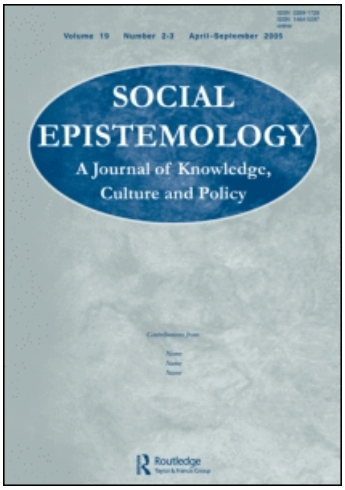

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Practical Values and Uncertainty in Regulatory Decision-making

Oliver Todt, Javier Rodríguez Alcázar and José Luis Luján

Regulatory science, which generates knowledge relevant for regulatory decision-making, is different from standard academic science in that it is oriented mainly towards the attainment of non-epistemic (practical) aims. The role of uncertainty and the limits to the relevance of academic science are being recognized more and more explicitly in regulatory decision-making. This has led to the introduction of regulation-specific scientific methodologies in order to generate decision-relevant data. However, recent practical experience with such non-standard methodologies indicates that they, too, may be subject to important limitations. We argue that the attainment of non-epistemic values and aims (like the protection of human health and the environment) requires not only control of the quality of the data and the methodologies, but also the selection of the level of regulation deemed adequate in each specific case (including a decision about which of the two, under-regulation or over-regulation, would be more acceptable).

Keywords: Regulatory Science; Risk Assessment; Short-term Tests; Weight of Evidence Approach; Standards of Evidence; Methodological Decisions; Uncertainty

Introduction

The use of scientific data in order to support regulatory decision-making on science and technology is usually referred to as regulatory science (Jasanoff 1990). Regulatory science is used to assess the impact of new technologies and the toxicity of chemical substances, as well as to determine acceptable levels of exposure.

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Regulatory science is different from standard academic science in that it is oriented mainly towards the attainment of non-epistemic (practical) aims; namely, regulatory decisions. In that, it is governed not only by different standards but also applies different methods, as compared with academic science. Many of the methodologies of standard academic science are of limited usefulness for regulatory decision-making because they are driven by epistemic aims and values (for instance, accuracy). However, truth (or likelihood of reaching truth) is not the only criterion when choosing methods for risk assessment. Regulatory science is focused on the attainment of practical aims and values, like the generation of decision-relevant data under strict legal, time and budgetary constraints, the rapid assessment of large numbers of substances or the management of uncertainties about possible future impacts.

Over the past two decades, the limits to the relevance and usefulness of academic science for regulatory decisions, as well as the role of uncertainty, have been recognized more and more explicitly in regulatory decision-making. As a consequence, regulatory agencies have started to introduce regulation-specific scientific methodologies (short-term tests, structural analysis, weight-of-evidence approaches, etc.) in order to generate decision-relevant data. One of the main drivers for this change is the problem of scientific uncertainty with respect to the possible health and environmental impacts of new technology. In fact, the growing application of such "non-standard" scientific methodologies in the regulatory context stems from the problems encountered by standard, academic methodology in managing uncertainty.

In this sense, regulatory science illustrates, as will be shown below, the limitations of the thesis of the value-neutrality of science and points to the importance of non-epistemic values in the scientific enterprise. The values, aims and methodologies of academic science are of limited usefulness and applicability in the context of regulatory decision-making. However, recent practical experience with non-standard methodologies indicates that they themselves may also be subject to important limitations, too. In consequence, our paper argues for the need of additional layers of evaluation and data quality control on a case-by-case basis in science and technology regulation.

Science, Regulatory Science and Values

One reason why regulatory science is different from academic science is because it is mainly driven by non-epistemic goals. These goals also play a certain role in standard science, as we shall point out below, but they carry more weight in regulatory science, in the sense that the latter aims at taking decisions concerning the regulation of a product or process. The difference stems also from the recognition that uncertainty is more widespread in regulatory science and that there are important limits to the relevance of scientific evidence for regulatory decision-making.

There are several key features that distinguish regulatory science from what might be termed "academic science" or "standard" scientific practice (or, at least, the standard image of scientific practice). Among those features three are especially noteworthy.

(1) The social relevance of its verdicts, as far as these directly affect human health and/or the environment. For this reason, those verdicts often become the focus of public debate.
(2) The higher degree of empirical under-determination (uncertainty). In regulatory contexts, decisions are based on data, but very often these data are scarce, doubtful, or compatible with mutually incompatible hypotheses. Hence, the interpretation of data can be extremely controversial.
(3) Finally, the importance of time. Very often (likely more often than in standard science) experts have to produce a verdict within a short lapse of time. The need to take a decision usually makes it impossible to wait until the above-mentioned situation of empirical under-determination is overcome (if at all possible).

In short, experts in regulatory science often face the task of rapidly producing outcomes under uncertainty, from scarce or contradictory data, on a controversial topic, closely watched by consumers, politicians, corporations and other concerned actors.

Time is important not only for economic reasons, but also for the protection of human health or the environment. Time is important, for instance, if a substance, whose potential toxicity is under scrutiny, happens to be a useful medical product whose commercialization lingers as the evaluation process plays out; and, conversely, in the case of a chemical compound already on the market that must be withdrawn rapidly if deemed to be toxic.

It is also sensible to take into account the costs of the tests. High costs may affect the economic viability of a product. If this were to happen, not only the economic interests of the producer would be affected; besides, consumers might lose a useful commodity.

Regulatory science seems, then, incompatible with the ideal of a value-free science. But this ideal has been formulated in several ways, so it is necessary to clarify whether regulatory science is, in fact, a counter-example to all the versions of this thesis.

One of the most radical among those versions can be found in the *Tractatus logico-philosophicus*, where Wittgenstein draws a clear-cut distinction between propositions (roughly, statements of fact) and value judgments, and identifies natural science with the class of all true propositions (see Wittgenstein 1999, §§ 2.1, 2.202, 4.01, 4.021, 2, 2.223, 4.11, 4.001, 4.003, 4.111, 6.41, 6.42, 6.522, 6.41). For Wittgenstein, then, there is no place for values of any sort in science. In a more moderate vein, authors like Reichenbach (1938), Weber (1917/1949) and Quine (1992) acknowledged the import of "epistemic" values like prediction and explanation in the election between rival hypotheses and theories. But all of them emphatically denied any role to non-epistemic, practical goals in theory choice.

On the other hand, historians and sociologists of science like Kuhn (1962), Proctor (1991), Barnes (1977), Bloor (1976/1991), Collins and Pinch (1993), and many others demonstrated the falsity of the value-neutrality thesis from the empirical point of view. As far as the facts were concerned, they all claimed, the thesis seemed to be a blatant myth, since many examples could be provided of the influence of extra-scientific factors, like non-epistemic interests, in the construction and success of scientific theories in every field.

But the most promising versions of the thesis are not formulated in historical or sociological terms. Rather, they are grounded on the old distinction, due to Reichenbach (1938), between the context of discovery and the context of justification, which defenders of value-freedom invoke to deny the relevance of socio-historical knowledge for the issue of the neutrality of science. In this version, defenders of the thesis claim that although the concept of practical values can clarify the context of discovery (i.e. the actual research practices of a certain scientific community), the *validity* or *justification* of the outcomes of scientific practices (i.e. scientific knowledge) is as independent of practical values as it is independent of the rest of the components of the context of discovery. Hence, they claim, validity should be established by taking into account only certain epistemic value(s) (Laudan 1984; Ovejero 1994). Some philosophers, like Kitcher (1993) and Worrall (1988), have added that these epistemic values or goals should remain fixed, together with the general traits of scientific methodology, in order to prevent relativism.

The identification of these epistemic values has been a controversial issue. Reichenbach (1938) and Quine (1992) pointed to prediction as the main epistemic goal of science. Kitcher (1993) maintained that the permanent, dominating epistemic aim of science is the attainment of "significant truth." Kuhn (1977) adopted a more pluralistic view in his essay "Objectivity, values, and theory choice," where he endorsed a list of five epistemic values: accuracy, simplicity, consistency, breadth of scope, and fruitfulness. According to Kuhn, these are permanent and constitutive values of scientific activity, although the interpretation of them, as well as their relative weight, changes over time. Laudan (1984) radicalized the pluralism of Kuhn's position, and abandoned its essentialism, by claiming that the list of scientific aims and values changes from discipline to discipline and from one epoch to another. But he remained faithful to the view that although scientific theories and methods pursue (and are judged by) certain aims and values, and although these may change over time, such aims and values are of an exclusive epistemic nature.

The question of whether this neutralism at the justificatory level can be defended is still controversial for science in general. But it is hard to maintain in the case of regulatory science. Kristin Shrader-Frechette (1988, 1989) showed the crucial importance of non-epistemic values (moral values, in particular) in the choice between research methods in applied science and, hence, in deciding on the validity attributed to scientific outcomes in this area. On these grounds, the same author claimed that the "reticulated model" of scientific rationality defended by Laudan (and according to which scientific change is the result of a permanent interplay between the theories, the methods and the epistemic goals of science) was incomplete, because a reference to moral values was missing in it. In her insightful study of a case in hydro-geology, Shrader-Frechette describes a controversy between two groups of scientists concerning the explanation of why plutonium and other radionuclides were found two miles off the radioactive waste dump in Maxey Flats (Kentucky, USA), only 10 years after the facility started operating. One group attributed this unexpected presence to flawed site management (improper dumping, filling, managing, etc.) and to subsequent surface migration. The other group blamed it on a flawed election of the underground site,

based on flawed science or, at least, on a flawed application of science (Shrader-Frechette 1988, 107). Authorities had to decide which group to trust, in a typical situation of empirical under-determination, since available data were consistent with both hypotheses. It was decided to trust the first group and allow the facility to stay open. Sometime later, however, radionuclides were found at an even further distance from the site, and, what was more significant, it was discovered that plutonium concentrations were higher at greater depths, thereby excluding the surface migration theory (Shrader-Frechette 1989, 209). The facility was finally closed, but only after severe environmental damage and adverse effects on people's health had ensued.

The important question here is not which group of scientists turned out to be right, once the situation of empirical under-determination was overcome. It is more interesting to ask what the right decision would have been at that precise point in time when an urgent decision had to be made in a scenario of empirical under-determination. According to Shrader-Frechette, since neither resorting to data, nor to scientific (hydro-geological) methods, nor to epistemic values could settle the controversy, authorities should have taken into account moral values. Protecting the public should have been, in this case, the ultimate criterion for choosing, at least provisionally, among competing hypothesis. And the right decision at that moment would have been to close the site, no matter what hypothesis was finally shown to be true by new data.

This case study shows how, in the case of regulatory science (and, perhaps, in applied science in general), the value-freedom thesis turns out to be unconvincing, not only at the descriptive level but also at the justificatory level. In such contexts, the choice of epistemic values, methods and hypotheses can and must depend upon previous choices of practical values.

Other authors agree that under the above-mentioned circumstances it is morally irresponsible to claim that scientific practice must pursue solely epistemic aims. Carl Cranor, for instance, claims that the aim of risk assessment should not be defined in terms of discovering the truth. Rather, the aim should be that of minimizing the social costs incurred by false positives and false negatives, as well as the economic costs of testing substances for possible health and environmental impacts (Cranor 1997).

The choice of the aims to be pursued by regulatory science is, obviously, of normative character. It is a decision with important moral, social and political consequences, and it is crucial to note that decisions of this sort have moral and social import not only when the task is to select those aims or methods that are likely to minimize the social costs. For even if one wanted to stick to *purely epistemic aims*, social consequences will ensue.

One consequence of pursuing the aims of standard academic science in the context of regulation is a likely increase in costs. But there is a second, more important, consequence: the increase in the number of false negatives. Since standard scientific practice aims at the highest possible degree of certainty, it tends to treat potentially toxic substances as "innocent until proven guilty." Therefore, the straightforward application of standard scientific methodology could allow many potentially toxic substances to stay on the market until it has been established, in the rigorous, conclusive and *slow* manner of academic science, that they are toxic. In other words, the

decision to stick to the ideal of value-free science is not a morally neutral election, since we can anticipate who are going to be the likely winners and losers (Cranor 1999).

Again, the practice of regulatory science contradicts the claim that the justification of scientific methods and results should not take into account practical values. But it also contradicts the essentialist claim (Kitcher 1993; Worrall 1988) that the criteria for the evaluation of such methods and results do not change over time. This is because the development of new ways of applying scientific knowledge has cast doubt upon very deeply rooted convictions about what counts as *good* scientific practice and how to evaluate its methods and outcomes. The choice of values can determine the choice of the research method, and the latter, in turn, can determine the costs, length and even the results of research.

In the case of potentially carcinogenic agents, the best research methods, according to tradition, are epidemiological studies and animal bioassays. Bioassays are often preferred to epidemiological studies, because they normally require less time, and also because of the insufficient number of cases usually available for an epidemiological study. Bioassays, although not completely error free, are also highly reliable. But both bioassays and epidemiological studies typically require between five and seven years of work, and are very costly (around two million US dollars per substance; Cranor 1993, 1997). For these reasons, some regulatory agencies, like the Environmental Protection Agency of California (USA), authorized years ago the use of so-called short-term tests. This term designates a wide variety of research methodologies that are much faster and cheaper than those mentioned above, although slightly less reliable.

From the point of view of standard scientific method, short-term tests are inferior to epidemiological studies and bioassays, because they are not as accurate. But from the point of view of economy and, more importantly, health and environmental protection, they have advantages, at least under certain circumstances. And, given that truth (or likelihood of reaching truth) should not be the only criterion when choosing methods for risk assessment, they are to be preferred in the regulatory context.

A right choice of method in this context is the one that, given the empirical information available, the values we want to promote, and the order we establish among those values, will lead us to choose the method that is more likely to maximize the satisfaction of our decision criteria (see, for instance, Giere 1988). When assessing the toxicity of substances, the method to choose could be a cheap and fast procedure that provides us with a quite reliable verdict (although a bit less reliable than a much slower and more expensive method). And this holds even if it is possible (albeit unlikely) that a toxicity verdict obtained using a short-term test is finally proven false by a slower (and more expensive) standard research process.

Similar arguments hold for other non-standard methodologies. One that is commonly applied in regulatory science is the analysis of structure–activity relationships. Instead of testing each chemical substance for toxicity or carcinogenicity, those that are considered dangerous are identified on the basis of structural, molecular or other similarities they share with other substances that we already know are toxic or carcinogenic. For instance, one criterion for subjecting a substance to regulation could be its potential for bio-accumulation.

A third non-standard methodology is the weight-of-evidence approach. This methodology bases regulatory decisions on the accumulated weight of information from a wide variety of sources, rather than using only one specific study or source of information about, for instance, the toxicity of a chemical substance or the health effects of passive smoking (Environmental Protection Agency 1993). While no single study or source of information at our disposal may be sufficient to substantiate a cause–effect relationship, all of the available information taken together could suffice for taking a decision. In practice, this means a certain relaxation of the standards of proof (Tickner 1999).

In sum, the selection of research procedures (and hence, in some cases, the outcome of the research) depends on the previous election of values and their relative weights. Following this line of argumentation, the usual way of defending the application of non-standard scientific methodologies in the regulatory context can be summed up as the idea that applying the aims and methods of a "value-neutral" (academic) science is not a morally neutral way of proceeding. Given the social and environmental consequences, regulatory decision-making has to make use of decision-relevant methodologies (whose selection and design is necessarily influenced by non-epistemic aims).

Non-epistemic Standards in Regulatory Science, and Their Limitations

However, the application in regulatory practice of non-standard methodologies, specifically chosen to produce decision-relevant knowledge, is not without problems. At least in some cases, their application does not necessarily facilitate the attainment of the desired non-epistemic values and aims (like better protection of human health and the environment). They face certain limitations that commend care in their application. In fact, as we will argue below, it may be necessary, in each specific case, to strike a balance between epistemic and non-epistemic values and aims when selecting the methodologies and analyzing the data.

As we have already seen, the introduction of non-standard scientific methodologies is driven by the increasingly explicit recognition of the role of uncertainty in regulatory decision-making and by the growing understanding of the limited usefulness of scientific evidence in that same context. Science and technology-related regulation has started to take account of scientific uncertainty. Relevant examples of this are recent European Union directives with respect to biotechnology (Todt 2004) and food safety (Todt et al. 2007, 2009).

While non-standard methodologies obviously do not reduce scientific uncertainty in the context of research, they can be understood as a way of reducing uncertainty *in decision-making*: they make scientific uncertainties more manageable for decision-makers, by sacrificing some accuracy and internal consistency for operability and robustness. As a consequence, the problems faced by non-standard methodology because of uncertainty are of a different kind than the ones faced by "standard" methodology in academic science. Some of these problems will be illustrated in the following by the phenomenon of "manufactured uncertainty."

Industries that are confronted with regulation of their products often dispute the validity of the scientific evidence that regulators use as a basis for their decisions. One of the ways of questioning regulation is by sponsoring studies that attempt to show that the research made use of by regulators is not reliable, or that, because of persisting uncertainties, it is insufficient for deducing cause–effect relationships. Another way is to re-analyze data from studies employed in regulatory decision-making in order to produce findings that contradict the original results. Typically, all such industry-sponsored studies try to highlight or magnify the inevitable uncertainties to be found in scientific research, in order to raise doubts about the scientific evidence on which the regulation in question is based. Their ultimate objective is to avoid, delay or otherwise influence regulatory decisions.

Michaels and Monforton (2005) call this process "manufacturing uncertainty." One of the most important cases of manufactured uncertainty is the response of the tobacco industry to studies on the health effects of smoking. In the face of mounting scientific evidence that smoking may cause cancer, the tobacco industry designed strategies to counter those research results, promote uncertainty as to the cause–effect relationships and create controversy. For several decades, starting in the 1950s, the industry sponsored studies that challenged the scientific evidence indicating a link between smoking and cancer. Interest groups close to the industry tried, by means of specialized publications, to stimulate debate over the growing scientific consensus by emphasizing contradictions and uncertainties in the research about the health effects of tobacco (Michaels 2008). Other, similar cases include the regulation of a number of potentially carcinogenic chemicals, but also of other industrial products ranging from lead or asbestos to food additives and plastics. Analogous debates, some of which still persist today, arose in relation to the mounting scientific evidence for anthropogenic factors in global warming. In all of these cases the industries affected by regulation tried, more or less successfully, to question the need for regulation by either throwing into doubt the validity of the available scientific evidence or by sponsoring the generation of data that challenged the evidence used by regulators. In this way, they created uncertainty not only among regulators but also in the public sphere.

Pointing to or magnifying the existing uncertainties is all the more an efficient way of trying to influence regulation as different regulatory agencies may apply different standards, for instance, with respect to adequate methodology. One example is the choice among alternative dose–response curves and of the methods for extrapolating them. Both constitute important methodological decisions that have to be addressed in regulation, particularly in setting standards for the exposure to chemical substances or radioactive materials. In some instances it may, for instance, be unclear whether the dose–response curves are linear (any exposure to the substance in question may be harmful and cause, for instance, cancer) or non-linear (there is a threshold level below which exposure is very unlikely to cause harm). In other, related cases the question is how to extrapolate well-known dose–response curves to cover low-dose exposures for which it is difficult to generate reliable data (Schoeny et al. 2006; Shrader-Frechette 2004). According to the chosen dose–response model, the regulatory response can vary significantly, especially in terms of the permitted maximum exposure levels.

Different regulatory agencies do not necessarily apply the same dose–response curves as basis for regulation even of the same product or technology. As a result, regulation may be more severe in some places than in others. Popp, Crouch, and McConnell (2006) show this in the case of the different dose–response models used by the World Health Organization and the US Environmental Protection Agency for regulating the same chemical substance. The authors also demonstrate that a weight-of-evidence approach for analyzing the available data on different dose–response curves may help to identify the model that is most adequate for regulation. Even though this kind of analysis cannot provide scientific proof, its result is sufficient for decision-making; that is, for helping regulators decide between alternative dose–response curves.

However, weight-of-evidence analyses can be very sensitive to the available body of evidence. In the present example, any additional study concerning one or the other dose–response model as well as any doubts raised about existing research could influence the results of the weight-of-evidence analysis. In other words, regulatory decisions may not only be affected by disagreements between, on the one hand, risk assessments employed by regulatory agencies and, on the other hand, studies promoted by industry. If in addition there is debate even among regulators about the appropriate methodology (dose–response model), it is even more likely that manufactured uncertainty may seriously delay the introduction of regulation or that different regulators end up adopting different standards.

The Quest for Certainty

The occurrence of cases of manufactured uncertainty has to be understood in the context of changes in the judicial and legislative frameworks, especially in the United States, which aim at promoting certainty in the scientific data used in judicial or regulatory proceedings. The demanded level of certainty is extremely high, beyond, in fact, what can be considered scientifically reasonable (or possible) in such contexts (Haack 2005).

One example is a 1993 judicial decision that establishes limits on the use of scientific evidence (for instance, related to health effects of chemical substances) in judicial proceedings in the United States (Cranor 2006). As a result, it is now easier for a defendant, by making reference to existing scientific uncertainty, to demand the exclusion of scientific data that indicate negative health or environmental effects (Jasanoff 2005).

This demand for certainty stands in open contrast to the growing recognition of uncertainty in current regulatory practice, a situation that creates additional difficulties for regulators: on the one hand, there is the possibility of having to exclude evidence because of persisting uncertainties; on the other hand, regulation may face manufactured uncertainty. Both potentialities have important implications for the practical application of the above-mentioned non-standard scientific methodologies in regulation. Methodologies like the weight-of-evidence approach are used in order to facilitate decision-making under uncertainty, by basing decisions on a wide range of available data from a variety of sources, even though all those studies are based on different standards and methodologies, implying that their results are not directly comparable.

However, basing regulatory decisions on the combined results of different and, in principle, non-comparable studies about a specific issue (active or passive smoking, global warming, a chemical's toxicity, etc.) implies the question as to the quality of these studies. In other words, there is a need for quality control, for assessing whether all these studies were executed under the same conditions of scientific excellence, whether they applied adequate scientific methodology and whether all of them should be considered in decision-making.

Given that manufactured uncertainty may influence regulatory decisions and that in certain cases quality control could prove to be difficult, Shrader-Frechette (2004) argues that standard scientific methodology remains fundamental for regulatory science. In some instances, regulation, in order to effectively protect human health and the environment, needs to recur to standard scientific methodology based on criteria of academic excellence. There are, for instance, cases in which special interests could try, on the basis of questionable data, to dismiss the existence of health or environmental impacts and prevent stricter regulation. In such circumstances, only standard scientific methodology is capable of generating the data required for decisive regulatory action. Shrader-Frechette cites as an example the case of low-dose radiation and, in particular, the health impacts from the atmospheric nuclear tests of the 1950s and 1960s. These impacts may be extremely grave and affect hundreds of thousands of people all over the world, thereby presenting a serious health (as well as regulatory) issue. According to the author, powerful interest groups for decades have tried to block the assessment of such impacts. To this aim, they have been recurring to flawed or questionable methodologies in order to generate data with the aim of denying that nuclear testing had any measurable or relevant health impacts. Given the contentiousness of the issue and the difficulties of generating data (due to the global reach of the effects and the need of demonstrating cause-effect relationships), Shrader-Frechette argues that only large-scale epidemiological studies and standard quantitative analysis would be capable of producing sufficiently convincing scientific evidence to counteract attempts to avert regulation.

Non-standard scientific methodologies guided by non-epistemic (decision-oriented) values and aims do not necessarily facilitate regulatory decision-making under uncertainty. Precisely by departing from standard scientific methodology and by taking into account a diversity of data from different sources, as in the case of weight-of-evidence analyses, they could be used to question or delay regulatory action. The production of risk studies whose methodological quality may be unclear has the potential of influencing regulatory decisions. The sponsoring of large numbers of such studies by special interest groups opposed to regulation could even cast doubt on the results of standard academic research (like epidemiological studies). The likelihood for this is even greater if all these industry-sponsored studies entered, without further screening, into a weight-of-evidence analysis (e.g. on the health effects of smoking or the toxicity of a chemical compound). To sum up, the phenomenon of manufactured uncertainty questions the general validity of many of the arguments in favor of applying non-standard methodology in regulatory science.

Conclusions: Necessary Improvements in Regulatory Science

The introduction of non-standard scientific methodologies, like weight-of-evidence analyses or short-term tests, can be interpreted as the result of a process of methodological learning (Luján 2005). This process is concomitant to the recognition of scientific uncertainty. But it also aims at bridging some of the conflicts inherent to science and technology policy and regulation (Todt and Luján 2008). However, the case of manufactured uncertainty shows that methodological learning in risk assessment is not sufficient to guarantee a high level of protection of human health and the environment.

Other, wider-reaching considerations are necessary; most importantly, a differentiated case-by-case analysis of values, aims and methodologies (beyond the assessment of the scientific data). In other words, the overall conclusion from the above discussion is twofold: on the one hand, the requirement for quality control of the data and methodologies used in decision-making; on the other hand, the need for evaluating not only the technology under consideration but also the very process of regulating it.

This last point is particularly important because current regulatory and legislative practices tend to be built upon highly formalized, regularized and standardized procedures. As a consequence, in many instances the same procedure or methodology (for instance, analysis of structure–activity relationships) is supposed to fit all cases of a certain class (for instance, identifying potentially carcinogenic substances). On the contrary, we argue that at least in some instances it may be necessary to assess each case on its own, strengthening or relaxing the standards according to the specific circumstances. This includes a decision about which of the two, under-regulation or over-regulation, would be more acceptable. It also means that regulatory processes would have to be sufficiently flexible to be able to respond dynamically to changes, as would be required in the case of manufactured uncertainty.

Data quality control is more necessary than ever. Its mission here is to decide which of the entire range of available studies and sources of data on a specific topic have to be taken into account in weight-of-evidence analyses, and how to select from all the available studies the "acceptable" ones. This evaluation supplements the more traditional goal of ensuring that the data of a scientific study are sufficiently reliable to justify a specific regulatory decision.

Non-standard methodologies, designed to put into practice certain practical values in regulatory science, do not resolve the problem of the quality of the evidence (nor that of scientific uncertainty). The use of standard scientific methodologies, driven by "traditional" epistemic values, will still be important for regulation aimed at health and environmental protection. One of the most important roles of standard methodology is to counteract "manufactured uncertainty" and facilitate quality control of the *methods* on which scientific studies are based (Shrader-Frechette 2004). Thus, regulatory processes have to develop ways of efficiently combining the application of both non-standard and standard scientific methodology.

All available scientific studies and sources of information would have to be screened by the regulatory agencies for their underlying epistemic values and aims (leading, for instance, to the exclusion of studies with unclear or questionable scientific

methodology). Data quality control cannot be limited just to one of the two levels; both epistemic and non-epistemic aspects have to be assessed.

Beyond data quality control, there is the need for a two-level evaluation of processes and products under consideration: on the one hand, a Technological Options Analysis (Ashford 2005) (i.e. an evaluation of the technology in question, as well as possible alternatives and their consequences); on the other hand, as already argued, a "technology meta-assessment" (i.e. the *evaluation of the process of regulation itself*). This last point means that the regulators themselves should review, actively and continuously, the regulatory procedures and methodologies in order to check their adequacy, detect possible problems or respond to changes (e.g. the emergence of a phenomenon like manufactured uncertainty). Scientific knowledge about risk is a necessary element in all these assessments, but it is far from being the decisive one. In fact, the decisions with respect to technology and its regulation retain an irreducibly political component (Luján and Todt 2007; Moreno, Todt, and Luján 2010).

This situation is especially true of regulatory decisions related to the acceptability of over-regulation or under-regulation. In cases in which there is some evidence of possible negative impacts of a product or process, one way of managing scientific uncertainty (be it "manufactured" or not) would consist of an overall increase in regulatory demands. A practical strategy for strengthening regulation is, for instance, concentrating on the reduction of false negatives (rather than false positives) in the generation of decision-relevant knowledge. This strategy is, obviously, contrary to the pursuit of the highest possible scientific accuracy, but results in more robust regulation.

Still, this strategy may lead to an over-regulation that could delay or impede the introduction of socially useful innovations. But for many technological applications, the social and environmental consequences of over-regulation or under-regulation are not the same. This means that every innovation, as well as its possible risks and social benefits, have to be analyzed in order to decide which of the two possibilities, over-regulation or under-regulation, would be more acceptable in this case.

The problems faced by non-standard scientific methodologies do not invalidate their use nor do they indicate that scientific practice in regulatory decision-making has to remain "value-free." On the contrary, the attainment of certain non-epistemic values and aims (like the protection of human health) is only possible by assuring the quality of the data and the methodologies, as well as selecting the level of regulation deemed adequate in each specific case (including the decision about which of the two, under-regulation or over-regulation, would be more acceptable).

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