance, "an ongoing process of prudent vigilance that carefully monitors, identifies, and mitigates potential and realized harms over time."[1] Since synthetic biology is an evolving science whose future is unpredictable, the PSCBI argues that regulation should not be too strict. Commission members argued that inhibiting innovation may even be counterproductive to security and safety, because it could prevent researchers from developing effective safeguards for synthetic life developed elsewhere. In contrast, the PCSBI sees a general support for basic research as the best way to maximize benefits and minimize harms—both those that can already be expected, as well as those that are currently unknown. To prevent the same discussion from occurring whenever a new technology comes into view, the commission stresses that its recommended approach of "Prudent Vigilance" is appropriate for the regulation of emerging technologies in general.

The more specific recommendations of the PCSBI show that "Prudent Vigilance" boils down to a combination of self-regulation and careful oversight. On the one hand, the commission wants to improve the scientific community's capacities for self-regulation: For example, all researchers in the field should go through ethics education. The PCSBI also suggests the creation of an independent institution like FactCheck.org, where scientific claims related to emerging technologies are evaluated. The institution should enable the general public to suggest claims about the field for review. On the other hand, the PCSBI acknowledges the responsibility of the government to prevent the public from severe harms potentially caused by synthetic biology. Risk assessment should, therefore, precede the field release of synthetic biology products. That sounds quite similar to the EGE's position, but the devil might be in the details. While the EGE states that the data resulting from risk assessment should be evaluated in the light of the Precautionary Principle, the PCSBI explicitly rejects an "extreme precautionary approach that blocks technological progress until all possible risks are known and neutralized."[2]

Political Responsibility

A joint meeting of members of the PCSBI and the EGE in March of this year (under the auspices of the Woodrow Wilson Center) revealed that the Presidential Commission had interpreted the Precautionary Principle rather narrowly. If there is, as the PCSBI stated, an "extreme" precautionary approach, there must also be less extreme versions. Indeed, the closer you look, the clearer it becomes that the Precautionary Principle is not the hard and fast governance rule that one might expect it to be. Instead, the principle has been understood in quite different ways. Only in its strongest form it demands a moratorium on research and development—even if the suspected risks are speculative and the costs of precaution are high. The rationale behind this strong version of the principle is a "better safe than sorry" attitude in regard to innovation. Following the strong precautionary approach, a strict regulation of new technologies can only be relaxed if new scientific findings prove that no harm will result from further research and development.

Compared with this reading of the principle, the EU has arrived at a considerably weaker interpretation that includes cost-benefit analysis. The EU also demands some evidence for the likelihood

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of occurrence and the severity of harms. As outlined by the EU commission, a precaution-based approach does not need to be equated with a search for zero risk. Even a comparison between the most likely positive or negative consequences of action *and* inaction should be taken into account. Moreover, the possible "action" does not need to be a moratorium, but could also consist of a passing on of information to the public about possible adverse effects of products. The EU commission is very clear that the Precautionary Principle is no clear-cut tool that can be mechanically applied. In the end, political decision-makers must determine which level of risk is "acceptable" for the public.

In accordance with the statements of the EU commission, the EGE also subscribes to the weaker version of the Precautionary Principle. Therefore, while the positions of the EGE and the PCSBI might not be identical, they are not as different as it may appear at first glance. There is clearly room for transatlantic dialogue. The meeting of members of the two commissions has demonstrated the possibility of mutual understanding.

At the end of the day, neither of the two commissions released policymakers from their responsibility. Both reports acknowledge that in the face of uncertainty, technocratic decision-making cannot be applied. In the fast moving world of emerging technologies, regulations must be repeatedly readjusted and our knowledge of possible benefits and harms can never be complete.

Technoscientific progress seems to transform the world itself into a laboratory in which the outcomes cannot be predicted and failure is always possible. Europeans still lack confidence in this laboratory that their political and natural environment has become, while the PCSBI believes that U.S. citizens will accept their technoscientific future—as long as they are (via dialogue and public vigilance) part of the process.

NOTES

[1] Presidential Commission for the Study of Bioethical Issues, (2010): "New Directions. The Ethics of Synthetic Biology and Emerging Technologies," Washington D.C.:December 2010, p. 8, <http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12-16-10.pdf> (29 June 2011).

[2] Presidential Commission for the Study of Bioethical Issues (2010): New Directions.The Ethics of Synthetic Biology and Emerging Technologies, Washington D.C.:Ibid., 26.

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AICGS is grateful to the German Academic Exchange Service (DAAD) for its generous support of this essay.