

Dealing with Uncertain Technological Risks

Report on the workshop Dealing with Uncertain Technological Risks:
Improving the Appraisal and Regulation of Risks from Emerging Technologies,
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Introduction

The risks posed to society from “emerging technologies” constitute a topic of intense academic and societal debate. The Program on Emerging Technologies at MIT, the UK ESRC Innogen Centre and the Genomics Policy and Research Forum (based at the University of Edinburgh), the Netherlands Environmental Assessment Agency and the Pugwash Conferences on Science and World Affairs share an interest in this topic – each from different angles related to a variety of roles and disciplinary backgrounds. The workshop “Dealing with Uncertain Technological Risks: Improving the Appraisal and Regulation of Risks from Emerging Technologies” brought together 17 highly qualified international participants from five countries (Japan, Mexico, Netherlands, UK, USA) and from disciplines including nuclear physics, condensed matter physics, chemistry, synthetic biology, neuroscience, environmental science, theology, law, journalism, sociology, science and technology studies, and political science. The workshop was held in Edinburgh, Scotland, from 31 May to 1 June 2008.

Three main questions were discussed in consecutive sessions: (1) What are “emerging technologies” and what is really new about them?; (2) To what extent do existing regulatory structures and voluntary initiatives adequately address old and new risks?; (3) How can safety/sustainability/security and other emergent properties of technologies be enhanced through design?

I The nature of emerging technology

Synthetic biology

The workshop started with a short introduction to “synthetic biology.” While synthesis of DNA has been around for quite some time (we could even call recombinant DNA research “mundane” nowadays), the thrust towards standardization of components of biological systems is relatively recent. The field of “synthetic biology” is hard to define; do we include all synthesis activities, or do we limit the term to the science of principles of assembly and standardization of pieces of DNA? In this first session, the two central questions studied were: (a) what are the societal risks involved and (b) can we anticipate these risks? In synthetic biology, one of the matters that are already at issue is whether synthesized organisms will be safe and whether people will believe that safety is achievable in the first place. Also Intellectual Property (IP) rights issues immediately come to the fore when exploring the social impacts of these new technologies: Who will have access to the benefits?

Nanotechnology

A brief introduction to “nanotechnology” followed. “Nanotechnology” is a very broad field; it might be better to speak of “nanotechnologies,” in order to represent the variety of technologies involved rather than referring to a single technology. Emphasis in the definition may lie on (1) miniaturization: making things smaller, e.g. robots; (2) manipulation of matter at the atomic level; or (3) the improvement of synthesis of chemicals. It is popular in the field to make couplings with “social impact” projects. There are large problems with categorizations under the heading of “nanotechnology,” since the activities that take place under this umbrella are so widely different. In the early days of the field, too much attention was paid to futuristic scenarios (robots), while real-life applications of nanotechnology, such as the use of nanotubes or particles in a variety of products, have only lately been assessed, mostly with respect to toxic effects.

Politicization of risk assessment

In response to the latter introduction, it was asked why – if the widespread social interaction on nanotechnology did not seem to have a major impact, i.e., did not lead to a focus on health impacts – we keep hoping that broader discussion will improve decision making. In response, it was confirmed that the discussions surrounding nanotechnology were very political from the beginning. The new technology was pushed as being “revolutionary,” and this basic narrative was kept alive for quite some time, attracting a lot of the political attention. Another participant observed that with the emerging technologies of Genetically Modified (GM) crops in the 80s and stem cells, nanotechnology and synthetic biology more recently, we have started talking about them in a public forum much earlier than compared with previous emerging technologies. This leads to a very early competition between technology promoters and opponents. In this participant’s view, it takes too long before concrete risks of actual applications can be discussed (i.e., before some credible knowledge about these risks becomes available); we start speculating about very uncertain risks involved in the fundamental science, first, and this leads to too large an emphasis on precaution, which is counterproductive for the development of the technologies. Other participants agreed that indeed there is very little discourse “in the middle” (in-between that of uncritical promoters and overly critical doom predictors); this leads to the undesirable situation that when there *is* serious evidence of harm, for instance toxic effects of nanoparticles (e.g., see a Royal Society report in 2004), governments find it very difficult to take the lead in managing those risks.

Differences between “old” and “new” emerging technologies

In summarizing the previous discussion, it was concluded that the tendency toward “upstreaming” – that is, involving society in an early stage of development – has the effect of setting up frames that may be wrong. Upstreaming proposals often seem to be based on an inadequate understanding of the dynamics of innovation (but, tacitly, seems to presume a more or less linear relationship between intentions of those directing technological development and the eventual social and technical outcomes). Still, two sets of questions arise related to a possible change, over time, in the nature of emerging technologies: (1) To what extent are “new” emerging technologies different from “old” emerging technologies? Is there a difference in irreversibility, i.e., a greater risk of irreversibility? Other technologies, such as combustion technologies that led to CO₂ emissions from, e.g., power plants, have also posed such risks; (2) To what extent is there more public debate on the characterization of uncertainty, compared with “old” emerging technologies? Can we find examples of similar public debates much earlier in history? And preliminary to these two sets of questions, another question is to what extent the concept of “emerging technology” itself is new.

Explicit anticipation of risks

Before addressing these questions, however, the workshop had to deal with the preliminary issue of what constitutes “anticipation.” It was pointed out that there are different ways for a society to “anticipate” uncertain risks. First of all, we must acknowledge that it is very hard to credibly assess the very uncertain risks and benefits of emerging technologies (explicit anticipation). In some cases, by differentiating between specific activities that take place under labels such as “nanotechnology” or “synthetic biology,” we may be able to identify areas for which we can reasonably predict what will happen, and separate them from areas for which we cannot. But it is striking that, in many cases, explicit anticipation has not even been tried. Take, for instance, the laser: there was no concern about this new technology in the 1960s. And even when there is concern, organizations such as the National Academy of Sciences are usually not asked to address questions, such as “What are the relative dangers of nanotechnology?” Why are they not?

Anticipation as “societal preparedness”

In addition, “anticipation” could also include elements such as the social and economic resilience to the introduction of new risks. Typically, institutionalization of the response to risks comes too late (that is, after the risks have already developed). Are there ways, other than through explicit anticipation and policy response, to prepare society for dealing with new uncertain risks?

Lack of anticipation of risks in Japan

In response to the earlier question of whether we can observe differences in the treatment of “new” emerging technologies versus “old” emerging technologies, the workshop was briefed on the general lack of anticipation of risks in Japan. Nanotechnologists in Japan unreflectively stress the innovative nature of the technology and rush towards the development of products that they think will sell. Meanwhile, they claim that the risks that nanotechnologies could pose are conventional and can be managed within the existing regulatory framework and that there is therefore no need for additional regulation. Scientists, as distinguished from technologists, in Japan are generally more honest: they say that they do not know the risks.

Differences in regulation

There was some debate during the workshop on the importance of differences in regulation between different emerging technologies. One participant argued that there is nothing fundamentally new about the current emerging technologies; since large parts of the life sciences are already regulated, the presence of regulation gives us the time to think about impacts and to differentiate between technologies which we try to anticipate and those which we do not worry about. Several objections to this line of reasoning surfaced, however. First, there are also large areas in the life sciences that are not regulated, such as alternative medicine, or are less regulated, such as diagnostic technologies. Second, the influence of the regulatory structure for decisions that are taken by large pharmaceutical companies can be questioned. Third, the level of regulation varies strongly when we move outside of the life sciences. In IT, for instance, the impacts of new technologies are largely framed in individual frames – an exception being security issues, which do call for regulation. For pharmaceuticals, a combination of individual risk acceptance and societal regulation for safety can be found. In the case of synthetic biology, the impacts are not regarded as a matter of individual risk acceptance. And finally, the whole question of why areas become regulated was argued not to relate to essential differences in the technologies – the differences in regulation should be more considered as historical contingencies, e.g. response to crisis events, a prime example being the BSE crisis, which led to new legal structures. Still, we should be on the lookout for examples of a design change without catastrophic events preceding it.

Problem of labeling at too high a level of aggregation

The participants shared the view that labels such as “GM,” “nanotechnology” or “synthetic biology,” cluster many widely different things. The phenomenon of how such labels are used in a society and how they are spread, is worth studying systematically. The process through which labels arise, seemingly accidentally, is an interesting one. Other historical examples include the labels “radiation” and “nuclear.” It was said that we must be aware that there are lobbies behind it as well. It was a goal for Greenpeace to make a coherent thing of “GM,” while patient groups representing patients with genetic disorders, might want to do the opposite, that is, not cluster but focus on a particular technique or application. Additionally, whole scientific disciplines, many long-existing areas of science, were gathered under this umbrella. When the doom scenarios about some specific futuristic developments in nanotechnology led to a societal reaction, this reaction also affected the scientific work that had nothing to do with the risks at issue, merely because it had been placed in the big bad box of “nanotechnology.” There was consensus among the workshop participants that the grouping of new technologies at too high a level of aggregation leads to too wide a variety of different effects, that are then also clustered together. It is desirable to be able to distinguish between *thinking* and *worrying* about emerging technologies. Since all of these effects deserve further thought, but only some should lead to real worry (e.g., changing social interactions for some ITs; human health and the environment for some nanotechnologies; and human health, brain chemistry effects and more ethical effects for some biotechnologies), we must find a way to select those specific developments that we should worry about.

Framing of “uncertainty” and “risk”

One participant was concerned with the different meanings of the term “risk.” In one – sometimes dominant – vocabulary a distinction is made between “risks” for which probabilities are known and “uncertainties” for which they are not known. Many aspects of which we are talking, are uncertain and not part of risk in that sense. If we do not make this distinction then there is a danger that we try to extrapolate statistical notions to areas for which they do not apply. Other

participants did not share this worry. People do talk about “risk” when it comes to emerging technologies. While Greenpeace did not really think that GM was dangerous (the uncertainties were too large), they chose to use “risk” terminology, implying danger. What did worry some participants is that pressure groups often determine what governments think about. Under what circumstances would it be valid to allow the values of one group to “determine” the values of society as a whole?

DNA synthesis, synthetic biology and biosecurity

To facilitate a somewhat more in-depth discussion on a particular area of development, a brief presentation was given on DNA synthesis, synthetic biology and biosecurity. While the *short term* (< 5 years) impact of synthetic biology techniques seem to be minimal versus conventional techniques, the *medium term* impacts will be larger: the defensive benefits are likely to be small but significant, including better biosensors, improved production of therapeutics and vaccines, and better identification of new drug targets; the offensive benefits are likely to be substantial, potentially allowing both making it easier to obtain natural pathogens and to construct artificial agents, allowing the creation of new capacities. The possibilities for behavioral/ attitudinal change and new sleep agents give rise to difficult questions. In the *long term*, we may witness a diffusion of capabilities and increased uncertainty: a transformation from tacit to explicit knowledge is a key component of the synthetic biology enterprise; removal of tacit knowledge “de-skills” the manipulation of living organisms, allowing many more people to learn to do so much, more quickly, decreasing investment costs and flattening the gradient between elite and periphery. Even though there will always be a certain level of tacit knowledge needed, we will increasingly be confronted with particular technologies that are relatively easy to use. Moreover, a greater ease in utilizing discoveries from other fields of biology and a focus on modular assembly, suggest the potential for rapid changes in capabilities and threats. In the NSF SynBERC project “principles of secure design” are studied, focusing on the following questions: Is it possible to design parts and/or chassis so that they cannot be used in weapons, and if so, how? Is it possible to include design features that aid in detection/forensics? Are there analogies from computers/chemicals/other areas that can help us? What else can we do? How do we design this technology so that it is difficult to use as a weapon, now that we still have the chance to do so? One of the final conclusions of the presentation was that it is very hard to concretely identify risks that are becoming real. People tend to overstate consensus in the field of synthetic biology. Typically, commentators with less expertise were more convinced of the feasibility of particularly risky developments. There is a tendency to linearize nonlinear phenomena. Related to the issue of biosecurity is the question of which things can and should be kept secret. Think for example about the publication of the Spanish flu virus. To what extent will/should publication be prevented? On this question, the participants’ opinions diverged. Some thought that it would not be preventable, but others disagreed, claiming that there will be specific cases where it is possible to keep some developments secret.

The importance of tacit knowledge versus interactional expertise

During the workshop, a reference was made to the debate within the sociology of science on the different notions of expertise (e.g., see Harry Collins and Robert Evans, 2007: *Rethinking Expertise*, University of Chicago Press; an earlier exposition can be found in H.M. Collins and R. Evans, 2002: *The Third Wave of Science Studies: Studies of Expertise and Experience. Social Studies of Science* 32: 235–296). Both “skill expertise” and “interactional expertise” play important roles in science, even though it is hard to make a sharp distinction between them. Skill expertise is required to practice in a certain field of science, while someone like a chief scientific

adviser can – with a lot of interactional expertise – be able to give sound advice; he or she does not have to be a skilled expert in everything.

New discoveries often result from tinkering (tacit skills)

While *fundamental* researchers may think of long or very long trajectories and anticipate new developments based on their theoretical understanding, *engineering* researchers often try to see what happens, which often leads to big breakthroughs. Think, e.g., of the study of “junk DNA”: the approach of the engineer here is typically to just “kick it out” and see if it works, before understanding all the interactions. A lot of trial and error, and thus tacit knowledge, is involved in doing such experiments. This again emphasizes how difficult it is to anticipate future developments within a certain area of science.

Technology Assessments: “good” or “bad”?

To what extent are assessments of emerging technologies “good” or “bad”? One participant observed that low-level regulators with a high level of expertise typically tend to stress the complexities of the technology involved and do not fully share the “ethos” of high-level regulators, who think that assessing the technology is do-able. Actually, much of the field of “Technology Assessment” (TA) was not developed by experts, but by institutions without expertise. Still, there is not much evidence that scientists understand the social implications of their work or that people in a particular field can see any further than those outside that field. What do we all really know about “downstream” developments? When we look at particular historical examples of technology assessment, it can be said that, for instance, the Chernobyl disaster was predictable, but that nobody guessed Three-Mile Island: after the latter nuclear accident a team had to assess which lessons could be learned from that accident. And in the early GM case, plants were not considered by the experts to be an issue, while later this turned out to be a false hypothesis. The psyche of the expert community makes it hard to conceive what may really happen.

Problems with Technology Assessment

Two issues with respect to Technology Assessment can be distinguished: one is methodological and the other is institutional. The methodological problem is to predict the unpredictable. Some TA reports are useless since they only anticipate impacts from extrapolation. In Japan, a standard part of TA as it is done abroad – to compare a particular technological development with alternative technologies that may serve the same need – was cut from the method. The institutional issue is more complicated. Those who pay for or conduct the assessments often determine the outcomes. It is difficult for agencies to assess impacts beyond their regulatory responsibilities. Since the promoters of emerging technologies only look towards the positive impacts of their technologies, we need independent third-party agencies.

Further research on TA needed

Some participants expressed that there is a need for a comparative study of past Technology Assessment efforts, acknowledging differences among countries. Examples of interdisciplinary assessment of risks mentioned in the workshop include the now-defunct US Office of Technology Assessment (OTA), the US National Research Council (NRC), the Intergovernmental Panel on Climate Change (IPCC), several UK bodies (among which now also the Cabinet and Treasury), the Netherlands Environmental Assessment Agency and Rathenau Institute. Other participants, however, pointed out that there already is a fair amount of research and discussion on TA in the literature.

Contextualizing risk assessment

In evaluating past risk assessments, we have to be aware of the particular contexts in which the risks were assessed and anticipated, and for whom. There is a lot of social construction involved in identifying a problem with an emerging technology. Thus, societal values – and their dynamics – play a large role here, as do religious beliefs.

Dealing with uncertain technological risks

During this first session, the workshop discussed the problem of projecting or understanding potential danger. On the one hand, there is uncertainty about technological developments in different arenas. On the other hand, there is sociological uncertainty about what could happen in the economy. For instance, the actual use of a particular technology might be different from the prescribed use. The default rule for dealing with uncertain risks may be: let the new technologies develop and wait with regulation until we know more, after which we can adapt to the new insights. The question then arises: under what conditions should we deviate from this rule? This was the topic of the next session.

2 Limits of past risk regulation

Limits to innovation in genomics due to regulation

This session began with a brief presentation of the limits of past regulation in the life sciences. A distinction was made between the innovation system, the regulatory system and public perceptions. The question was addressed whether regulation (at least in the EU) has been stifling GM crops innovation. Environmental groups took the initiative to predict/stimulate a backlash against GM crops, which indeed materialized. The interactions between these systems determine which products will be developed. Regulation, for instance, determines the possibilities for innovation, e.g. by limiting certain developments and stimulating others. The past paradigm of regulation was reactive/preventive: action was taken when harm was observed. The “precautionary” paradigm is relatively recent: it means action is taken preceding evidence of harm. The form of regulation can make a difference to the regulation’s effectiveness and efficiency. Two sets of criteria play a role here: (1) enabling vs. constraining regulation and (2) discriminatory vs. non-discriminatory regulation. An example of this can be seen in the history of developments in fungicides, in the 1980s. The overall outcome was counterintuitive and characterized by a complete dominance by large multinational companies. In general, there is a relative lack of groundbreaking innovation in the life sciences. The regulatory system is too rigid and too expensive for innovators. If you want to change the innovation system, radical reform of the regulatory system is needed.

The need for planned adaptation

A second introductory presentation stressed the need for “planned adaptation.” Two extremes of dealing with uncertain technological risks – which may both be unsatisfactory – are: worry and study (too much emphasis on precaution) and wait and react (too much harm may be done). We need to seek a middle ground and consider the intermediary method of “planned adaptation.” We do not have to wait for disaster to strike, before we start regulating developments. An example of this is the history of the regulation of the health standards for particulate matter. This history involves the emerging technologies of pollution control techniques and techniques for the detection of smaller particles (so these emerging technologies helped to determine the consequences of earlier technologies which caused the emission of particulate matter). In the early days, within the EPA there was often too little time to assess all the available information before new regulation was put in place. There was a lack of a feedback system, of self-improving regulation. While learning from history often takes place in the private sector and in science itself, it is hardly ever observed in government. Only after a congressional decision (not necessarily taken with this wisdom in mind), a regulatory rule was set up to review the scientific evidence on particulate matter every five years. In addition, there was an allocation for dedicated research, largely funded by EPA, but overseen by the National Academy of Sciences. This makes the particulate-matter example a case of “planned adaptation” (even though the review cycle – of about once every eight years – works a bit slower in practice than was originally envisaged).

Constructivist critiques of naive view of “self-improving regulation”

Some participants advised the workshop to take into account four possible critiques on the notion of “planned adaptation” from a constructivist viewpoint. *First*, we should not focus too much on the law itself. At least as important is how the law is interpreted and used by the different actors. We may then discover that “self-improvement” of regulation is not really something new. *Second*, the notion rests on a presumption of what constitutes “better” regulation. Industry, obviously, does not like different regimes, in some cases. There are

examples of regulatory reform that do not constitute improvements from the overall societal perspective (e.g., the Delaney clause which includes a ban on food additives that are proven to be carcinogenic to animals but that are not necessarily carcinogenic to humans): usually, when proposing such reforms, not all consequences are assessed. Thus, it must at least be made explicit from what perspective changes are viewed as improvements. Even when the perspective comes from “common sense,” we do not always consider or know all the costs and benefits. An interesting case to study would be the REACH directive for chemicals in the EU. This constitutes a radical regulatory reform; however, it remains to be determined what, if any, difference it will make. We may learn from a focused study on why this reform was so controversial from different perspectives. Another interesting case is changes in vaccination schemes (see, e.g., the MMR scare in the UK). How are the benefits and risks framed in such cases? A final important theme to study in this context is compensation schemes to offset risks. A *third* critique is that the model of planned adaptation, as it is presented here, seems to fall under only one model of public administration: the rational-instrumental paradigm (vs. the deliberative constitutive paradigm). A problem with this model is how the public administrators can be held accountable, since they are unelected. A similar problem exists with EU comitology (the system of committees chaired by the European Commission). And there are differences in legal culture between the US and the EU, as well. The US culture of how the parties operate through courts and settlements can be characterized as “adversarial legalism.” Courts there have taken different views on the roles of risk regulators. In the UK, hardly any courts have been involved in this kind of issue. At the EU level, it is only just beginning (Court of First Instance). And a *fourth* critique of the model of planned adaptation is that generally there are no strong incentives for politicians to revise standards in advance of crises. The arguments are: if a certain regulation is working well, leave it intact; only if and when it turns out that there really is a problem, then fix it. There are important, fundamental choices to be made, for instance: do we favor a liability culture or a safety culture?

“Planned adaptation” more specifically defined

During the workshop it was stressed that before we can assess whether examples of “planned adaptation” are common or uncommon, we first need to better define what it is. An important component of planned adaptation must be the systematic acquisition of knowledge. This middle road between too much precaution and acting too late, entails the possibility for different actors to agree to disagree on whether the current information warrants action. But they might at least reach an agreement on what information would be needed to enable a better assessment of the risks, not necessarily implying that there will be only one way to look at the acquired new information, or that automatic action triggers need to be agreed upon. An important research question to address is: since a lock-in of policy positions may prevent the strategy of planned adaptation from working, what are the sources of such lock-ins? We may think of economic factors, implying the possible need to buy off particular industries, or even a more general resistance to change, which can be analyzed in a constructivist framework (focusing on legitimating/delegitimizing claims made by the actors involved). A good case to study, in this respect, would be the pharmaceuticals case. After recent reforms, a sort of self-correcting system has been put in place, including budgets for gathering information. In this case, questions arise as to which real risks need to be considered and which intermediate steps need to be taken, when a drug is introduced. Another case might be the TSE road map exercise.

Examples of planned adaptation

According to one participant, several additional examples of planned adaptation can be identified. One example is the UNECE CLRTAP (long-range air pollution) process, where a whole

knowledge apparatus was set up, including monitoring of consequences of air pollution. Another example is air pollution policy-making within the UK, where a learning process takes place in which modeled concentrations of contaminants are confronted with stakeholders' insights into actual exposures and monitoring is continuously improved.

The views of industry on planned adaptation

The idea of planned adaptation led one participant to ask a specific political question about industry players: some players obviously want certainty; is it not the case that they just want to know what the rules are, after which they will follow the rule? It was replied that, to find this out, first, we would need to talk to strategists in industry, but beforehand it is not clear why they would not go along with temporary agreements.

Planned adaptation within or beyond existing institutions

Although there are many good examples of self-improving regulation that reside under the responsibility of *existing* institutions, the question was raised of how we can go beyond those institutions? For example, cosmetic nanomaterials are being sold already, while no regulation covers this type of product. Similarly, there is no regulation on sophisticated toys (e.g. toy robots) – these can be used for terrorist purposes. Conversely, some useful technologies may be stifled by falling under an inappropriate institution. For example, in Japan there are no incentives to introduce technologies for improving food safety, since the Ministry of Health's rules on food additives ban nearly everything which is not proven to be completely safe (cf. the earlier example of the US Delaney clause). From a cost–benefit analysis perspective, however, it would be prudent to apply more food irradiation techniques for instance. One participant concluded that what is clearly needed is an institutional space, an institutional apparatus, for reflecting on existing regulation.

International comparisons: planned adaptation in more or less litigious societies

When making international comparisons, the relevant question becomes what are the incentives and disincentives for planned adaptation among different regulatory and tort systems. In some cases, the court system can help to keep up with the science (within existing institutions). But here we encounter a paradox. On the one hand, people are afraid to reveal information for fear of being sued; and settlements contain secrecy clauses. Both result in an incentive to conceal, which is bad for adaptation. On the other hand, plaintiffs' attorneys seek information and litigations can serve as incentives for performing tests – an example is given by litigation concerning risks from breast implants. On the whole, however, one could say that the legal context provides negative incentives for the kind of experimental approach embodied in planned adaptation, as can also partially be inferred from the fact that Europe is often considered a good place to conduct clinical trials. Systematic research work on the benefits and risks of different institutional and legal elements in place in the UK and EU could potentially yield results that can be utilized elsewhere. One participant proposed that REACH is an interesting example, in which is regulated what information needs to be disclosed, with safety dossiers being made public. The participants were also reminded of the need for a trade-off between experimenting and monitoring in the regulation of GM crops (currently, to put it crudely, the US is experimenting without monitoring and the EU is monitoring without experimenting). Under the planned adaptation paradigm, if activities are taking place, they should be monitored in order to extract information from them.

Planned adaptation in international regimes

It was observed that the literature on international regimes not often addresses uncertainty or pays systematic attention to self-correction in international regimes and that while it is generally difficult to modify regimes, international regimes are particularly rigid, compared with the more flexible national regimes. Often the international regimes override the national regimes, at least in a legal sense. Examples are the International Whaling Commission, where a monitoring system is related to the setting of quotas; the Montreal Protocol, which has provisions for information acquisition; the UNFCCC, which has the IPCC feeding into its negotiation process; and UNSC resolution 1441, which dealt with the uncertainty around the presence of WMD in Iraq. These are all law-like agreements – although, as we have seen in the case of the latter example, nations may decide not to abide by the agreement (actually some analysts claim that all treaties are failures). International regimes do not always take precedence over national regimes, an example being the International Commission on Radiological Protection. And knowledge-gathering organizations, such as the IPCC and the WHO, are not regulatory institutions themselves in the sense of enforcing anything, the Codex Alimentarius Commission (which partly resides under the WHO) being an exception. The Codex is an interesting case in itself. How well does this institution work in terms of planned adaptation? Another interesting case to study is the International Council on Nanotechnology (which has some elements of the IPCC in it). Finally, one good example of a long-established adaptive international regime for risk regulation seems to be that of nuclear non-proliferation, even though this regime is now in danger of rapidly deteriorating. The NPT also plays an increasing role at least in framing the biotechnology & security issue: what international controls should be put into place on synthesis and training?

The specific regime of standard setting

The question was asked of how standard-setting regimes, such as ISO standards, should be looked at in this context. A distinction must be made between two reasons for standardization: (1) safety/security concerns and (2) interoperability. It seems that the social implications of standard setting (e.g. social aspects and privacy protection in the setting of IT standards) have not been well-studied. There is competition between ISO and the EU and US regulatory systems concerning standards. In the US, standardization largely takes place on a voluntary basis – a *laissez-faire* attitude. In the EU, we witness a displacement of national standards by European ones. This makes it easier to interact when creating and adopting ISO standards. Japan and the US are now discovering that Europe is, in fact, setting many standards. Still, many of the most important standards have been set by US multinational firms.

Governance of conduct and setting of standards by subcommunities

It was observed that there is a tradition in standard setting among engineers, see for instance the codes of the American Society of Mechanical Engineers. At the beginning of the 20th century, boilers were installed without there being standards. We have to note that having scientists and industry setting up standards takes a long time (e.g., nuclear safety standards evolved over a long period). Newly proposed codes of conduct for, e.g., nanotechnology attempt to get research in a certain direction; if they were taken literally, though, they would stop a lot of work. The idea behind such codes is often that we should not legislate scientific practices. In general, it can be concluded there are important subcommunities of experts that govern conduct. Standards and conventions are set through subcommunities and this standard-setting work is hardly ever taking place at the governmental level. An example is the Internet: this is regulated by specialist sets of codes, with minimal governmental regulation on the Internet as a whole.

Responses of developing countries to risks from emerging technologies

The question was raised how developing countries respond to the risks discussed; these countries often give interesting responses, on our or their own terms. Participants emphasized that there is indeed a rich legal culture among developing countries, while at the same time there is a huge push for harmonization. And while laws may look the same, the administrative discretion may be very different (e.g., in China people go to jail for pollution offences, while this happens to no-one in the UK). It makes no sense to throw all developing countries in the same bucket, so to speak. In many developing countries it is hard to get people and policymakers interested. At the same time, China and India are starting to produce products that include nanoparticles. It was mentioned that some analysts argue that standards in the developed and developing world *must* be different at a particular moment in time (e.g., presently, the water cannot be as clean in the developing world as it is elsewhere). Also, from that viewpoint, the use of DDT might still make sense in the Congo.

Some specific issues vis-à-vis developing countries

Several specific issues were flagged for consideration vis-à-vis developing countries and how they handle risks from emerging technologies. With regard to IP rights, developing countries offer interesting exemptions for fundamental research. It is still too early to know if, for synthetic biology and nanotechnology, a “competition in laxity” argument (involving changes in negotiating power between firms and states where one state offers lower regulations) will hold. And in the field of food safety we see that, due to a reaction to problematic products from China, there is now an increased demand *in* China for food safety. It is clear that globalization of technological development leads to quandaries on the globalization of oversight: for instance, whose standard will India be using to regulate its stem cell research? Another issue that must be considered is the possible displacement of products from poor countries, as a consequence of the introduction of emerging technologies in developed countries.

Some conclusions for future research

Some participants pointed at the methodological weaknesses of previous internationally comparative work in this field. We need to work on research methods for this kind of work, including basic criteria about dos and don'ts for comparative research. Key here is that methods are emerging and that we are facing both an interdisciplinary challenge and a policy challenge – also we must recognize that the literature is driven by people's agendas. Furthermore, category use (the use of labels such as “nanotechnology,” “synthetic biology,” “globalization,” etc.) has to be studied in itself and these categories need to be deconstructed. Finally, it was concluded that there is a demand for research on uncertainty, adaptation and learning (a middle road) and on the implications of emerging technologies for developing countries.

3 Successes of past risk management – improved design

Design, testing and demonstration for emergent properties

How can emerging technologies be designed, tested and demonstrated in a socially robust way? This session opened with a brief presentation on that question. The rapid development and diffusion of technology was pointed at, as context for answering this question. The pace of technology development and the global diffusion of technologies are both accelerating. Biological engineering, information technology, nanotechnologies and other emerging technologies are advancing at exponential rates. Studies on the speed and cost of information processing, costs of moving and processing materials and information, and costs of DNA sequencing and synthesis show acceleration of functional capabilities derived from underlying technical change. Casual anecdotes and systematic studies also suggest that emerging technologies are diffusing at extraordinary rates. The rise of IT production and research in Bangalore and surprise wins by Slovenian and Chinese teams in the 2006 and 2007 IGEM competitions inform conventional wisdoms on globalization. Systematic studies on internationalization of education, investment, and R&D strongly reinforce this view. Several official US organizations have expressed their concern. With rapid advances in DNA synthesis, assembly and engineering, the NSABB/RAC Roundtable on Synthetic Biology asks “What kinds of efforts have been, or are being, taken to engineer containment into synthetic systems/organisms?” and then asked researchers to rise to the challenge. And with global diffusion of DNA synthesis and assembly capabilities, the State Department Bureau of International Security and Nonproliferation highlights the need for “cooperative international programs that promote the safe, secure and responsible use of biological materials that are at risk of accidental release or intentional misuse.” It is crucially important to define new roles for experts and policymakers in appraising benefits and risks and to work jointly with scientists and engineers on projects that focus on design, testing and demonstration. MIT is preparing an NSF proposal for a project that does just that.

Work that needs to be done in safe/secure/sustainable design: different layers, different players

Reflecting on the issue, one participant asked: Who are the players? Experts? But who are the experts when it comes to principles of design? Issues of ease of access and subcontracting need to be addressed. Various levels of work are related to design, with different people involved: (i) research; (ii) products of research; (iii) standards (building code like); (iv) professional standards. With the diffusion of technologies throughout the world, how do you maintain safety and rigor? Other workshop participants acknowledged that we do not have a clear understanding of how technologies will develop and we do not know what they will mean in practice (e.g. whether there will be any form of centralization or not). Furthermore, it was pointed out that for regulatory issues (e.g., safety or environment), we typically try to control unintended harm, but not harm resulting from wilful malevolence.

The examples of the “terminator gene” and GM switches

One participant wondered why there is reluctance in policy communities to consider the use of technological solutions to ensuring the environmental containment of GM crops, for example, genetic use restriction technologies. The phrase “terminator gene,” with its public relations hazards, has contributed to the reluctance of policymakers to require the use of these technologies as a standard. Even in the absence of risk of self-replication over the long term

it could have been a “precautionary” design to satisfy the public. The suggestion that genetic use restriction technology should have been included in GM crops was qualified by other participants, who commented that in a culture where you buy seed each year this may be OK, but in cultures where everyone saves seed this is bad; in developing countries, farmers do not want to buy seed every year. Another participant observed that there is a similar example to the terminator gene debate in the field of synthetic biology, where extreme symbiotic capabilities are involved. Having GM switches is one of the synthetic biology design principles. However, Monsanto grabbed the principle – in an IP context – and this “poisoned the well.”

The importance of retrospective studies

The general consensus in the workshop was that work is needed on retrospective studies, with points of comparison and contrast chosen beforehand. We speak with different voices about history and the future; and in itself it is interesting to study what happens when the future becomes history. One prime example of a retrospective case would be bridge design; bridges are typically ten times stronger than they need to be. Technologies need to be tamed. Historically, in such processes, a lot of people have died, but we can see that these processes have been *learning processes*. These learning processes feature episodes of discrete failure and reactive response. Of course, we do not have to wait for failure, especially when irreversible processes may be triggered by emerging technologies. Still, it may be difficult to identify discrete failure in a biological context. Therefore, it is not easy to determine how safe design will feed into biological technologies. With respect to the example of bridges, one participant commented that bridges, nowadays, are still failing. Apparently, we still do not understand all forces on bridges; more monitoring is needed. Another participant found this to be a frightening observation. It was concluded that the case of bridges is a great example. Why did people not take up the recommendation for increased monitoring? Are the technologists stupid? Probably not; the real issues seem to be: (1) who is believed and why and (2) adaptation and learning. A similar discussion could be held about aircraft crashes for which we do seem to have an appropriate learning system in place, at least for wind shear. However, procedures related to air safety are still incomplete, with a lot of reporting being done voluntarily. Other examples that were proposed for further study were steam traction engines, cars, railways, and other transport systems. We also have to observe changes in what we regulate, over time.

Methodology of case studies

The workshop participants were generally in favor of performing case studies. The importance of maintaining a multiplicity of narratives was emphasized. We should recognize that there is not one uniform way to interpret case studies. So at least the existence of other narratives – when exploring only one – should be acknowledged, or the different narratives should be treated in parallel. One of the workshop participants asked the (self-)critical question to what extent we become complicit when we study emerging technologies. It is important to be reflexive in the analysis.

Culture of safety? The example of nuclear reactors

The nuclear reactor was mentioned as the paradigmatic case of design for safety – can we *really* do it, i.e. make reactors failsafe with multiple systems and designed to forestall catastrophic failure? For this example, the answer may nudge to the positive. There is also an effect of design on the sense of security: the presence of a safety culture and the ability to run the designs. But do we also think that we have the right capacity to handle synthetic biology well? Other participants thought that indeed the question is why we have intense regulation for nuclear safety, but there is less attention paid to design for safety in the GM field? A large part of the

answer is that apparently the design for safety in biotechnology cannot reassure the public. It is an interesting question to study whether there indeed is a culture of design for safety in nuclear engineering, and to see what we could learn from that. Still, you cannot situate nuclear power reactors everywhere. It all depends on whether people trust the experts. The workshop participants agreed that there is a whole list of classic reasons against nuclear power (including the issues of waste and nonproliferation risks), just as there are strong reasons against synthetic biological products (e.g. the issue of reproduction).

The need for experimentation, e.g. tiered release

It was observed that there is a huge pressure to get there fast, for example, in the case of nanotechnology, but also in the case of pharmaceuticals: people do want cures. The proponents say almost nothing about the risks. We could make more use of schemes of “tiered” or “cascading” release: (1) test before release; (2) repair obvious mistakes, but realize that the tests are not complete; (3) tiered release or cascading release with limited numbers of patients; (4) reappraise with off-label use (the practice of prescribing drugs for a purpose outside the scope of the drug’s approved label), with torts as incentive for reappraisal through courts. From this it can be concluded that, for such a scheme to work, we should monitor much more: we really monitor too little. And more generally, the conclusion drawn by the workshop was that there is a need for experimentation, given the uncertainty.

Focus on evidence? Or focus on accountability?

It was recognized that it is hard to determine what constitutes good evidence of harm. The way evidence is treated by different groups often serves their self-interest and ideology. We can clearly see campaigns being fought out, with both sides treating evidence the way they want to, see for instance the global warming debate. Moreover, the concept of evidence is discipline-based and, thus, varies across contexts. Evidence is used in different ways, which we must more fully understand. A similar issue arises around “demonstration.” We must be aware that there is a difference between an experiment and a demonstration. Let us also deconstruct demonstration and think about who needs to be brought to the table before the demonstration. This brings us to a more basic issue: we should focus not so much on evidence, but on accountability. Our primary concern should be the design of a *process* and not of a product. Already, there is enough interest in outcomes. We should think harder about what makes processes work.

Social learning and risk regulation

Some of the participants were very positive about the proposed MIT project, in particular because it works with the scientists, offering them a reflexive space, a learning component. We do not only learn about the technical aspects of potential unsafety, but we also learn about social systems related to safety. From the case of mad cow disease lessons can be learnt about the process of social and ethical oversight. Other participants noticed the uneven social abilities to react against “green” (food/materials/fuels), “red” (human health applications) and “white/black” (microbes, beer, etc. – “black” referring to malevolent applications) biotechnology. There are noticeable differences in societal responses to these different applications of biotechnology. A plea was made for more humility. Regulatory strategies may have perverse consequences, as unintended outcomes. We need training in “hedging and flexing.” Reflexive adaptation and review are key. We often make mistakes when we regulate things that we anticipate. A key question here is: how strongly coupled are the different types of social learning and particular technologies. There can be couplings, with novelty in kinds of social learning arising in conjunction with a new technology. We may need a sociology of social learning. Oftentimes, we find that information is suppressed. It is critical for society to orient itself on learning. There is

a strong link between the social acceptability of a particular technology and the regulation of its risks.

Problems related to the (perceived) public acceptability of testing

As an interesting twist was added, that technologists' ideas about public acceptability can also stand in the way of testing for understanding. The example was given of NASA's Space Shuttle booster redesign for safety. What was needed was for the problem to be approached in a scientific way: not a simple fail/pass test, but testing to actually improve the design. However, NASA did not like that approach to testing; for reasons of not wanting to endanger public acceptability of the risk, NASA did not want to talk about other possibilities for testing.

Importance of intermediary institutions between science and policymaking

It was emphasized that it is also important to focus on the institutions that are in place for telling decision makers what they should do. Some participants contended that academics are increasingly focused on understanding, and not on advising. Other participants advised that we should not forget to deconstruct what is said by the people who are consulted. Still, there was a widely shared interest among workshop participants to learn more about how scientific advisers can get decision makers to listen, when they have advice to offer.

Intra- and intercultural value differences and their impact on design choices

We should be aware of the fact that particular values are inevitably built into a design, so what happens in a societal debate – ultimately – must have an influence on the design choices. Not surprisingly, we see large differences between cultures in what people find controversial. For example, in the UK and China, the regulatory systems and the roles of learning within them are completely different.

Deconstruction of false promises

The workshop participants would like to see that the construction of promise is studied, and how the benefits are shaped. What kind of promising claims are attached to synthetic biology? We have Venter who promises an energy source, we have the promise of biobricks, and maybe several more promises. It would be interesting to tie the plausibility of these constructions to the history of the cases. In the large number of cases studied by the MIT PoET group, it was found that none of the past promises were kept. We should not be surprised, since the protagonists of particular emerging technologies often feature a "wilful lack of rightness"; they do not have any predictions on offer (that is, they do not aim to be right), but things to sell.

Conclusion

This following summary of this session was offered: first, we need to study broad cases that run across regulatory cultures and, second, study narrow cases that pay attention to constructed elements. We do not need to cover everything, however. And, third, there is a prospective element: technologists working on current developments want advice and to learn from earlier pitfalls. Finally, we need studies on uncertainty adaptation and self-correction. These studies should address different uncertainties, different cultures, false negatives and false positives. They should focus on the process of transition, the emergence of the technology: how the emergence takes place, with particular attention being paid to institutions. Obviously, the definition of the technologies should not be taken for granted.

Participants

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2. Jane *Calvert* (University of Edinburgh, ESRC Centre for Social and Economic Research on Innovation in Genomics) [only session 3]
3. Claire *Cotterill* (Genetic Interest Group)
4. Kevin *Finneran* (Issues in Science and Technology)
5. John *Finney* (University College London, Department of Physics and Astronomy; British Pugwash Group; Council of the Pugwash Conferences on Science and World Affairs)
6. Liz *Fisher* (University of Oxford, Faculty of Law)
7. Larry *McCray* (MIT, Center for International Studies)
8. Gautam *Mukunda* (MIT, Department of Political Science)
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14. Joyce *Tait* (University of Edinburgh, ESRC Centre for Social and Economic Research on Innovation in Genomics)
15. Robin *Williams* (University of Edinburgh, Research Centre for the Social Sciences) [only session 3]
16. Steve *Yearley* (University of Edinburgh, ESRC Genomics Policy & Research Forum)
17. Neelima *Yeddanapudi* (MIT, Engineering Systems Division)