



Nanotechnology is an extremely multifaceted and complex phenomenon. Both the amorphous boundaries of 'nanotechnology' as an entity and the correspondingly varied safety requirements of products and production processes make it virtually impossible to adapt existing legal regulatory mechanisms.



Let us have a look at classical legal regulation: As historian of technology Otto Mayr has shown, the governor or regulator of a steam engine is a technology that can be taken to stand for dynamic self-regulating systems such as the free market or – when the market on its own is not enough – the modern state (Mayr 1986). This immediately becomes apparent when we look at the characteristic mode of functioning of the steam engine's governor: in the boiler of a steam engine water is brought to the boil so that the steam pressure thus generated can be translated into work. This is a dangerous operation because if the pressure rises too high the boiler will simply explode. This is where the governor steps in to do the work of regulation. It consists of a few balls revolving around an axis: the faster the axis rotates, the higher the balls fly up, as in a carousel. Now the axis is driven by steam. The greater the pressure in the boiler, the faster the balls revolve. When the pressure rises to a dangerous level, the balls fly so high that they cross a threshold and open a valve, allowing steam to escape from the boiler. As the pressure drops again, the governor rotates more slowly, the balls fly lower and the valve closes. Without this system the operation of the steam engine would not be safeguarded at all.

The regulation of technical processes, new materials or consumer goods works in a similar way, where the role of the governor is typically taken by regulatory bureaucracies. These institutions sometimes work

in a slow and routine way and at other times respond rapidly to social pressure or a growing potential risk. If a certain threshold is exceeded, the institution intervenes and may prohibit, for example, any further distribution of a given product or material. The thresholds in question are usually already established in advance (how much of a specific harmful substance is permitted in a certain item of food, for example) or else they are established through the legislative enactment of regulatory measures. Rather than preventing certain things from occurring in the first place, the governor – like the regulatory body – functions as part of a system's automatic mechanism of self-observation: the system is able to develop freely until it comes up against critical limits that could put its continued existence – only guaranteed by regulatory practice in any case – at risk. Just as the governor in a steam engine has a regulating function, so too the regulatory practice just described is an essential instrument of the "governance" of modern societies.



But the limits to and gaps in knowledge are plentiful concerning nanotechnologies – including a lack of standards, characterization and testing procedures etc. – and pose a special challenge to safety research and regulatory measures. It is not clear at all anymore where to put limits for a "governor" because there isn't enough knowledge. Attempts exist to make up for these systematic deficiencies in the legal regulatory system by means of 'soft' measures, such as:

- (1) continual observation of developments (system of permanent awareness or vigilance, for example, in observatories),
- (2) industry self-regulation via codes of conduct, and
- (3) multi-stakeholder dialogues intended to establish legitimation.

However, such measures – guided as

☞ they are by a vague notion of precaution – are not capable on their own of meeting the challenges posed by ‘nanotechnology’ in any appropriate way. By themselves, they do not satisfy the need for regulation. They are an attempt to transform ignorance into a kind of assurance. The phenomenon of ‘nanotechnology’ also confronts us with systematic limits to knowledge that cannot be overcome in a preventative manner. Many of the opportunities and risks associated with nanotechnologies will become manifest and quantifiable only in retrospect – in the course of product use.

The ‘soft’ measures associated with an ‘extended’ concept of regulation represent a departure from the principles of classical legal regulation. The latter include public oversight, political transparency and legal certainty and are guaranteed by a publicly accountable and responsive institution, permitting effective intervention. The ‘soft’ measures alluded to above, however, constitute a retreat from these principles, whereas the option of intervening in and influencing innovation processes is indispensable for dealing in a responsible and socially robust way with the uncertainties encountered in this new field of technology.

The wish to use such soft measures, especially observatories, is also nurtured by an idea that is often called ‘risk radar’, namely an early warning system that could identify very risky areas of research or development or business, and that would have the

effect that nobody would ‘go’ there or push activities further in this direction. Again, this is a rather passive concept that does not deal with intervening in or influencing innovation processes in a more direct way.

Given these considerations, a ‘reflexive adjudication procedure’ seems both necessary and appropriate as a collective learning process and a means of generating public trust. This procedure would provide a means of assessing regulatory practice in a way that is both open to public scrutiny and politically transparent; its focus would be on what is required in terms of knowledge, communication and action, as well as on the scope and suitability of measures taken thus far in the context of an ‘extended’ concept of regulation. The outcomes of observations from the special observatories, ‘code of good practice’ procedures and stakeholder dialogues could be integrated into such a reflexive adjudication procedure. Its guiding question would be: ‘Is nanotechnology in good hands?’ (For further information and a model concerning such a ‘reflexive adjudication procedure’ see Lösch/Gammel/Nordmann 2009).



STEFAN GAMMEL

---

## 📖 Links to other Portfolio sheets:

📖 Code of Conduct   📖 Risk   📖 Observatory

## 📖 Literature: Print & WWW

Mayr, Otto (1986): *Authority, Liberty and Automatic Machinery in Early Modern Europe*. Baltimore and London: The John Hopkins University Press.

Lösch, A., Gammel, S. and A. Nordmann (2009): *Jenseits von Regulierung – Zum politischen Umgang mit Nanotechnologie*. [„Beyond Regulation: On the Political Governance of Nanotechnology“; contributions in English language, extensive English summary]. Berlin.