Regulating BFRs – from science to policy

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You may well ask what a philosopher can contribute to the risk assessment and management of brominated flame retardants and related compounds. I will try to show you that insights from the philosophy of science and decision theory can help us clarify the relationship between science and policy and thereby improve their interaction. Our societies need to make better use of science in policy-making, while at the same time preserving the integrity of science. The crucial distinction that I will emphasize is that between what we philosophers call theoretical and practical rationality. Theoretical rationality concerns how we choose what to believe in, and practical rationality how we choose what to do in order to achieve our practical aims. Confusions between the two types of rationality have often impeded risk assessment. I am going to argue that this distinction is particularly important in the case of BFRs.

The basis of risk assessment is of course scientific knowledge. I will begin with a brief account of the knowledge production process in science. Scientific knowledge begins with data from experiments and other observations. Through a process of critical assessment, these data give rise to the scientific corpus. (See the diagram.). The corpus can, roughly, 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 our continued research, and thus not questioned unless new data give us reason to do so. (Hansson 1996)

The corpus is constantly updated. When we leave a workshop at this conference, all convinced that a previously unsettled issue about BFRs has now 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 scientific hypothesis or claim to have discovered a new phenomenon have the burden of proof, and we apply fairly strict standards of evidence when evaluating their argumentation. In other words, the corpus has high entry requirements. This has to be so in order to prevent us from going too often collectively in the wrong direction.

But scientific knowledge is not only developed for its own sake. It is also used to guide decisions. In some sciences this happens seldom. In environmental chemistry and toxicology it happens all the time. Whenever it does, we must be careful to distinguish between the practical decision to be guided by science and the scientific process itself. Should we consider it an established fact that prenatal or early postnatal exposure to PBDE-99 can cause developmental neurobehavioural defects in humans? This is a scientific issue, to be determined with the criteria of evidence that we have developed for the internal dealings of science. Should we prevent human exposure to PBDE-99 in order to avoid potential neurotoxic effects? This is distinctly different issue, although the same scientific data that guides 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 (arrow 2 in the diagram). 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 legitimately influence some practical decisions. To exemplify this, suppose that we discover 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 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 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 (arrow 3 in the diagram).

This bypass route for scientific information is practically important in environmental toxicology and chemistry. We typically wish to protect ourselves against suspected health hazards even if the evidence is weaker than what is required for full scientific proof. Furthermore, the bypass route is more relevant for persistent and bioaccumulative substances such as many BFRs than for most other substance groups. A major reason for this is that for many such substances we have experimental indications of potential serious effects in humans, but we seldom have the incontrovertible evidence from exposed humans that would be needed to consider the issue definitely settled.

The bypass route is an essential part of many practical decision-making processes. However, it is a difficult road to take. There is a risk that scientific data will be judged according to whether they suit preconceived policy ideas rather than according to their scientific value. When conflicting parties in a decision use science in this way, the result can be a "science charade"[1] in which policy disagreements are camouflaged as disagreements on scientific detail. In order to avoid this, I propose that we apply three simple principles:

1. The same type of evidence should be taken into account in the policy process as in the formation of the scientific corpus. Suppose, for instance, that we want to decide whether or not to restrict the use of a substance that is suspected to be a reproductive toxicant. Then the same type of reprotoxicity studies should be used as a bases for the policy-specific process (arrow 3) as in ordinary science (arrow 1). Policy decisions are not served by the use of irrelevant data.

2. 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.

3. 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 how we appraise the severity of the possible danger, have a legitimate role.

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[1] Wendy E Wagner Wendy E Wagner "The Science Charade in Toxic Risk Regulation", Columbia Law Review, 1995.

How is all this related to the precautionary principle? In one sense, my argument is closely related to that principle. A sensible interpretation of the precautionary 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. This means essentially that the bypass route for scientific information is accepted as legitimate.

However I see a problem with describing 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. 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 we apply it in most other contexts. If we obtain strong scientific indications that a volcano may erupt in the next few days, we evacuate its surroundings, rather than waiting for full scientific evidence that the eruption will take place.

More generally speaking, practical rationality requires that we base our decisions on the available evidence of what can happen if we choose different options. When considering a possible negative event or effect we take into account both its probability and its severity. 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 with 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.

For a simple example, consider two substances A and B. We know that substance A is transformed to CO_2 fairly fast whereas B is a vPvB substance, i.e. it is very persistent and very bioaccumulative. Nothing is known about the potential toxicity of the two substances. Hence, we do not know if any of them damages the environment. Should then rational decision-makers treat them equally? A strong case can be made that they should not, for the simple reason that if substance B turns out to be for instance a reproductive toxicant, then the effects will be much more severe than if substance A turns out to have such an effect. This can be used as an argument against the production and use of vPvB substances, even if they are not known to have any toxic effects. 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.

Note that in order to motivate this type of reasoning we do not need to invoke the precautionary principle or some other special principle of cautiousness. I have only appealed to the standard principles for practical reasoning that we apply in other areas.

But there are those who do not want to apply these principles to chemicals regulation. The demand that only well-established scientific fact should be used in decision-making has particularly outspoken proponents in chemical risk assessment. The alternative view is that measures to protect the environment should only be taken if they can be based on fully established scientific fact. This has been called the application of “sound science”. Proponents of this principle often use the current European regulations

of PBDEs as a prime example of what they consider to be "unsound science".[2] Their central claim is that we should use the intrascientific burden of proof for practical decisions that are based on science. This means that when there are indications but not full proof of danger, we should treat the substance as innocuous, i.e. act in the same way as if the probability of danger is zero. These critics are certainly right that the probability for instance that penta-PBDE is neurotoxic to humans is not equal to one, but it is equally obvious that this probability is not equal to zero. "Sound science" advocates want us to behave as if this probability is zero. However, the practice of programmatically setting non-zero probabilities at zero is not 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. Nobody has ever tried to apply "sound science" to all policy areas. Those who apply it to environmental measures tend to honour other principles in other decision areas. As one example of this, the Bush administration has taken large steps towards the "sound science" ideology in environmental issues, but it does not apply anything like it in issues of national security. (Consider the level of evidence that was required for the decision in 2003 to act as if Iraq had weapons of mass destruction.)

It is not our task as 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 our job to explain what science can and cannot do. If we succeed in this, 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. We are still far away from such a well-informed and principled division of labour between science and policy.

Of course each of us is free, as a citizen, to also have a say in the policy issues. I will conclude by doing that. Personally I am strongly convinced that the regulation of BFRs and other chemical groups with many persistent and bioaccumulative substances is an area in which it would be particularly unwise always to wait for conclusive scientific evidence before action is taken to protect human health and the environment. Policy-makers have urgent tasks in protecting human health and the environment on which we depend. They can only do this if we scientists provide them with the information and the insights that they need to fulfil this responsibility. In this communication between science-makers and policy-makers there is still a long way to go.

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[2] Lawrence A Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science", National Foreign Trade Council, Washington DC 2003, www.nftc.org.