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Evidence-based policy and the precautionary principle: friends or foes?[1]

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A key theme in our volume is the connection, or, most pertinently perhaps, disconnection, between science and decision-making. In this chapter, we start from the experience of the European Union with two foundations of risk regulation: evidence-based policy and the precautionary principle. The two are often contrasted for reasons of political advocacy, but – we will argue – they can coexist, at least within the sphere of the limits of freedom of scientific research. Our argument that evidence-based policy and the precautionary principle can and should be reconciled, however, is conditional, not absolute. We offer a proposition for public policy in which limits to the freedom of scientific research are removed in the name of the precautionary principle. Indeed, we argue that it is precautionary not to place limitations on the freedom of scientific research, because there are many possible adverse consequences for prosperity, innovation, welfare, health and society. At the same time, this lack of governmental intervention has to be balanced by a dialogic relationship between scientists and society. In the end our proposal is about a social contract: scientists obtain freedom but guarantee self-regulation and an active dialogue with society.

Governing risk in the European Union

In the experience of the EU, two foundations of risk regulation have emerged. Broadly speaking, we can call one foundation evidence-based policy and the other the precautionary principle. Evidence-based policy is, in principle, the main foundation of regulatory decision-making in the OECD countries and the EU. Evidence-based policy goes beyond risk regulation. Indeed, it is a cornerstone of the better regulation policy of the EU (European Commission 2015). It is a commitment to use evidence systematically in the life cycle of regulations. In fact, the Commission's regulatory policy is at least in principle anchored to evidence utilisation in the development of new EU legislation, risk analysis and ex-post legislative evaluation (European Commission 2015). This commitment to evidence on the part of the European

institutions reflects a more general international trend. To illustrate, we find commitments to evidence-based policy in government guidelines for the development of laws and regulations, where the main policy instrument supporting public choice is regulatory impact assessment (Dunlop and Radaelli 2016).

Let us look at impact assessment because it provides a good example of how commitments to evidence-based policy operate at the level of decision-making. The thrust of impact assessment is to bring evidence to bear on regulatory choice: in taking a regulatory decision, for example whether to ban certain experiments with stem cells or the diffusion of genetically modified organisms, policymakers have to explain the reasons behind their choice, consult a wide range of stakeholders and – most relevant for our discussion – carry out an empirical analysis of the likely effects in terms of costs and benefits.

Thus, impact assessment has a core objective of identifying and possibly quantifying the likely effects of a proposed rule – imagine, for example, a regulatory proposal to set limitations to medical research or scientific experimentation. Typically, impact assessment revolves around the economic effects – costs and benefits – for different categories of stakeholders. But it can also look at intergenerational dynamics, the overall macroeconomic effects, the benefits and costs in terms of trade in open economies, CO_2 impact, demographic implications, income distribution and jobs. However, impact assessment embraces the evidence-based approach in a broader sense, comprising the obligation to state the reasoning behind regulatory intervention and to consult widely. In a nutshell, impact assessment and more generally evidence-based approaches to decision-making establish both rights and obligations: obligations for the regulators or lawmakers, and rights for those affected groups, professions and citizens who want to make their voices heard, and have the right to know about the empirical foundations of a regulatory proposal. The normative stance (i.e. what ought to happen, not necessarily what happens) of impact assessment is the following: in the absence of evidence and the possibility of discussing and criticising it, there is no social authorisation for regulation. Governments and institutions such as the European Commission cannot regulate unless they explain and illustrate empirically the reasons supporting regulation and allow for public comment. This normative stance is reflected in administrative procedure acts across the world, and therefore it governs administrative–regulatory interventions beyond the domain of impact assessment. As explained earlier, it is a manifestation of evidence-based policy as a foundation for public choice.

Let us now explore another aspect of this foundation. Regulations allow or prohibit certain types of behaviour. Some regulations restrict freedom of scientific research, often in the name of the environment, public health or ethical–religious principles. The evidence-based foundation for policy has a problem with these restrictions. Indeed, if we think from an evidence-based

policy point of view, we should reason that regulators and policymakers have general duties – to protect the environment and public health, for example – but they need to be authorised via evidence-based tools each time they propose specific regulatory interventions.

Thus, there is something else (i.e. not evidence-based) that informs regulatory decisions. Here we come to another foundation of risk regulation: the precautionary principle. The conventional narrative, indeed, has pitched this principle against evidence-based policy. Before we critically consider this juxtaposition, we will clarify what the precautionary principle involves. In the context of the EU, the precautionary principle is enshrined (yet not defined) in Article 191 of the Treaty on the Functioning of the European Union of 2013 (TFEU). This article refers to the environment. It states that

> Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

In 2000 the European Commission published guidelines on how to use the precautionary principle in a variety of policy domains. The precautionary principle 'applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU' (European Commission 2000). In order to decide which kind of measure to take, there are some requirements. Indeed, any precautionary measure should be proportional, non-discriminatory, consistent with comparable measures already in place, be anchored to an examination of the benefits and costs of action and inaction, be subject to review and capable of assigning responsibility for producing the scientific evidence for a more comprehensive risk assessment (European Commission 2000: 3).

The precautionary principle should not be confused with prevention, where science 'can reliably assess and quantify risks' (COMEST 2005: 7), or pessimism, which is an inclination towards certain beliefs (Sandin 2004). We are dealing with risk management. The starting point is scientific uncertainty, which may be the consequence of either the need for further evidence (in certain cases total ignorance), or of the fact that we are dealing with trans-scientific issues, which are framed in the language of science but cannot be answered (at this moment in time or perhaps forever) by science (Weinberg 1972; Majone 2010). Although the definition of the principle is legal, it is political considerations that determine how and when constellations of actors invoke it (Tosun 2013).

Originally limited to environmental policies, the principle has been expanded by courts to public health and safety. There are traces of

precautionary approaches in financial regulation too (Tosun 2013). In terms of regulatory philosophy, it is a foundational principle for the EU, like evidence-based policy. Given our word budget, we cannot rehearse the story of the principle, its possible interpretations (Gollier and Treich 2003) and its controversial applications to EU regulation (see Alemanno 2007: esp. chs II and III). We can, however, emphasise two points. First, as explained by Jale Tosun (2013), political considerations determine how the precautionary principle is invoked and triggered. A corollary of this political precautionary advocacy is the lack of transparency on how the interaction between precaution and evidence-based considerations is moulded in decision-making. We insist that the point is about the use of the principle, not something inherently political/opaque/anti-empirical in the principle itself. And in fact – our second point – the 2000 Communication of the European Commission (as well as regulation 178/2002 art. 6 on the European Food Safety Authority) anchors the principle to a set of requirements that are compatible with evidence-based policy – so much so that the Communication allows the EU regulators to trigger precaution only if the decision is based, among other things, on proportionality and benefit–cost considerations regarding intervention and inaction, and is subject to review in light of new scientific evidence. At least in legal and conceptual terms (if not in its usage), the precautionary principle is not incompatible with the other foundational principle of evidence-based decisions (Alemanno 2007). Unfortunately, we do not have sufficient case law regarding whether the conditions for triggering the precautionary principle have been met by the European Commission or EFSA (Alemanno 2007) – the European courts have been reluctant to provide a clear answer on this point.

A proposition for precaution to limit regulatory interventions, not to support them

As mentioned, it is political advocacy (not robust conceptual analysis) that has pitched the two foundations against one other: regulators either proceed on the basis of evidence or they invoke the precautionary principle. In Europe, we have seen this battle of principles being fought in many domains (European Risk Forum 2011; Garnett and Parsons 2016), from BSE (Monaghan et al. 2012: 181) to milk aids for cows, from regulation of medicines to chemicals (European Risk Forum 2016).

One of the best-known case concerns genetically modified food. Since the 1990s the European public has rejected GMOs, and authorities have implemented stringent regulations, 'sometimes citing vaguely' the precautionary principle without the support of strict scientific evidence. More complex social, ethical, cultural and economic factors were at stake (Wiener et al. 2011: 50). Recently, the use of bisphenol-A has been restricted, even though EFSA concluded that the evidence is too limited to draw any conclusions for human health. Another example is glyphosate. The European licence

for the use of this substance has not been renewed yet (only extended for eighteen months), despite the findings of high-quality scientific assessments carried out by EFSA (European Risk Forum 2016: 34). Indeed, the European agency ruled that glyphosate is non-carcinogenic, drawing heavy criticism for its lack of data transparency and for being in contradiction of the IARC judgement that glyphosate is 'probably carcinogenic'.

So, are we predestined to follow one foundation of regulatory choice or the other? Not necessarily. First consider this: logically, there should be at least a minimum of empirical evidence to lead to the conclusion that 'we do not know enough' and opt for precaution. This is why in 2000 the Commission set evidence-based requirements for the use of the precautionary principle in decision-making. Second, consider the jurisprudence of the World Trade Organization: regulators cannot simply go for unqualified precaution, otherwise the use of the precautionary principle becomes equivalent to protectionism in disguise (Majone 2000). Third, at least in the EU, the principle is formally endorsed. It cannot be disposed of lightly. It has to be used with the other foundational principle of evidence-based policy, which is equally endorsed in all the strategic documents on regulation of the institutions of the EU. If the two are incompatible, we should conclude that the regulatory foundations of EU public policy contain two contradictory principles. Instead, as explained by Alemanno (2011), the two souls of EU risk regulation ought to improve their coexistence. Alemanno (2011) talks about humanising some features of risk analysis and asks for more transparency regarding how the two foundations come to play together in decision-making. This chimes with the debate on the other side of the Atlantic, where the Obama administration issued guidance on humanising cost–benefit analysis (Sunstein 2011).

But how exactly can the two foundations come together? We do not have a general answer to this question. But we suggest a solution in the special case where the core issue is freedom of scientific research. In this domain, we argue that the principle of precaution should survive, but (and this is the point) inside, not outside the empirical basis of decision-making. We therefore propose the following:

> Given that there is irreducible uncertainty in terms of technological risks and the economic and ethical issues caused by regulations that prohibit medical and scientific research, it is precautionary *not* to prohibit any scientific research unless there is empirical evidence showing that the costs and damage to people and environment outweigh the benefits of freedom of research.

This proposition takes an angle for the precautionary principle that has not been explored so far. The principle is typically used to regulate and ban, while we draw attention to domains where precaution suggests non-intervention. These domains are those where the key regulatory question is scientific research (as opposed to more applied stages such as innovation

and the development of technology). To illustrate, we might think of regulations that prohibit research on assisted reproduction or on human embryos.

We hasten to add that our proposition is not unconditional. It is qualified by its own feasibility conditions. The first condition is that there has to be a certain maturity and institutionalisation of evidence-based practice in a given country or jurisdiction. Indeed, when we say 'unless there is empirical evidence', we mean that our argument is valid only if there is diffuse capacity to undertake empirical analysis. Evidence shows that the capacity for impact assessment, consultation and cost–benefit analysis differs widely across countries (Dunlop and Radaelli 2016).

The second condition is the social background that undergirds our formulation of the precautionary principle. Practically, we are thinking of a situation where science and society meet upstream, with several opportunities and instruments for public engagement at an early stage (Wilsdon and Willis 2004). The marriage of evidence-based policy and the precautionary principle does not materialise in a social vacuum. On the one hand, we need social trust. On the other, we need scientific responsibility on the part of the communities of science.

Social trust in science cannot be taken for granted. It has to be constantly produced and reproduced with appropriate forms of public engagement. Think of questions such as: what are the boundaries between basic and applied research? When does a scientific research project become a dangerous military application? How do we share the basic values of a certain development of medical research? In the past, governments have tried to 'educate the public' about science. This is the so-called deficit model (Ziman 1991; Sturgis and Allum 2004) in which the lack of trust in science is attributed to ignorance. Educate the masses, fill in their deficit of knowledge and there will be more trust in science. Today we know that scientific education, teaching statistics to journalists and other approaches have a very valuable role to play. But the reasons behind lack of trust are much deeper than ignorance.

At the same time, the solution cannot be limited to deontological codes. Our societies, and the EU especially, need a wider reconciliation between citizens and scientists. Let us consider all the dimensions of our equation. The government does not ban or limit scientific research unless there is compelling evidence of serious risk of harm to people and or the environment – this is the formulation of our principle. The scientists offer responsibility and engagement with society. Science becomes socially accountable, but not via governmental intrusion, regulations and, in the worst cases, faith-based obligations and prohibitions. All this amounts to a new role for the scientific community in society. This is possible if we identify a strong paradigm that generates self-regulation of scientists, accountability and dialogic attitudes.

Conclusion

This chapter offers a new definition of the precautionary principle, which goes hand in hand with the evidence-based policy in fostering freedom of research. We have argued that the precautionary principle should recommend non-intervention in scientific research, unless there is clear evidence showing that costs and damage outweigh benefits.

The challenge for the effective implementation of such a principle is first to create mature and institutionalised evidence-based practices. Yet this is not enough. Our version of the precautionary principle is effective only in a social environment characterised by social trust and scientific responsibility. How to build up this new 'social contract' between citizens, individual scientists, the scientific communities and the policymakers is the key issue for future research and public policy.

Note

1 We wish to thank Marco Cappato, Filomena Gallo and the Luca Coscioni Association for having invited Claudio Radaelli to present the initial draft of this chapter to the World Congress for Freedom of Scientific Research in Rome, 4–6 April 2014. We gratefully acknowledge the comments on the first draft provided by Alberto Alemanno, Lorenzo Allio, Claire Dunlop and Simona Giordano – the responsibility for mistakes and omissions remains ours.

References

Alemanno, A. (2007), *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO*, London: Cameron May.

Alemanno, A. (2011), 'Risk vs. hazard and the two souls of EU risk regulation: a reply to Ragnar Löfstedt', *European Journal of Risk Regulation* 2.2: 169–71.

COMEST (2005), *The Precautionary Principle*, Paris: UNESCO.

Dunlop, C. A., and Radaelli, C. M. (eds) (2016), *Handbook of Regulatory Impact Assessment*, Cheltenham: Edward Elgar.

European Commission (2000), *Communication on the Precautionary Principle* (COM 2000/001), Brussels.

European Commission (2015), *Communication from the Commission. Better Regulation for Better Results – An EU Agenda* (COM 2015/215), Brussels.

European Risk Forum (2011), *The Precautionary Principle. Application and Way Forward*, Brussels, www.riskforum.eu/uploads/2/5/7/1/25710097/erf_pp_way_forward_booklet_.pdf (last accessed 8 December 2016).

European Risk Forum (2016), *Scientific Evidence and the Management of Risk*, Brussels, www.riskforum.eu/uploads/2/5/7/1/25710097/erf_-_scientific_evidence___eu_risk_mgmt_16.pdf (last accessed 8 December 2016).

Garnett, K., and Parsons, D. J. (2016), 'Multi-case review of the application of the precautionary principle in European Union law and case law', *Risk Analysis*, 37.3: 502–16.

Gollier, C., and Treich, N. (2003), 'Decision-making under scientific uncertainty: the economics of the precautionary principle', *Journal of Risk and Uncertainty*, 27.1: 77–103.

Majone, G. (2000), 'The Credibility Crisis of Community Regulation', *JCMS: Journal of Common Market Studies*, 38: 273–302.
Majone, G. (2010), 'Foundations of risk regulation: science, decision-making, policy learning and institutional reform', *European Journal of Risk and Regulation*, 1.1: 5–19.
Monaghan, M., Pawson, R., and Wicker, K. (2012), 'The precautionary principle and evidence-based policy', *Evidence & Policy*, 8.2: 171–91.
Sandin, P. (2004), 'The precautionary principle and the concept of precaution', *Environmental Values*, 13: 461–75.
Sturgis, P., and Allum, N. (2004), 'Science in society: re-evaluating the deficit model of public attitudes', *Public Understanding of Science*, 13.1: 55–74.
Sunstein, C. R. (2011), 'Humanizing cost–benefit analysis', *European Journal of Risk and Regulation*, 2.1: 3–7.
Tosun, J. (2013), 'How the EU handles uncertain risks: understanding the role of the precautionary principle', *Journal of European Public Policy*, 20.10: 1517–28.
Weinberg, A. M. (1972), 'Science and trans-science', *Minerva*, 10.2: 209–22.
Wiener, J., Rogers, M., and Hammitt, J. et al. (2011), *The Reality of Precaution. Comparing Risk Regulation in the United States and Europe*, Washington, DC: RFF Press.
Wilsdon, J., and Willis, R. (2004), *See-through Science: Why Public Engagement Needs to Move Upstream*, London: Demos.
Ziman, J. (1991), 'Public understanding of science', *Technology & Human Values*, 16.1: 99–105.