

Rivaling Evidence-bases and Politics in Regulatory Science

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Summary: In line with contemporary political and sociological research on science and regulation, this article problematizes the notion of ‘scientific evidence’ as something independent from and prior to political values. The production of scientific or technical criteria supporting regulatory politics is referred to as ‘regulatory science’ in the fields of policy studies and the sociology of science and technology. Evidence-bases are an example of regulatory science and they illustrate the latter’s intimate relation with political values. I will briefly outline how evidence-bases are not a neutral basis for politics, but that they are constructed *through* politics and interested groups. Taking the European health claims debate as an example, I show that there exists no unitary notion of evidence, but a confrontation of two scientific frameworks, supported by different expert networks, and proposing different conceptions of what scientific ‘evidence’ is. In regulatory matters, scientific evidence alone cannot settle disputes once and for all because the evidence is precisely what’s at stake.

Introduction

In 2012, the European Food Safety Authority (EFSA) celebrated its 10th anniversary. Since its creation in 2002, the agency has done an impressive amount of work on different food-related subjects, and not the least contentious ones at that. The agency was established in the

wake of a series of food crises and meant to embody the value of independent scientific expertise. In a recent News Focus article, *Science* stated that: "Amid Europe's food fights EFSA keeps its eyes on the evidence" (1). This article is a reaction to that statement. I propose a more complicated and realistic perspective on scientific expertise and the nature of 'evidence' in regulatory science. The article is based on empirical, qualitative research conducted between 2010 and 2013. Material was gathered from scientific journals; newsletters related to food science, law and marketing; the author's participation in colloquia and seminars on health claims; and in-depth interviews with actors from academic food research, the food industry, EFSA, and the European Commission. A more comprehensive account will be published as a PhD thesis in 2014.

Traveling Scientists, Networks and Hubs

Being a member of one of EFSA's thematic scientific panels is not a full-time job. Scientists applying for a position in one of these panels have a career independent of EFSA. However, every individual's career is carefully screened in order to manage potential conflicts of interest. Hence the hassle about Diána Bánáti's appointment in May 2012 as the new Executive and Scientific Director of ILSI Europe, an organization funded by the food industry. Bánáti was Chair of EFSA's Management Board and brows were raised about the ease with which she switched positions, a phenomenon known as the 'revolving door'. But the controversy about Bánáti's appointment involves more than the career switch of one singular person, and this is where the bigger picture of science-policy interactions steps in, along with some basic social anthropology. An agency such as EFSA can be defined in terms of its role and mission, as they are described in official documents of the European Commission. Another way to describe EFSA is to look at the individuals that make up the organization, what they do, and how they move about. A different, but complementary picture then emerges

to that of EFSA as an agency with a fixed location and a bureaucratic structure. Even though EFSA has a permanent staff, the drafting of scientific opinions is done by a network of experts who regularly meet in Parma, flying in from all over Europe. Dependent on international experts, EFSA is a hub for traveling scientists. Diána Bánáti became the Executive Director of the International Life Sciences Institute's European branch (ILSI Europe). ILSI is a global network of experts, headquartered in Washington DC, and divided into regional branches covering for example the USA, South America, Europe and South-East Asia. Each regional branch has an administrative headquarter with a limited permanent staff ensuring public relations, communication, scientific publications and the organization of events. Next to the permanent staff, each ILSI branch is composed of a number of thematic task forces, much like EFSA's thematic panels. However, these task forces do not judge evidence, but act as think tanks to produce regulatory concepts *defining* 'evidence'. For example, ILSI Europe, based in Brussels, has a well-developed functional foods task force, and also a pre- and probiotics task force. This is by no means a coincidence, as the food industry's major players have been anticipating a European legislation for health claims since the 1990s.

EFSA and ILSI have in common that they host traveling scientific experts in specific working groups. Occasionally, the same expert is called upon by both the agency and the Institute. This doesn't mean that EFSA and ILSI formally collaborate, nor does it mean that individuals influence agendas or decisions in either expert body. What it points at, rather, is the socio-professional condition of today's 'linked in' scientific experts. The more diverse a scientist's professional experience is, the more he or she will be valued not only for technical knowledge, but also for managerial capacities and hands-on expertise in policy matters. It is not surprising that the same expert pops up in different advisory committees, and in transnational bodies such as the World Health Organization or the Codex Alimentarius.

Indeed, it is not surprising then, that Bánáti took up a position within ILSI Europe. She continues being scientific advisor, but she now occupies a different place in a transnational network of 'policy-trained' scientists.

Rivaling Evidence-bases for health claims

So what about independent scientific advice? Does the sociological reality of transnational networks of scientists run counter to the institutional separations we create between politics and science? Yes and No. No, because institutions like EFSA and the European Commission are real enough and EFSA takes great care to manage any potential conflict of interest (2). In addition, differences between food legislation in Europe and the US, or disagreements within Europe, show that institutions and national contexts matter. To put it bluntly: there's no such thing as a global conspiracy of scientific experts. However, transnational networks do exert an influence on policymaking that transcends personal contacts between individuals. Networks are breeding spots for ideas, concepts, and scientific programs. In addition, they provide the channels for the diffusion of those ideas. Evidence-based medicine is such a program, originally drafted by a group of university clinicians that quickly became adopted as a set of international standards (3,4). Another example is the principle of 'risk analysis', conceptually separating risk assessment from risk management, and originally elaborated by the US National Research Council. The principle was diffused across various international expert bodies before it became a dominant administrative framework and the institutional template for European food policy and EFSA's role as a risk assessment body providing scientific advice to the Commission as a decision-maker and risk 'manager'. (5,6). An example that illustrates both the complementarities and rivalries between frameworks pushed by international expert networks on the one hand, and a public agency like EFSA on the other, is the current debate on food-related health claims in Europe. Between 1995 and 2006, in an

anticipative movement towards the EU's health claims regulation (7), two consecutive international projects dealt with the topic of functional foods and how to define them, along with a template to assess health claims on food products. The projects were called *Functional Food Science in Europe* (FUFOSE) and *Process for the Assessment of Scientific Support for Claims on Foods* (PASSCLAIM) respectively (8,9). Both initiatives received financial support from the EU, and the scientific coordination was in the hands of ILSI Europe. PASSCLAIM provided scientific guiding principles for the EU's health claim regulation and assessment procedures, and is recognized by EU officials as a useful template. However, when EFSA started evaluating health claims on a case-by-case basis, all this preparation work led to what industry and academic nutrition researchers see as a disappointing list of approved health claims: vitamins, minerals, and an occasional sugar-free chewing gum. Best-selling probiotics, or promising new variants of these have been disapproved one by one through EFSA's assessments. Former collaborators of the FUFOSE and PASSCLAIM projects, and members of the 'ILSI family' as they sometimes call themselves, launched a counter-initiative in the journal *Nutrition* in 2011 (10). In this article, they complain that the PASSCLAIM assessment proposal has been interpreted and used according to the norms of Evidence-Based Medicine, which was not part of their intentions. For the authors, the main problem is the importance given to randomized clinical trials in the assessment of food-related health claims. They esteem that this evidence-base is suitable for drug research, but not necessarily for nutrition science, as the latter should deal with systemic interactions at low dosage over long periods of time. A new range of markers, intermediate endpoints, models and assessment methods would thus be needed to advance our understanding of the interactions between food ingredients, human health and diet. In short, the authors make a plea for a scientific program to develop a proper set of norms for nutrition science - a program that they choose to call *Evidence-based Nutrition*. What we witness in the European health claims debate is a

confrontation of two scientific frameworks, supported by different expert networks, and proposing different conceptions of what scientific 'evidence' is. One is the framework used by EFSA, which resembles the principles proposed by Evidence-based Medicine (EBM), with the difference that clinical endpoints are required from human trials *in a healthy population* to avoid any confusion with drugs. The other framework took form through a lineage of projects and papers that started with a consensus definition of 'functional foods' in the 1990s, and that amounted to the concept of Evidence-based Nutrition (EBN) in 2011. This framework is largely supported by the food industry, but also by academic food science researchers, although the reasons for both groups may differ. While the food industry wants to stay far from concepts related to disease and drugs, for financial and marketing reasons, food scientists feel that there should be no regulatory ban on the use of disease endpoints in clinical trials, and that these endpoints do not necessarily turn functional foods into drugs, as dosages are low. In any case, both industry and a large group of academic scientists seem to have found a common cause, and they both disagree with EFSA's evaluation scheme for health claims (11).

What this confrontation of evaluation frameworks or evidence-bases points at, is the *specificity of regulatory science*. Too often, it is assumed that scientific results speak for themselves, and that the regulator simply looks at the 'evidence' in order to make informed decisions. However, as the controversy about health claims shows, regulatory science is an activity in itself. It involves weighing different types of evidence, agreeing upon a hierarchy of scientific evidence, and actively making *choices*. EBM is a clear example of this: proposed by a group of university clinicians, it historically evolved to a set of international guidelines and norms, implemented across the globe in national and regional health policies. EBM is a framework for regulatory science, and EBN is aspiring to become such a framework. This shows that regulatory science is something different than merely 'applying' existing science to

policymaking: it involves decision-making; prioritizing what a given scientific community finds important; and the implementation of a notion of 'evidence' that is as much judicial as it is scientific. (12)

Science, Politics & Society

What do transnational expert networks, institutions, and regulatory science frameworks teach us about the question of independent scientific advice to policymakers? First of all, we see that scientific advice and policymaking are hard to disentangle (13). EBM and EBN provide policy recommendations, along with a specific notion of scientific evidence. They basically stipulate which type of evidence puts more weight into the scale, and how this should be assessed. Second, it invites us to take into account broader dynamics than institutions or agencies alone. Experts travel round the globe, and many of them have become skilled 'panel members' in committees of all sorts. If someone like Bánáti swaps one institution for another, this obviously raises questions about the permeability of the boundary between independent and industry-led institutions. But this dualism doesn't help us to understand the bigger picture where EFSA is bound to be criticized all the time, either for being too industry-friendly, or too strict and thus inhibiting innovation (14). The problem is that EFSA is forced to make judgments, thereby imposing a unitary vision on scientific evidence, reiterated by a journal like *Science* in the aforementioned News Focus article. Evidence can mean very different things, and replacing the question of the independence of institutions by an analysis of rivaling regulatory science frameworks has the merit of bringing this diversity to the surface. The question is not only about 'sound' evidence, but also about the projects one gives political priority to. The recent discussions in the European Parliament (EP) on GMO's provide another good illustration of the entanglement of regulatory science with politics. In July 2011, the EP voted to endorse the principle of Member-State freedom to make decisions about

GMO cultivation. Contrary to what the Commission proposed, the EP asserted that Member-States may use *scientific* arguments next to ethical arguments, acknowledging that different regulatory frameworks may yield *different* conclusions about GMO's environmental safety, diverging from those made by EFSA (15). In the case of health claims, the EU radically opted for consumer protection as its project: a political option translated in EFSA's language of science and quasi-pharmaceutical assessment methods for health claims on food. More than a mere technical question, establishing regulatory science frameworks involves political stakes, corporate interests, and the translation of scientific concepts to legislative texts by expert committees. Shaped through international networks, organizations and rivaling frameworks, regulatory science is both a product and an organizational principle of society. In this context, scientific evidence is not a value-neutral haven outside and despite Europe's food debates, but it is precisely what's at stake.

Conclusion

The production of scientific or technical criteria supporting regulatory politics is referred to as 'regulatory science' in the fields of policy studies and the sociology of science and technology. I have argued that the construction of an evidence-base for regulatory purposes is as much a political as a scientific endeavor. Policymakers know this very well. It is important, however, to acknowledge the particular nature of such evidence, as it is very often confounded with the idea of scientific, objective 'truth', and this has problematic consequences. Let me briefly return to the article in *Science* that I mentioned in the Introduction. I will cite the title of the article again: "Amid Europe's food fights EFSA keeps its eyes on the evidence". This is true in a sense, although it is a particular form of evidence that EFSA is looking at. The trouble begins with the subtitle: "Europe's food-safety watchdog (...) wins praise for sticking to the science – even when Europeans prefer not to hear it." The

particularities of regulatory practice and the construction of evidence-bases are confounded with ‘science’ in general. This is problematic for two reasons. Firstly, it does no justice to fundamental research, where hesitation, reinterpretation and transforming existing knowledge are the motor of advancement rather than selecting and judging evidence. Secondly, it renders political and societal priorities, such as consumer’s protection and public health, vulnerable and dependent on particular forms of evidence (confounded with scientific truth) as the primary source of information. EFSA is “sticking to the science – even when Europeans prefer not to hear it”. The American journal suggests that Europeans are not ready to face the facts of ‘scientific truth’. Although it is not entirely clear what is meant by ‘Europeans’, the assertion seems to imply that those who do not provide the right facts, or a different expertise altogether (farmers, citizens, NGO’s,...) are not considered to be equivalent partners in debates on GMO’s and health claims, the two examples discussed in the *Science* article. Indeed, the prestigious journal prefers to call these debates ‘fights’ – irrelevant quarrels that miss the point. I argue that on the contrary, by recognizing and taking into account the political dimensions of regulatory science, we may prevent closing down our discussions too quickly.

References and Notes

- (1) K. Kupferschmidt, *Science* **338**, 1147 (2012).
- (2) See for example <http://www.efsa.europa.eu/en/faqs/faqcriticisms.htm>.
- (3) D. Armstrong, *Biosocieties* **2**, 73-84 (2007).
- (4) S. Timmermans, E.S. Kolker, *J. Health and Soc. Behavior* **45**, 177-193 (2004)
- (5) *Risk Assessment in the Federal Government: Managing the Process*. (National Academy of Sciences, Washington DC, 1983).

- (6) D. Demortain, in *Scientific Advice to Policy Making: International Comparison*, Lentsch, J., Weingart, P., eds. (Barbara Budrich Publishers, Berlin, 2009) pp.141-160.
- (7) EC 1924/2006.
- (8) A.T. Diplock *et al.* *British Journal of Nutrition*, **81** (1), 1-27 (1999).
- (9) P.J. Aggett *et al.* *Eur J Nutr* (Suppl 1) **44**, I/1-I/2 (2005).
- (10) H. K. Biesalski *et al.*, *Nutrition* **27** (10), S1-S20 (2011).
- (11) See the petition on www.gut-health.eu. In the open letter, the regulatory ban on the use of clinical endpoints related to disease is questioned.
- (12) For an ethnography of decision-making in law, see B. Latour, *The Making of Law: An Ethnography of the Conseil d'Etat* (Polity, Cambridge, 2010).
- (13) For US casestudies, see S. Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Harvard Univ. Press, Cambridge, MA, USA, 1990).
- (14) K. Hendrickx, B. Penders, *Nature* **485**, 582 (2012).
- (15) F. Wickson, B. Wynne, *EMBO reports*, **13**, 100-105 (2012).