

# Analyzing Precautionary Regulation: Do Precaution, Science, and Innovation Go Together?

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In this article we argue that the precautionary principle, as applied to the regulation of science and technology, cannot be considered in any general manner inconsistent with the norms and methods of scientific knowledge generation and justification. Moreover, it does not necessarily curtail scientific-technological innovation. Our argument flows from a differentiated view of what precaution in regulation means. We first characterize several of the most relevant interpretations given to the precautionary principle in academic debate and regulatory practice. We then use examples of actual precaution-based regulation to show that, even though science can have varying functions in different circumstances and frames, all of those interpretations recur to scientific method and knowledge, and tend to imply innovation in methods, products, and processes. In fact, the interplay of regulation and innovation in precautionary policy, at least in the case of the interpretations of precaution that our analysis takes into account, could be understood as a way of reconciling the two fundamental science and technology policy functions of promotion and control.

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**KEY WORDS:** Innovation; methodology; precautionary principle; regulation; risk analysis

## 1. INTRODUCTION: THE DEBATE ABOUT PRECAUTIONARY REGULATION, SCIENCE, AND INNOVATION

In the ongoing debate about the place of the precautionary principle in regulatory decision making it has repeatedly been stated that precautionary regulation tends to marginalize science in decisions and stifle scientific-technological innovation. In this article, we argue that precautionary regulation cannot be considered by its own nature opposed to scientific-technological development, or inconsistent with the processes and norms of scientific knowledge genera-

tion. We concede the possibility that some applications of precaution may imply a disaccord with scientific analysis or block particular innovations. We claim, however, that several of the most relevant interpretations of the precautionary principle, in academic debate as well as regulatory practice, not only recur to scientific method and knowledge but may even prompt their improvement. By the same token, they imply innovation in technology, products, and processes.

Even though authors differentiate in a very general manner between “strong” and “weak” varieties of the precautionary principle,<sup>(1,2)</sup> the critics of its application to regulation rarely recur to detailed analyses of the specific aspects that tell apart different types of precaution, such as the epistemic features of scientific knowledge, or the origin and nature of scientific uncertainty. However, we argue that those aspects are critically relevant to the question of what

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science and innovation mean in precautionary regulation.<sup>1</sup> Detailing the diversity of conceptualizations of precaution and specifying in which ways they diverge from one another seems a necessary exercise in order to be able to analyze the role of science for precaution, as well as the possible implications of precaution for innovation.

Thus, in this article we want to show that the general argument that precaution is inconsistent with sound science and curbs innovation is difficult to sustain if we take such a differentiated and close-up look at the precautionary principle and its varying understandings. To this end, we start out by specifying three different interpretations that cover a relevant part of the diverseness of conceptualizations of precaution to be found in legislation, regulatory decision making, and the academic literature. We then identify the particular role of scientific method and knowledge in each of them. Finally, we highlight, one by one, the potential for innovation offered by these alternative interpretations of precaution. In support of our argument we use examples from current precautionary regulation.

We would like to emphasize that the argument we present here is not intended as a defense of the precautionary principle itself. Likewise, we do not mean to espouse any particular interpretation of precaution. We merely argue that if we analyze the different conceptualizations of science that underpin the precautionary principle, we conclude that this principle cannot be understood as inexorably marginalizing the role of scientific knowledge.<sup>(3)</sup> To the contrary, the application of precaution—at least in the versions of the principle considered in this article—clearly rests on science, which plays a varying but always crucial role. The precautionary principle does not emerge in some general or necessary way as “literally paralyzing”<sup>(4:104)</sup> scientific-technological innovation, or as a “threat”<sup>(5:3)</sup> to it. As we will show, the interpretations of precaution we

contemplate here do imply innovation, of varying degrees and types.

We do not question that precaution introduces elements into regulatory decision making that may be foreign to the precepts of standard academic science, or that it may alter, even drastically, the course of scientific-technological innovation, or in particular cases negatively affect specific fields or technologies. What we dispute is the generalized assumption that with precautionary regulation scientific-technological innovation will falter, or that scientific method and knowledge simply cease to play any relevant or constructive role in regulatory decision making.

## 2. THE PRECAUTIONARY PRINCIPLE IN REGULATORY DECISION MAKING

The basic idea underlying the precautionary principle is that development of a technology has to be regulated whenever there are reasonable indications of possible important (highly damaging, irreversible, systemic, etc.) impacts on human health and the environment, even in the face of inconclusive data, lacunae in scientific knowledge, and doubts about the respective cause-and-effect relationships.<sup>(6-8)</sup> Contrary to standard risk management, precaution means a decision to proceed with regulation even though conclusive scientific evidence is currently not available and may not become available in the future.<sup>(9)</sup>

Starting in the 1980s, the precautionary principle gained increasing relevance in policy making, particularly in the European Union (EU), but also on the international level.<sup>(8,10,11)</sup> In the EU there currently are a number of science- and technology-related processes and products that are subject to precautionary regulation, or to regulation that includes—explicitly or implicitly—some elements of precaution. Examples include biotechnology, chemical products, water management, protected areas, and food safety.

Contrary to hopes that implementing precaution in public policy would reduce controversy, neither has precautionary regulation led to closure of public debate about technology nor does it seem to have significantly improved trust in regulators or regulatory processes.<sup>(12-14)</sup> Rather, precaution has turned into a topic of public discourse. It has become part of a wider social debate in contemporary society over the process and freedom of innovation, and the legitimacy of the intervention of public policy in scientific-technological development. Such debates

<sup>1</sup>In fact, an important part of the critique of the precautionary principle by and large hinges on the underlying notion that there is only one single type of “science.” This, however, is not at all clear. Work in the history, philosophy, and sociology of science shows that a diversity of activities, procedures, methods, and outcomes are commonly subsumed under the term “science.” The same goes for the concept of innovation. While many a critic of precaution understands the concept of innovation basically from the point of view of the development of new technological products, there certainly are other kinds of innovation, from organizational change to methodological progress, as well as varying ways of generating such innovation.

often appear to be focused on particular technologies. However, more often than not they turn on more fundamental questions of control or governance of science and technology.<sup>(15-17)</sup>

One of the key reasons underlying these ongoing debates is that there does not exist a universal, clear-cut definition of the precautionary principle. Likewise, the conditions or frames for its implementation, scope, or operation are not at all clear.<sup>(7,18-21)</sup> Different analysts or stakeholders may operate with conflicting interpretations of what precaution means in the policy context.<sup>(22)</sup> In fact, in practice we are not faced with one single principle but rather with multiple “precautionary principles.”

Arguably, it is precisely this lack of definition and of clear implementation guidelines that has contributed to making the debate more intractable. For one, lack of specificity facilitates criticism. Absence of a clear definition has led to difficulties in practical implementation, and has not helped the principle’s acceptance among many stakeholders.<sup>2</sup>

To sum up, since precaution means different things to different social actors, debate is inevitable, mostly because the principle is just that: a general legal and regulatory principle, and not a concrete procedure, action plan, or application scheme.

### 3. CONTROVERSY ABOUT PRECAUTION

Many advocates of precautionary regulation, regardless of their precise interpretation of the concept, argue in one way or the other that it stimulates innovation.<sup>(24)</sup> One of their most prominent arguments is that applying precaution to technology development will reduce uncertainty about the latter’s implications, which in turn facilitates decision making. In other words, the underlying idea is to actively direct technological development toward solutions that imply (or seem to imply) fewer uncertainties with respect to their possible health and environmental consequences, thereby fostering technological and organizational innovation.

The usefulness of precautionary regulation has been questioned by a number of critics,<sup>(4,25-29)</sup> particularly on the basis of the notions that precautionary regulation limits the freedom of innovation, weakens the standards for the generation of decision-relevant scientific data, and even dissolves the boundary be-

tween scientific knowledge generation and decision making.<sup>3</sup> Such critique weighs more heavily since, as we have seen, there does not exist a unanimous interpretation of what “precaution” and the “precautionary principle” really mean in the regulatory context.<sup>(2,31,32)</sup>

An important critique of precaution concerns the place and function of scientific knowledge in risk regulation.<sup>(4,33)</sup> A typical argument is that regulation based on the precautionary principle turns into an alternative to risk analysis because regulatory decisions would be taken without recourse to (quantitative) scientific data, or at most be confined to qualitative methods alone. And, as far as precautionary decisions are understood to recur to scientific data, those data would not conform to the standards of sound science for having been generated through the methods of a specific “precautionary science.”<sup>(34)</sup> The critics point out that the use of nonstandard scientific methodology (short-term tests, etc.<sup>(35)</sup>) in precautionary science may imply a discouragement of standard (academic) methods of scientific process (like bioassays or other methods of data gathering in a controlled laboratory environment, or—alternatively—standard epidemiological or similar methodologies). Sunstein<sup>(25)</sup> particularly rejects the use of “precautionary” scientific methodologies aimed at minimizing false negatives—in contrast to the methods of standard academic science that are concerned with avoiding false positives—with the argument that both errors of type I and type II can produce serious social consequences.<sup>4</sup> This idea is in line with Wildavsky’s argument that both regulating as well as not regulating creates risks.<sup>(36)</sup> Graham, points out that precautionary regulation tends to divert precious regulatory resources toward “speculative hazards,”<sup>(5:1)</sup> that is, away from scientifically well-fundamented and documented problems that can be subjected to regulation on the basis of sufficiently justified (as well as quantitative) evidence.

Thus, the critique concerns as much process as outcomes (for instance, the opportunity costs of new

<sup>2</sup>Some authors, in fact, consider the clarification of the precautionary principle a particularly urgent problem of regulation and environmental policy making.<sup>(23)</sup>

<sup>3</sup>The distinction between knowledge generation and decision making, in the form of the strict separation of risk assessment from risk management, is considered fundamental to classical risk analysis.<sup>(30)</sup>

<sup>4</sup>As a methodological alternative to precautionary regulation, Sunstein argues for the use of quantitative cost-benefit analysis throughout risk regulation. According to the author, systematic quantification of risks and benefits would increment the role of scientific knowledge in risk analysis and allow for economically efficient regulatory decisions.

products that for precautionary reasons are withheld from market release). Critics also tend to consider that any proposed precautionary approach would have to provide justification as to how it differs from standard, academic scientific process, as well as the supposed advantages it offers. Introducing precautionary procedures as an alternative to standard methods of risk assessment and management without sufficient rational justification would be tantamount to arbitrariness.<sup>(28)</sup>

A different, prominent line of critique of the precautionary principle points to its implications for technological innovation.<sup>(4,5,25,26,33)</sup> Precautionary regulation is understood to slow down innovation by raising development costs and distorting the market. It is contrary to economic efficiency and curtails the freedom of innovation. As we have already seen, Sunstein<sup>(4,25)</sup> considers that regulation based on the precautionary principle cripples technological development. In the same line of thought, Wildavsky<sup>(26:30)</sup> points out that taking precaution to an extreme would literally make impossible even the tiniest innovation because of the possibility of adverse effects.

In other words, the claim is that precautionary regulation will constrain or severely curtail scientific-technological innovation and progress. What these authors propose instead is that scientific-technological development be allowed to play out even if it entails certain problems that will have to be resolved after the fact. On this view, innovation necessarily relies on trial and error. This allows for useful developments to be identified, while in the process eliminating others. In a similar way, any undesired side-effects of otherwise beneficial technologies would be dealt with on the basis of quantitative and reasonably well-founded data. That is, regulation based on standard academic science helps make this process of trial-and-error more efficient by intervening once unwanted effects have been scientifically demonstrated.<sup>(5)</sup>

Precaution, in contrast, curtails trial and error. In fact, it implies technological development without the possibility of learning from error because such error in principle could not occur in the first place.<sup>(26)</sup> Neither could the potential of new technology be clearly circumscribed in practice, nor its possible undesired effects be positively ascertained. In other words, not only would we never know what real benefits the new technology might bring. We would also never know if the possible negative effects really exist, if they can be resolved or mini-

mized efficiently, or if they may turn out to be acceptable given the overwhelming benefits derived from the technology in question. After all, the history of science and technology shows that most technologies can be adapted to new social demands, and be modified in ways that make them more efficient, as well as reduce their environmental impact or effects on human health. “Safety comes from use,” in the words of Wildavsky.<sup>(26:35)</sup> Precautionary regulation would simply truncate such processes. Regulators would impose certain “acceptable” ways of development while blocking others, without real-world knowledge of the (positive and negative) effects in *either* case.<sup>(33:15)</sup> Precaution as a regulatory guideline thus is seen to sideline or circumvent science in decision making: decisions—instead of being based on standard scientific knowledge—are taken on the ground of the (extra-scientific) precautionary principle, as would be the case when regulators impose one technology over another without real-world knowledge of its future effects. Critics consider that as a result precaution blurs the separation between risk assessment (scientific knowledge generation) and risk management (decision making based on such knowledge, as well as societal values and objectives).

In sum, freedom of innovation is curtailed, hindering the development of new technology, while science is marginalized in decision processes or even excluded from them. Entrepreneurs are not at liberty to proceed with innovation trajectories that may maximize social, economic, or other benefits (even if negative side-effects could not be ruled out). Some authors<sup>(37)</sup> even consider that guaranteeing freedom of innovation is tantamount to promoting health and environmental protection because curtailing innovation reduces wealth, which in turn increases risks for public health. In other words, costs incurred due to excessive regulation cost human lives.

We will now attempt to better specify what precautionary regulation is, and what its implications for innovation and science are, by recurring to a classification of different interpretations of the principle. This classification will then serve as a basis for analyzing the arguments against precautionary regulation.

#### 4. DIFFERENT KINDS OF “PRECAUTION”

The critique of precautionary regulation makes recourse to a variety of arguments. As we have already stated, a discerning analysis of those arguments

makes necessary a clarification of the different understandings of precaution, as well as a specification of their characteristics and differentiating elements in relation to science and innovation. Therefore, in order to systematically analyze the debate, we propose to identify and specify in detail several key interpretations of precaution held by relevant social actors. As we will see, such concrete interpretations of precaution are directly linked to the understanding of uncertainty, the role of science in decision making, and the epistemic characteristics of scientific knowledge.

For our analysis, we recur to a systematization of alternative interpretations of precaution adapted from Luján and Todt.<sup>(38,39)</sup> This classification explicitly links different conceptualizations of the precautionary principle to particular understandings of scientific knowledge and method, as well as their functions in regulatory decision making. For this reason, it is useful for our present purpose. The taxonomy was developed from an analysis of academic debate and regulatory practice by means of a study of the specialized literature about the precautionary principle, including legislation and regulatory documents, analyses of precautionary regulation from several academic fields (risk studies, sociology, philosophy of science, etc.), as well as regulatory case studies.

The analysis presented in this article relies on interpretations of the precautionary principle specifically in relation to scientific knowledge and technological development. Therefore, other differentiations that can be found in the literature, particularly between “weak” and “strong” types of precaution,<sup>(1,2,33)</sup> are, as stated before, not considered adequate for our purpose.<sup>5</sup> They represent essentially a gradation of more or less precautionary decision making and either do not make explicit reference to the questions of science and innovation, or can be subsumed under the more extensive, three-level classification we have chosen to apply here.

In the following we present the three different understandings of precaution and precautionary regulation.<sup>6</sup>

<sup>5</sup>We are interested here in the varying *interpretations* given to the precautionary principle by regulators, academics, and institutions. We therefore exclude from consideration the ongoing debate about its nature, for instance, if it expresses rules of choice, procedural requirements, or epistemic principles.

<sup>6</sup>As we have already stated in the Section 1, the three interpretations of precaution we will be using for our analysis are not

#### 4.1. Precaution Based on Standard Academic Science

On this interpretation, the precautionary principle is understood as one alternative form of risk management. Precaution is judged relevant in cases in which scientific knowledge about risks and impacts is incomplete, but there are some *scientific data*, however fragmentary, to suggest that important negative impacts may ensue.<sup>(40)</sup> Regulation here is fundamentally risk-based regulation (risk management based on previous risk assessment). Precaution, though, indicates which data are missing and are important to be generated in the future. Many policy-makers and regulatory authorities subscribe to this interpretation.<sup>(41)</sup>

However, some critics would contend that even this relatively inconsequential intervention is unacceptable because it curtails the process of trial and error and makes it subject to regulatory control.

#### 4.2. Precaution Based on Decision-Oriented Science

This interpretation is based on the notion that the inherent epistemological limitations of scientific method and knowledge are impossible to eradicate, implying that the process (including any methodological decisions) by which scientific knowledge is generated is not normatively neutral.<sup>(42)</sup> Scientific knowledge is always riddled with nonreducible uncertainties. In order to produce decision-relevant knowledge, the use of modified, nonstandard scientific methodologies is considered necessary.<sup>7</sup> Among such nonstandard methodologies are short-term tests, weight-of-evidence approaches, the reversal of the burden of proof, and the use of specifically tailored inference guides.<sup>(35,43–49)</sup> The data produced by methodologies like these do not conform to all

supposed to cover the entire spectrum of possible interpretations of precaution but rather offer a selection of several highly relevant understandings of precaution in regulation. Their purpose is to help us structure our analysis. In other words, they represent our reconstruction of the relevant *use* of precaution in regulation, but not our views about precaution itself (rather, they present the views of different relevant analysts and stakeholders that participate in regulatory procedures, as well as in its debate and academic study).

<sup>7</sup>Scientists deal with scientific uncertainty by means of explicit methodological decisions about, for example, which dose-response models to apply. In this sense, nonstandard scientific methodologies are the outcome of methodological decisions and embody values like protection of health and the environment that correspond to the objectives of risk assessment and management.



the quality demands of standard academic science. Nonetheless, they are more directly relevant to regulators (whose objective, after all, is taking decisions to effectively protect human health and the environment). In other words, such innovation in methodology is oriented toward the obtainment of what Whiteside<sup>(9)</sup> calls a “better science” as basis for decisions (which could also be important for other science-related fields, e.g., innovation policy). Methodological innovation comprises not only analyses of how methodological decisions affect research outcomes, but also of new procedures for assessing effects and impacts of technology, and for taking regulatory decisions. This interpretation of precaution can be found mostly in the academic debate, but has also been adopted, at least in certain cases, by regulatory agencies.

Recurring to scientific methodologies that do not absolutely conform to the standards of academic science is considered by a large number of critics as not justifiable in scientific terms (“junk science”). In their view, all regulatory decisions have to be based on “sound science,” that is, completely standard, academic scientific methodology and procedure (epidemiological studies, bioessays, quantitative risk assessment, etc.).

#### 4.3. Precaution Based on Science-Generated Alternative Trajectories

On this interpretation, the key to decision making is identifying a technology’s “capacity for producing harm,” which is determined on the basis of certain traits inherent to that technology (inflexibility, complexity, irreversibility, uncontrollability, etc.). Therefore, detailed studies of possible risks or negative effects are considered unnecessary. Precaution is equated with avoiding or severely restricting the use of technologies judged to present a high capacity for harm and/or high levels of uncertainty about possibly severe impacts.<sup>(50)</sup> Management (decision making) is oriented toward selection of some technologies over others, or substitution of certain scientific-technological trajectories with alternatives that are judged to present fewer undesirable characteristics. The principal activity for science is the generation of such alternative (technological, organizational, etc.) solutions. This interpretation is typically espoused by environmentalists.

Many critics would contend that this interpretation is tantamount to excluding scientific knowledge from decision making, given that science only inter-

venes in the preparation of the various decision options, but not in the decisions themselves.

### 5. PRECAUTION AS SCIENTIFIC, AND INNOVATIVE

The three alternative interpretations of precaution that we have presented allow us to analyze in a more discriminating manner the questions as to the roles of science and innovation in precautionary policy.<sup>8</sup> We use current examples of precautionary regulation in order to ascertain—for each of the three interpretations—what role (if any) science plays and in what way innovation manifests itself. Our analysis recurs not only to actual regulatory applications of the precautionary principle, but equally to social actors’ perceptions about them. We also take into account those actors’ particular interpretations of precaution, including about how it should *ideally* be applied to regulation.

#### 5.1. Precaution Based on Standard Academic Science

Science here has a crucial mediating function between regulation and innovation. An important example of this is an early (and fairly implicit) implementation of precaution in the European legislation concerning genetically modified organisms (GMOs).<sup>(51)</sup> This regulation introduces a case-by-case and step-by-step approach: instead of regulating entire categories of genetically modified (GM) products, each product has to be analyzed and authorized individually, and regulation proceeds through various stages of analysis (scientific analysis of the product’s characteristics, limited field trials, time limits on market authorization, traceability requirements, postcommercialization analysis). This staged regulatory procedure has fundamentally changed the product development process in industry. Each of its

<sup>8</sup>These three alternative interpretations of the precautionary principle are sufficiently different from each other that basing public policy and decision making *exclusively* on any one of them will produce one kind of results while using any of the others as a basis will lead to very different outcomes. This does not preclude the possibility that precautionary regulation (particularly in complex regulatory frameworks like the EU chemicals regulation REACH) may present a mixture of elements of two or even all three interpretations, or that it is interpreted by different analysts and stakeholders in different manners. In other words, closure of the debates with respect to precautionary regulation cannot be expected while a universally accepted definition of precaution does not exist.

individual steps has triggered or accelerated technical innovation in processes and outcomes. One example is the substitution of antibiotic resistant markers in GMOs.<sup>(52)</sup>

Postcommercialization scientific monitoring, in particular, is a regulatory innovation adopted as a precautionary measure because of persisting uncertainty about the large-scale and long-term effects of commercial GM crops. Once a product has received the go-ahead for being placed on the market, it may still be subject to scientific follow-up studies to examine its environmental impact. In order to adapt to these regulatory requirements, the biotechnology industry had to develop new lines of research, particularly on environmental interaction and health effects. The traceability requirement has spurred the development of a number of technologies that can be used in the tracing of all kinds of substances and foodstuffs.<sup>(52)</sup> Postmarketing monitoring has spawned an entire new field of interdisciplinary research.

Another example is the EU chemicals regulation REACH.<sup>(53)</sup> It was introduced because many chemical substances that are currently on the market have never been tested for toxicity (or other undesired effects). REACH implements a large-scale program of preventive scientific analysis that aims at testing all those substances. Not only does this create an incentive for innovation in methodologies for testing chemicals, the objective of identifying all dangerous but hitherto unregulated commercial chemicals also stimulates scientific and technological innovation, for instance, in improvements of a given production process, or in the substitution of one particular substance for another.

The academic-science-based interpretation of precautionary regulation can be understood as a very sophisticated version of the process of trial and error, into which certain precautionary adjustments and improvements are introduced, always on the basis of scientific knowledge (like the introduction of tracing technologies or the replacement of particular chemicals). Precautionary regulation, on this view, has the aim of preventing negative effects due to critical errors, without, however, limiting the overall innovation process in any important way.

To sum up, our analysis shows that the trial-and-error character of the process—which, according to critics like Wildavsky,<sup>(26)</sup> is the key to facilitating innovation—is retained, even under precaution. Far from obstructing innovation, the precautionary element fomented methodological, as well as specific

technological product and process innovation (as the cases of the European GMO and chemicals regulations show).

## 5.2. Precaution Based on Decision-Oriented Science

Knowledge generation on this interpretation is a specific kind of scientific activity whose objectives are decision oriented, and whose methodology has been adapted to those objectives. Again, a good example is provided by the European REACH regulation because it features several critical methodological innovations.<sup>(54)</sup> One of the most important is the shifting in the burden of proof.<sup>(44)</sup> For certain substances that are considered potentially dangerous, REACH places the burden of proof on the substance's manufacturer. This is a substantial methodological departure from standard regulatory practice in which the burden of proof usually falls on the regulator (who has to demonstrate a product's harmfulness). In order to decide if a chemical substance may be potentially harmful (and has to be analyzed in further detail), another recent innovation in scientific methodology is employed: structure-activity relationships (SAR). Under the SAR regime, substances are classified as innocuous or potentially harmful according to certain common characteristics. Such traits, which make a substance *potentially* more dangerous (but do not imply by themselves harmfulness), include their molecular structure, capacity for bioaccumulation, and persistence or mobility in the natural environment.<sup>(55)</sup> REACH, in fact, has spawned an entire field of European research in methodological innovation for analyzing substances.<sup>(56)</sup>

Another example for innovation in scientific methodology is related to the debate about the use of biomonitoring methodologies, sparked in part by REACH.<sup>(57,58)</sup> In this debate the use of animal bioassays for the generation of regulatory data has been questioned on the grounds that animal data are not necessarily relevant for predicting the effects of chemical substances in humans. As an alternative it is being suggested to accelerate development of new scientific methodologies for the biomonitoring of human subjects in order to generate the data necessary for regulatory decision making.

The key to this understanding of precaution is the process of methodological learning by which it is characterized. Methodological learning operates through the improvement of scientific processes

and the optimization of the generation of decision-relevant data. According to this interpretation of precaution, scientific methodology has to be modified in such a way as to facilitate analysis of the effects that the underlying choices in selecting methodologies, models, or objectives have on outcomes. In other words, it implies a type of meta-analysis that consists in a systematic study of the variance in scientific results as a consequence of adjustments in the methodology for obtaining those results. In turn, methodological learning and meta-analysis foster innovation because they indicate necessary changes in technological products and processes, as well as ways of minimizing health and environmental impacts.<sup>(59)</sup>

Precaution implies methodological innovation in risk assessment. Not only does innovation take place but it is based on science, even though a decision-oriented variety of science.

### 5.3. Precaution Based on Science-Generated Alternative Trajectories

Science here has the task of evaluating different alternative scientific-technological scenarios and trajectories (particularly “inherently safe” ones), as well as developing new scenarios and trajectories that can be compared to existing ones (and that promise to mitigate or avoid some of the latter’s undesirable effects). The ultimate objective of this third interpretation of precaution—(de)selecting trajectories—hinges on this fundamental science-based task of generating and assessing alternatives.

As an example we can recur to the current debates about the implementation of the REACH directive. The European authorities interpret that REACH’s precautionary content is limited to asserting the harmfulness of individual chemical substances in order to replace them with others, while in the process applying certain nonstandard scientific methodologies (see above). However, there exists an alternative point of view: several authors<sup>(60)</sup> consider the European Commission’s point of view inadequate and inefficient. Their interpretation of precaution is that REACH should directly promote the *abandonment of entire classes of substances* that are shown to possess certain common traits, for example, high capacity for bioaccumulation or persistence in the environment, irrespective of their potential toxicity.

On this view, REACH should encourage the systematic analysis of better alternatives for replacing these chemicals, for instance, through the develop-

ment of new substances, product improvement, as well as organizational, manufacturing, and process changes that make certain substances superfluous.<sup>(61)</sup> This would spur precaution-driven innovation on many levels.<sup>(62)</sup>

Even though decision making (to adopt or abandon technological trajectories) is based on extra-scientific criteria, scientific knowledge still is essential in this process. Without the scientific analysis of alternative trajectories the regulatory process would be impossible to operationalize: when deciding to abandon one particular technological trajectory it is usually indispensable to propose alternatives that will resolve the problems at hand. One example is nuclear power. Any decision to curtail deployment of this technology, or abandon it altogether because of its “inherent uncontrollability,” implies the need for developing feasible alternative trajectories for power generation and management, for the analysis of which science is imperative. Improvement of existing energy sources, as well as outright substitution, will stimulate (even necessitate) innovation in alternative ways of generating and managing energy.

Clearly, this interpretation of precaution implies innovation, based on scientific knowledge. It requires research and development programs oriented toward the generation and assessment of completely new scientific-technological trajectories. Of the three interpretations, this one could be considered the one that places its focus most directly on the issue of scientific-technological innovation because it implies the development of new technology that conforms to specific aims (like “green production”).

To sum up, even though the specific role (and even the very form) of science varies considerably from one interpretation of precaution to the next, it is evident that none of them marginalize scientific knowledge in decision making. It becomes equally clear that precautionary regulation, in none of its forms, blocks or limits scientific-technological innovation in any general or necessary sense.

However, precaution may certainly affect *particular* technologies or scientific-technological fields in particular moments. We therefore want to emphasize that our aim is limited to countering the notion that precaution, in all its disguises, is *inescapably* “anti-innovation” or that somehow it *automatically* “marginalizes science.” Precautionary regulation clearly may produce instances in which certain scientific-technological developments are truncated or severely limited, and precautionary



decision making in particular cases can be shaped exclusively by extra-scientific factors. This, however, makes it all the more imperative to analyze the functions of scientific method in precautionary regulation, as well as the latter's effects on innovation in a differentiated manner.

## 6. CONCLUSIONS

As our analysis demonstrates, science *does* have a fundamental function in each of the three alternative versions (interpretations) of precautionary regulation. In each case, science holds a different but always crucial role.

This means that precautionary regulation, at least in the three interpretations that we have contemplated in our analysis, must be understood as a science-based enterprise: in none of the three interpretations is there decision making without—direct or indirect—recourse to scientific methodology or data. Even in the case of the third interpretation decisions ultimately rely on science-generated alternatives.

Furthermore, precautionary regulation in all three versions considered here is conducive to innovation. Without doubt, this potential for innovation and the kinds of innovative processes vary according to the specific interpretation of precaution. Taking the three interpretations in turn, innovation fostered through precaution chiefly takes the form of (1) specific technological and product improvements, (2) scientific methodological or meta-methodological innovation, and (3) generation of new scientific-technological trajectories. It should be clear that in all three cases analyzed here such precaution-driven innovation will most likely differ from any innovation processes that would take place in the absence of precautionary regulation.

This last point is important: our argument does not imply that the particular innovative processes set in motion by applying the precautionary principle are in any way comparable to (or “better” than) the innovation that would take place if regulators only applied standard risk assessment and management procedures. Scientific-technological innovation in the absence of precautionary regulation—at least in certain cases—could clearly be more intense and broad-based than the kind of innovation facilitated by the precautionary principle's regulatory application. However, this is a question too complex to be treated in this article, and probably impossible to answer either way in a universal manner.

We are now, in fact, in a position to add another decisive argument against the critics who consider precaution to inexorably marginalize science and curtail innovation. A corollary of the argument presented in this article is that precautionary regulation could be characterized as a way of reconciling promotion and control of science and technology (which would certainly be positive for innovation in the broadest sense).<sup>(63)</sup>

More specifically, given that on our argument precautionary regulation can be understood as science based and conducive to innovation, it could be interpreted as embodying each of the two fundamental functions of any technology policy: regulation and promotion. On one hand, it is oriented toward controlling or curtailing certain technologies or applications. On the other, it stimulates (more or less focused) technological innovation, as well as methodological learning in scientific knowledge generation.

However, these two basic functions of technology policy making have traditionally been at odds with each other.<sup>(64)</sup> From at least the 1950s onwards, both promotion and regulation have justified government intervention in technological change. Both scientific-technological development and the need for its regulation have consistently and systematically produced these two kinds of public policies, albeit disjointed and in constant tension with each other.

Precautionary regulation, though, because of its specific characteristics, may be able to reconcile regulation and promotion of technology. In fact, it may be able to do so in a balanced manner, given the variety of possible interpretations of precaution, as well as their respective implications.

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## REFERENCES

1. Steel D. The precautionary principle and the dilemma objection. *Ethics, Policy & Environment*, 2013; 16:321–340.
2. Ahteensuu M, Sandin P. The precautionary principle. Pp. 961–978 in Roeser S, Hillerbrand R, Sandin P, Peterson M (eds). *Handbook of Risk Theory: Epistemology, Decision Theory,*

- Ethics and Social Implications of Risk. Dordrecht: Springer, 2012.
3. Gray JS, Bewers M. Towards a scientific definition of the precautionary principle. *Marine Pollution Bulletin*, 1996; 32:768–771.
  4. Sunstein C. *Risk and Reason: Safety, Law, and the Environment*. Cambridge: Cambridge University Press, 2002.
  5. Graham J. *The Perils of the Precautionary Principle: Lessons from the American and European Experience*. Heritage Lectures no. 818. Washington, DC: Heritage Foundation, 2004.
  6. Tickner J (ed). *Precaution, Environmental Science, and Preventive Public Policy*. Washington, DC: Island Press, 2003.
  7. Sandin P. Common-sense precaution and varieties of the precautionary principle. Pp. 99–113 in Lewens T (ed). *Risk. Philosophical Perspective*. London: Routledge, 2007.
  8. Sadeleer N (ed). *Implementing the Precautionary Principle. Approaches from the Nordic Countries, EU and USA*. London: Earthscan, 2007.
  9. Whiteside K. *Precautionary Politics*. Cambridge: MIT Press, 2006.
  10. Wiener J, Rogers M, Hammitt J, Sand P (eds). *The Reality of Precaution*. London: Earthscan, 2011.
  11. Fisher E, Jones J, Schomberg R von (eds). *Implementing the Precautionary Principle: Perspectives and Prospects*. Cheltenham: Edward Elgar, 2006.
  12. Stirling A. Risk, precaution and science. *EMBO Reports*, 2007; 8:309–315.
  13. European Commission. *Taking European Knowledge Society Seriously*. Luxembourg: EC, 2007.
  14. Todt O. The limits of policy: Public acceptance and the reform of science and technology governance. *Technological Forecasting & Social Change*, 2011; 78:902–909.
  15. Barnett J, Cooper H, Senior V. Belief in public efficacy, trust, and attitudes toward modern genetic science. *Risk Analysis*, 2007; 27:921–933.
  16. Poortinga W, Pidgeon NF. Trust in risk regulation: Cause or consequence of the acceptability of GM food? *Risk Analysis*, 2005; 25:199–209.
  17. Todt O, Luján JL. A new social contract for technology? On the policy dynamics of uncertainty. *Journal of Risk Research*, 2008; 11:509–523.
  18. Weiss C. Scientific uncertainty and science-based precaution. *International Environmental Agreements: Politics, Laws and Economics*, 2003; 3:137–166.
  19. Sandin P. Dimensions of the precautionary principle. *Human and Ecological Risk Assessment*, 1999; 5:889–907.
  20. Peterson M. Should the precautionary principle guide our actions or our beliefs? *Journal of Medical Ethics*, 2007; 33:5–10.
  21. Renn O. Precaution and analysis: Two sides of the same coin? *EMBO Reports*, 2007; 8:303–304.
  22. Moreno C, Todt O, Luján J. The context(s) of precaution. *Science Communication*, 2010; 32:76–92.
  23. Gardiner S. *A Perfect Moral Storm: The Ethical Tragedy of Climate Change*. New York: Oxford University Press, 2011.
  24. Tickner J, Kriebel D, Wright S. A compass for health. *International Journal of Epidemiology*, 2003; 32:489–492.
  25. Sunstein C. *Laws of Fear: Beyond the Precautionary Principle*. Cambridge: Cambridge University Press, 2005.
  26. Wildavsky A. Trial and error versus trial without error. Pp. 22–45 in Morris J (ed). *Rethinking Risk and the Precautionary Principle*. Oxford: Butterworth-Heinemann, 2000.
  27. Holm S, Harris J. Precautionary principle stifles discovery. *Nature*, 1999; 400:398.
  28. Taverne D. *The March of Unreason*. Oxford: Oxford University Press, 2005.
  29. Goklany I. *The Precautionary Principle. A Critical Appraisal of Environmental Risk Assessment*. Washington, DC: Cato Institute, 2001.
  30. Roeser S, Hillerbrand R, Sandin P, Peterson M (eds). *Handbook of Risk Theory: Epistemology, Decision Theory, Ethics and Social Implications of Risk*. Dordrecht: Springer, 2012.
  31. Sandin P, Peterson M, Hansson S, Rudén C, Juthe A. Five charges against the precautionary principle. *Journal of Risk Research*, 2002; 5:287–299.
  32. Resnik D. Is the precautionary principle unscientific? *Studies in History and Philosophy of Biological and Biomedical Sciences*, 2003; 34:329–344.
  33. Morris J. Defining the precautionary principle. Pp. 1–21 in Morris J (ed). *Rethinking Risk and the Precautionary Principle*. Oxford: Butterworth-Heinemann, 2000.
  34. Tickner J, Kriebel D. The role of science and precaution in environmental and public health policy. Pp. 42–62 in Fisher E, Jones J, Schomberg R von (eds). *Implementing the Precautionary Principle: Perspectives and Prospects*. Cheltenham: Edward Elgar, 2006.
  35. Cranor C. *Legally Poisoned: How the Law Puts Us at Risk from Toxicants*. Cambridge, MA: Harvard University Press, 2011.
  36. Wildavsky A. *But is it True? A Citizen's Guide to Health and Safety Issues*. Cambridge, MA: Harvard University Press, 1995.
  37. Sunstein C. Health-health trade-offs. Pp. 232–259 in Elster J (ed). *Deliberative Democracy*. Cambridge: Cambridge University Press, 1998.
  38. Luján J, Todt O. Precaution in public. *Public Understanding of Science*, 2007; 16:97–109.
  39. Luján J, Todt O. Precaution: A taxonomy. *Social Studies of Science*, 2012; 42:143–157.
  40. Foster K, Vecchia P, Repacholi M. Science and the precautionary principle. *Science*, 2000; 288:979–981.
  41. European Commission. *Communication from the Commission on the Precautionary Principle, COM 1 (2000)*. Brussels: European Commission, 2000.
  42. Cranor C. The normative nature of risk assessment. *Risk: Health, Safety & Environment*, 1997; 8:123–136.
  43. Cranor C. *Toxic Torts: Science, Law and the Possibility of Justice*. Cambridge: Cambridge University Press, 2006.
  44. Steel D. Extrapolation, uncertainty factors, and the precautionary principle. *Studies in History and Philosophy of Biological and Biomedical Sciences*, 2011; 42:356–364.
  45. Krimsky S. The weight of scientific evidence in policy and law. *American Journal of Public Health*, 2005; 95:S129–S136.
  46. Weed D. Weight of evidence. *Risk Analysis*, 2005; 25:1545–1557.
  47. Wandall B. Values in science and risk assessment. *Toxicology Letters*, 2004; 152:265–272.
  48. Wandall B, Hansson SO, Rudén C. Bias in toxicology. *Archives of Toxicology*, 2007; 81:605–617.
  49. Hansson S. Adjusting scientific practices to the precautionary principle. *Human and Ecological Risk Assessment*, 1999; 5:909–921.
  50. Wynne B. Uncertainty and environmental learning. *Global Environmental Change*, 1992; 6(92):111–127.
  51. European Commission. *Council directive 2001/18/EC (12/3/2001) on the deliberate release into the environment of genetically modified organisms*. Official Journal of the European Communities, 2001; L106:1–39.
  52. Levidow L, Carr S (eds). *Special issue: Precautionary regulation—GM crops in the European Union*. *Journal of Risk Research*, 2000; 3.
  53. European Parliament and Council. *Regulation (EC) No. 1907/2006 of 18/12/2006, concerning the registration, evaluation, authorisation and restriction of chemicals*. Official Journal of the European Communities, 2006; L136:3–280.
  54. Rudén C, Hansson S. *Registration, Evaluation, and Authorization of Chemicals (REACH) is but a first step: How far*

- will it take us? *Environmental Health Perspectives*, 2010; 118: 6–10.
55. Schaafsma G, Kroese E, Tielemans E, Van de Sandt J, Van Leeuwen K. REACH, non-testing approaches and the urgent need for a change in mind set. *Regulatory Toxicology and Pharmacology*, 2009; 53:70–80.
  56. Breithaupt H. The costs of REACH. *EMBO Reports*, 2006; 7:968–971.
  57. Boogaard P, Hays S, Aylward L. Human biomonitoring as a pragmatic tool to support health risk management of chemicals—Examples under the EU REACH programme. *Regulatory Toxicology and Pharmacology*, 2011; 59:125–32.
  58. Menache A, Nastrucci C. REACH, animal testing, and the precautionary principle. *Medicolegal and Bioethics*, 2012; 2:13–29.
  59. Todt O, Luján JL. Values and decisions: Cognitive and noncognitive values in knowledge generation and decision making. *Science, Technology and Human Values*, 2014; 39. doi:10.1177/0162243914521019.
  60. Koch L, Ashford N. Rethinking the role of information in chemicals policy: Implications for TSCA and REACH. *Journal of Cleaner Production*, 2006; 14:31–46.
  61. Winter G. Risks, costs and alternatives in European Community environmental legislation. Pp. 313–329 in Sadeleer N (ed). *Implementing the Precautionary Principle. Approaches from the Nordic Countries, EU and USA*. London: Earthscan, 2007.
  62. Ashford N. Incorporating science, technology, fairness, and accountability in environmental, health, and safety decisions. *Human and Ecological Risk Assessment*, 2005; 11:85–96.
  63. Irwin A, Vergragt P. Re-thinking the relationship between environmental regulation and industrial innovation. *Technology Analysis & Strategic Management*, 1989; 1:57–70.
  64. Aichholzer G, Schienstock G (eds). *Technology Policy*. Berlin/ New York: de Gruyter, 1994.