Weighing the Benefits and the Risks: Better Defining Regulation of New Technologies

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In December 2003 the British Medical Journal published a tongue-in-cheek paper by Smith and Pell [1]. In it, they described how parachutes, instruments designed to prevent or minimise "major trauma related to gravitational challenge", had not been tested using randomised trials, which are the accepted system for testing medical devices. Without randomised and placebo controlled testing, could be we sure that parachutes were safe?

Automobiles are another example of where a widely accepted technology has slipped under the radar in terms of safety. Given the number of automobile accidents resulting in serious injury or death, the number of recalls of faulty automobiles announced through the media, the amount and type of pollutants released by automobiles into the environment, and the fact that automobile travel involves hurling ourselves across the ground on a heavy machine designed to create and sustain an explosion, why does the public not request a moratorium on further automobile production until companies can demonstrate the complete and absolute safety of such a technology?

What makes certain technologies the objects of intense public pressure for regulation and control instead of others, and how does regulation play a role in helping or hindering the delivery of a technology to the end-users? The answers to these questions are varied and will depend on a number of factors, including how information regarding the risks and benefits of the technology is presented, people's ideological and moral standpoints, and the uncertainty surrounding a technology and its impact on people's health, environment and general lifestyle. How do you design different regulatory systems which ensure an acceptable level of safety, reflect the values of society and allow those technologies which are beneficial to reach people? There are many examples of technologies and regulatory structures being developed in ways that illustrate the challenges these questions present. The answers to how we can overcome these challenges will depend on the transparency of the process, equitable demands and conditions for information regarding safety and/or harm, and equal parts cynicism and hope.

Perhaps the clearest example where a technology's development has been impeded by both the regulatory system and a lack of clarity and conflicting societal views is that of genetically modified crops or foods (GM foods). In places like the United States or Canada, the regulatory system begins with a political decision (in their respective cases, the assumption of no harm) and follows with a scientific assessment of possible harm. As a brief overview, data is gathered regarding safety, efficacy and possible environmental impacts, and if no evidence of harm is detected the new foods or crops are allowed onto the market [2][3]. In contrast, Europe begins the process with a political decision to base its regulatory system on the Precautionary Principle whereby if harm is seen as a possibility (even without scientific evidence), then approval of products can be withheld until further satisfactory evidence of their safety is provided. The European process also ends with a political decision in that, even if a positive assessment is given by the European Food Safety Administration (EFSA), the European Commission can vote to withhold approval. The result is a system that demands proof of a negative (the lack of harm – impossible to completely prove), and that rests on normative political perceptions [4].

Why is this problematic? Firms trying to produce GM products find it challenging because they invest a lot of resources trying to get through the regulatory system without any clear indication that they could be successful, even if they provided the evidence requested by regulators. Some firms would actually prefer a straight moratorium on GM products in Europe than an antagonistic regulatory system as they could then turn their resources and attention to other products [5]. Furthermore, the political decision to prohibit GM foods for cultivation in Europe is not necessarily democratic. There are farm and consumer groups that would like to have the option to purchase or cultivate GM foods, and the debate has been shaped by non-governmental organisations and lobby groups that do not necessarily represent the majority nor contribute to information on the nature of the technology in a balanced way [6].

The negative perception that GM technology has amongst large portions of the public despite scientific evidence to the contrary is worrying for scientists, industry and government in terms of other emerging technologies. Nanotechnology, for example, is one such technology which is still being defined in terms of its applications, and the associated benefits and risks. A range of potential benefits have been identified, from new materials with smart capabilities to nano-robotic technologies which could be used in medicine for cancer treatment or advanced diagnosis. The risks speculated include environmental damage, terrorist use, and health and safety concerns [7][8]. Synthetic biology – the ability to build and manipulate biological materials from scratch – is another emerging technology which is facing the same concerns [9]. The evidence around these different scenarios is tenuous at best, but the possibility has already prompted calls for early regulation. These calls are motivated on the one hand by the desire to minimise any potentially harmful effects before they emerge, and on the other hand to engage the public early on so that the negative perception and caustic opposition that arose around GM crops could be avoided. The fact that different groups, both in support and opposition

of these technologies, want to see regulation developed is understandable given what regulation can do if designed in different ways (it can be permissive, it can be prophylactic or preventive, it can be used to signal to funders what research to support) [7].

What regulation is being asked to address, if framed in a very simple manner, is not simply safety; it is being asked to address people's perception of risk. It is being asked to address the general public's perception of risk and fears regarding unknown (but possible) negative effects of emerging technologies. It is being asked to address the fears of industry in terms of facilitating their development of new markets, while providing a mechanism that can help prevent public backlash against their products. It is seen as a mechanism by interest groups to protect their own interests in regards to a technology or industry.

While I propose that regulation is being asked to address the perception of risk and to lower people's fear of uncertainty, what should the regulation of science and technology actually achieve? While opinions may differ as to the benefits of different new technologies and whether society is better or worse off, regulation should be seen as a mechanism that provides a balance between safety and facilitating the delivery of a technology's benefits to society. This requires transparency of information regarding the possible impacts of a technology; and in order to achieve this it is necessary to have a broadly accepted level of scientific grounding and rigour in the research that provides it. Transparency of information also means the provision of information to the general public in a non-technical manner. The provision of this information must also be seen as extending from a neutral party; part of the problem [10] is that industry and government have been portrayed as biased (and implicitly or explicitly as dishonest) regarding technologies such as GM foods and crops. For this reason, all parties engaging in the regulatory debate should be welcome to provide their evidence, but also expected to adhere to the standards of rigour and transparency, namely explaining where their evidence came from, how they are funded and who they represent. For example, some anti-GM groups are funded by organic farming organisations which stand to benefit from market share and improved public perception of their products if GM foods are portrayed as unhealthy or dangerous. The continued support for basic and applied research in universities from public funds would go a long way in helping build trust in the science and information provided around these technologies; third party funding can be seen as separate from industry other private agendas (e.g. from NGOs, lobby groups). Finally, the structures of a regulatory system should reflect values broadly representing the society it is in, but these should only be the starting point of a regulatory process; the process and decisions should then reflect the previously accepted scientific and technical processes. Regulatory systems which set rules, such as that for Europe's food and agriculture, ask for evidence based on these rules and give the impression that approval will be given if the conditions are met. However, this is not always the case. Often the "goalposts" are moved due to political pressures, which then leads to wasted resources on all sides, and more importantly, a breakdown of trust – the key ingredient of a sound and beneficial regulatory system.

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