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Regulating BFRs – From science to policy

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Abstract

An adequate distribution of responsibilities between scientists and policy-makers requires that a distinction be made between theoretical rationality (what to believe) and practical rationality (what to do). In chemical risk management, it is often necessary to base decisions on indications of risk that do not amount to full scientific proof. Guidelines are offered for how this can be done without infringing upon the integrity of science. Furthermore, it is shown that the application of standard decision theory to chemical risks yields conclusions very much in agreement with the precautionary principle.

Keywords: Brominated flame retardants; Precautionary principle; Sound science; Decision theory; Burden of proof; Risk assessment

1. Introduction

Modern societies need to make better use of science – not least environmental science – in policy-making, while at the same time preserving the integrity of science. It is the purpose of this article to show how insights from decision theory and the philosophy of science can be helpful in clarifying the relationship between science and policy, and thereby improve the ways in which scientists contribute to policy decisions.

One crucial distinction should always be kept in mind in investigations of the science-policy relationship, namely that between theoretical and practical rationality. Theoretical rationality concerns choices of what to believe. Practical rationality concerns choices of what to do in order to achieve practical aims. In the traditional division of the risk decision process into risk assessment and risk management, theoretical rationality is the decisive form of rationality in risk assessment, whereas practical rationality has the final say in risk management. However, the distinction between risk assessment and risk management is often imprecise. Partly as a result of this, confusions between the two types of rationality have often impeded risk assessment.

On a more fundamental level, theoretical and practical rationality may well be founded on the same basic principles. Rott (2001) has shown how important formal properties of theoretical rationality can be derived from standard rules for practical rationality. However, this does not detract from the need to distinguish between the two forms of rationality in risk assessment and management.

2. The scientific knowledge production process

The basis of risk assessment is of course scientific knowledge and scientific data, see Fig. 1. Scientific knowledge begins with data from experiments and other observations. Through a process of critical assessment, these data give rise to the scientific corpus, or mass of scientific knowledge. The scientific corpus can be described as consisting of those statements that could, at the time being, legitimately be made without reservation in a (sufficiently detailed) textbook. Alternatively it can be described as consisting in that which is taken for given by the collective of researchers in their continued research, and thus not questioned unless new data provide reasons to do so. (Hence, the corpus consists of generalizations and theoretical statements that are

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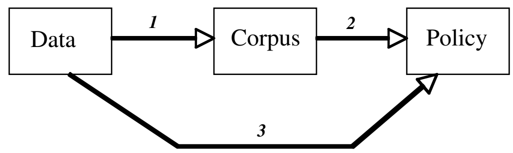

Fig. 1. How science can support policy.

based on experimental and observational data, but it does not include these data themselves (Hansson, 2008).

The corpus is of course not defined with perfect precision. In particular in areas with a highly complex subject-matter, such as the environmental sciences, it may sometimes be difficult to determine whether a particular statement belongs to the corpus. However, these cases are few in comparison to the immensity of the corpus. In other words, the fuzzy edge of the corpus is thin.

The corpus is constantly challenged and continuously updated. Whenever researchers agree for instance that a previously unsettled issue about BFRs (brominated flame retardants) has been settled, then a small part of the corpus of scientific knowledge has been updated. In the discussions leading up to such a conclusion, those who put forward a new hypothesis or make some other specific claim have the burden of proof. Furthermore, when colleagues evaluate their argumentation they apply fairly strict standards of evidence. In other words, the corpus has high entry requirements. This must be so because otherwise the collective of scientists would too often go collectively in the wrong direction (Hansson, 2007).

But scientific knowledge is not only developed for its own sake. It is also used to guide practical decisions. In some sciences this happens seldom. In environmental chemistry and toxicology it happens all the time. Whenever it does, it is necessary to distinguish carefully between the practical decision to be guided by science and the scientific process itself. Should it be considered an established fact that prenatal or early postnatal exposure to PBDE-99 (PBDE = polybrominated diphenyl ether) can cause developmental neurobehavioural defects in humans? This is a scientific issue, to be determined with the criteria of evidence that have been developed for the internal dealings of science. Should human exposure to PBDE-99 be prevented in order to avoid potential neurotoxic effects? This is a distinctly different issue, although the same scientific data that guide the scientific decision should be used here as well.

The most obvious way to use science for policy purposes is to employ information from the corpus (Fig. 1, arrow 2). For this the corpus is well suited in one important respect: The high entrance requirements guarantee that the information in the corpus is reliable enough to be trusted in almost all practical contexts. But from another point of view, the corpus is insufficient for many practical decisions: Due to the same high entry requirements the corpus will not contain all the information that may be useful for the practical decision. Information that did not make it into the corpus may nevertheless have sufficient evidential weight to have a legitimate influence on some practical decisions.

To exemplify this, suppose that it is discovered that a certain brominated substance leaks from feeding bottles for babies. Furthermore, suppose that there is weak but relevant evidence that this particular substance may be toxic to humans, and that most experts consider it to be equally plausible that there is a toxic effect in humans and that there is not. Given what is at stake in this situation, it would be perfectly rational for the company that produces the bottles – or for a government agency – to decide on this basis to remove the substance from the production of new bottles, and perhaps also to take some measures concerning the ones already in use. Such a decision would have to be based on scientific information that did not satisfy the criteria for corpus entry. In other words, a direct road from data to policy is required (Fig. 1, arrow 3).

3. How to use the bypass route

This bypass route for scientific information is practically important in environmental toxicology and chemistry. Decision-makers often want to protect the population against suspected health hazards even if the evidence is weaker than what is required for full scientific proof, i.e. entry into the corpus. In order to do this, the bypass route is needed. This seems to happen more often for persistent and bioaccumulative substances such as many BFRs than for most other substance groups. The reason for this is that for many such substances there are experimental indications of potential adverse health effects in humans, whereas incontrovertible evidence from exposed humans that would settle the issue is not available.

The bypass route is an essential part of many practical decision-making processes. However, this is often a difficult road to take. There is always a temptation to take science lightly, and judge scientific data according to whether they suit preconceived policy ideas rather than according to their scientific value. When two conflicting parties both do this, the outcome can be a "science charade" in which policy disagreements are camouflaged as disagreements on scientific detail (Wagner, 1995).

In order to use the bypass route in a rational way and at the same time defend the integrity of science, the following three simple principles should be followed:

First: The same type of evidence should be taken into account in the policy process as in the formation of the scientific corpus. Consider, for instance, a decision whether or not to restrict the use of a substance that is suspected to be a reproductive toxicant. The same type of reprotoxicity studies should be used as a basis for this decision that would have been used in a purely scientific review of the effects of the substance. Policy decisions are not well served by the use of irrelevant data.

Secondly: The assessment of how strong the evidence is should be the same in the two processes. If there is stronger scientific evidence that penta-PBDE exposure leads to toxic accumulation in biota than that deca-PBDE does so, then this evidence should be counted as stronger in policy discussions as well.

Thirdly: The two processes may however differ in the *required* level of evidence. It is a policy issue how much evidence is needed for a decision to restrict the use of a substance. The chosen level of evidence is a matter of practical, not theoretical rationality. This means that non-scientific criteria, such as social appraisals of the severity of the possible danger, have a legitimate role.

4. Cautiousness and the unknown

The bypass route is closely related to the precautionary principle. A common explication of that principle is that policy decisions in environmental decisions can legitimately be based on scientific evidence of a danger that is not strong enough to constitute full scientific proof that the danger exists (Sandin et al., 2004). This means essentially that the bypass route for scientific information is accepted as legitimate.

However, it is not unproblematic to describe environmental decisions as the application of some special principle for environmental policies, some sort of extra cautiousness that is presumed not to apply in other decisions. From a decision-theoretical point of view, allowing decisions to be influenced by uncertain information is not a special principle that needs to be specially defended. To the contrary, doing so is nothing else than ordinary practical rationality, as it is applied in most other contexts. If there are strong scientific indications that a volcano may erupt in the next few days, decision-makers will expectedly evacuate its surroundings as soon as possible, rather than waiting for full scientific evidence that the eruption will take place.

More generally speaking, practical rationality requires that decisions be based on the available evidence even if it is incomplete. When considering a possible negative event decision-makers will take into account both its probability and its severity – or at least, that is what decision theorists expect them to do if they act rationally. In formalized decision theory such reasoning is usually represented by expected utility calculations in which the value or disvalue of a possible outcome is multiplied with its probability. Hence a risk of 1 in 10 that ten people will die is treated as equally serious as certainty that one person will die. This is not an unchallenged approach, but it is the standard approach in formalized treatments of practical decision-making (Schoemaker, 1982). It is routinely used in economics and in applied areas such as finance and insurance.

However, there is a remarkable difference between on the one hand standard decision theory and on the other hand risk analysis as it is usually applied in chemical risk management. In standard decision theory, when a probability is unknown, the best available estimate of it is used, even if that estimate is very uncertain. In most applications of risk analysis to chemical risks, the tradition is instead to set, effectively, unknown probabilities equal to zero. In other words, if it is not known whether a substance has a certain negative effect, the tradition is to treat it in the same way as a substance known not to have that effect.

A schematic numerical example serves to show how problematic this can be in practice. Consider two substances A and B that are alternatives for being used in an application where they will be spread into the aquatic environment (Table 1). B is very persistent and bioaccumulative, whereas A is readily degraded in the environment. A has been extensively tested for ecotoxicity, and there are strong reasons to assume that it is ecotoxic. B has not been tested for ecotoxicity. The best possible estimate (based on structural analogies) is a 5% probability that B is ecotoxic. For decision-theoretical purposes tentative numerical values have to be assigned to possible outcomes. In this example, the (dis)value of spreading a toxic substance that is persistent and bioaccumulating is −500 units whereas that of spreading an equally toxic substance that degrades readily is −10 units. (Of course, the unit is arbitrary, and it is the ratio that matters.) This information is summarized in Table 1.

Applying standard risk analysis to this data would in practice mean that 0.05 is replaced by 0. The outcome of such an analysis is shown in Table 2. Since substance B is believed with 95% probability to cause no problem, it is treated as no problem at all. This argument would support a decision to prefer substance B to substance A.

In Table 3, standard decision theory is applied to the same problem. In other words, probability weighting is performed in the same way as economists do, without applying the special (implicit) principle in chemical risk analysis that unknown probabilities of danger should be reduced to zero. Hence, the values of outcomes are weighted according to the best available estimate of the

Table 1
The scientific information about two hypothetical substances A and B

Substance	Environmental fate	Effect on biota	Disvalue if toxic	Probability of toxicity
A	Non-PB	Ecotoxic	−10	1
B	PB	Ecotoxicity unknown	−500	0.05

"PB" means "persistent and bioaccumulative".

Table 2
Standard risk assessment of the two hypothetical substances

Substance	Environmental fate	Effect on biota	Disvalue if toxic	Probability of toxicity	Risk assessment
A	Non-PB	Ecotoxic	−10	1	−10
B	PB	Ecotoxicity unknown	−500	0 (reduced)	0

Table 3
Decision-theoretic assessment of the two hypothetical substances A and B

Substance	Environmental fate	Effect on biota	Disvalue if toxic	Probability of toxicity	Risk assessment
A	Non-PB	Ecotoxic	−10	1	−10
B	PB	Ecotoxicity unknown	−500	0.05	−25

probabilities. This argument would support a decision to prefer substance A to substance B.

This analysis supports what is usually regarded as a "precautionary" decision, namely in this case to treat substance B as – on the given level of knowledge – the more serious problem. Informally, the argument for this is that although it is not known if B causes environmental damage, if it does so then the damage may be very serious. If the severity of a possible danger is large, then it may be rational to take action against that danger even if the probability is relatively small that the danger will materialize.

It is important to note that this argument does not appeal to the precautionary principle or some other special principle of cautiousness. Instead, it is based on the standard principles for practical reasoning as they are used in other areas such as economics. This method, weighting outcomes according to the best estimate of their probabilities (without setting non-zero probabilities to zero), is called "risk-neutral" decision-making in economics. Of course, this is not the only possible principle for decision-making, but no valid argument seems to be available why it should be replaced by a decision process in which some non-zero probabilities are programmatically (although implicitly) reduced to zero.

5. Sound science

There are outspoken proponents of another view, namely that only well-established scientific fact should be used in decision-making. This means, in practice, that probabilities of danger are implicitly set at zero although the best estimates of these probabilities are clearly above zero. This has been advertised as the application of "sound science", and recently under new guise as "evidence-based toxicology".

Proponents of so-called "sound science" often use the current European regulations of PBDEs as a prime example of what they consider to be "unsound science" (Kogan, 2003). Their central claim is that the intrascientific burden of proof should be used also in practical decisions that are based on science. This means that when there are indications but not full proof of danger, the substance should be treated as innocuous, i.e. as if the probability of danger is zero. However, as has already been mentioned, the practice of programmatically setting non-zero probabilities at zero does not seem to be supported by any plausible account of practical rationality.

It should also be observed that the "sound science" proposals have only been targeted at specific, mostly environmental, decisions. Even those who apply it to environmental measures tend to honour other principles in other decision areas. Clear examples of this can be found not least in security policies. One of the most well-known recent examples is the American decision in 2003 to act as if Iraq had weapons of mass destruction. This decision was clearly based on a much lower level of evidence than the full scientific proof required by the "sound science" advocates in environmental policies.

Policy-makers may of course decide to apply much higher standards of evidence before acting against environmental threats than what they do before acting against other threats or perceived threats. However, it is not intellectually tenable to describe such a practice as a scientific principle, for the simple reason that it is something else, namely a policy principle.

It is not the task of scientists to tell decision-makers what level of evidence they should require for instance before they restrict the use of a potentially toxic substance. But it is the task of scientists to explain what science can and cannot do. If this is done successfully, then policy-makers will rely on scientific judgment when it comes to determining what evidence there is and how strong it is, but they will not ask scientists to determine whether the evidence is strong enough for action. Much remains to be done until such a well-informed and principled division of labour between science and policy is in place.

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