

The Royal Society of Chemistry (RSC) has been a very strong proponent of the use of risk assessment as being an essential step in the management of chemical use<sup>1</sup>. It has considered 'hazard assessment' as a critical and necessary part of the risk assessment process but insufficient on its own to be used for rational decision making about regulatory chemical controls.

All substances, both naturally occurring and synthetic, are known to have a range of different hazardous properties. Substances can, for example, be toxic to humans or the environment, explosive, corrosive, volatile, flammable or radioactive. This has long been recognised and accepted in the various regulations relating to classification, packaging and labelling. These hazardous properties rarely correlate with each other and thus a list of substances arranged in order of a specified human toxic impact such as carcinogenesis will be very different to one ordered in terms of flammability. Any attempt to classify substances into a single group of 'hazardous substances' has thus to be based on arbitrary rather than scientific criteria which frequently leads to unintended (and unexpected and often undesirable) outcomes. Furthermore, it is important to take account of the quantitative nature of the hazard i.e. how much of the substance is needed to cause the undesirable outcome.

Reliance on hazard assessment alone would dramatically, and unnecessarily, alter our lifestyle; both electricity and natural gas are inherently highly hazardous, drinking water is disinfected with either chlorine or ozone both of which are extremely hazardous materials, motor vehicles, both petrol and electric, derive their energy from hazardous materials carried in the vehicle in substantial quantities, and all solid state electronic devices, such as mobile phones, contain small quantities of highly toxic materials.

Therefore in order to come to rational decisions about the management of chemicals all intrinsic hazards and their associated risks need to be balanced against each other and considered together with information on potential exposure. In other words both a risk assessment and a risk benefit evaluation need to be carried out.

However, for many people 'hazard-based decision making' appears to be a logical mechanism to apply the precautionary principle. Since the RSC has been very critical of the adequacy of hazard based decision making, there is a possibility that we will also become characterised as being dogmatically opposed to the precautionary

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<sup>1</sup> Management of chemicals includes both the pre-manufacturing or pre-marketing assessment of hazard and risk, its evaluation, implementation of appropriate management measures and post-marketing surveillance systems aimed at confirming the adequacy of these management systems; and the management of incidents where there is suspected involvement of chemicals.

principle. Consequently this paper attempts to clarify the RSC view on this issue and to provide a rationale for the use of the precautionary principle.

### **The “Precautionary Principle”**

This is an Alice in Wonderland expression, in that it can mean whatever the speaker intends it to mean. Since most users of the phrase do not define their usage confusion is commonplace. For example, contrast these two expressions of the principle, both of which have been proposed by authoritative bodies.

***“Where there are threats of serious or irreversible damage, lack of scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation” (UN Conference on Sustainable Development, Rio 1992)***

***“The true application of the precautionary principle is in cases where there is reason to think that there may be an effect, but no evidence has yet been obtained for its existence or the evidence is inconclusive” (Royal Commission on Environmental Pollution, 21st Report par 4.47, 1998)***

Although it was not their intention, such statements have sometimes led to calls for draconian precautionary action being demanded in any chemicals management situation where there is any uncertainty in the available information, and to statements being made such as “If you are not certain don’t use it”, often associated with comments such as “better safe than sorry”. The implication is that the application of the Precautionary Principle always provides societal or environmental benefit, but this is clearly not so; there can also be negative consequences.

Firstly, where the science is uncertain, attribution of cause and effect can be fraught with difficulty. If the cause is wrongly diagnosed subsequent precautionary action may be either inappropriate or actually dangerous<sup>2</sup>. Secondly, there is an inherent tendency for regulators to be risk averse; thus the criteria used and the assumptions made in risk evaluation will essentially be conservative with a tendency to use multiple 'worst case' assumptions in the evaluation with the resultant potential to produce over precautionary conclusions. Finally, the elimination of all existing uses of a substance may also result in currently unrecognised but highly beneficial applications never being discovered.

In 2000 the European Commission published<sup>3</sup> an opinion on the ‘appropriate’ application of the Precautionary Principle in European Regulation. This document provides a pragmatic guide to when and how the principle should be used; unfortunately it is hardly ever referred to. The application of the Precautionary

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<sup>2</sup> This happens regularly with medically unexplained physical symptoms, idiopathic environmental illness and mass psychogenic illness. These somatogenic diseases are often misdiagnosed as being due to a chemical exposure, leading to extensive (and, often misdirected) investigations aimed at identifying an insignificant chemical exposure. The precautionary principle is then invoked to justify management procedures before the correct hazard, has been clearly identified. The use of precaution is, in this case totally non-precautionary as it is not directed at the correct cause. At best this is ineffectual; at worst it may be damaging and/or very expensive. [See Clay, Illing and Perrett, J Tox Env Health A 70, 1664-1669, 2007]

<sup>3</sup> Communication from the Commission on the Precautionary Principle [COM(2000)1]

Principle does not in fact require that the use of substances should be 'banned'. As the EU Document makes clear, although this might be an option, the management response needs to be proportionate<sup>4</sup>. It also needs to be *'based on an examination of the potential benefits and costs of action or lack of action.'*

It is important to recognise that a risk assessment and its associated evaluation is not a simple pass/fail procedure; it provides information on the most appropriate way for the use of a chemical to be managed and the degree of control that needs to be exerted depending on the use. It is thus entirely consistent with the Precautionary Principle, in that it uses best estimates of uncertainty to identify the appropriate level of 'precaution' necessary to minimise adverse consequences. The process is also iterative being periodically reviewed to take new information on hazard and exposure into account. However, risk assessment and evaluation is only useful where we are aware that a potential risk exists.

### **The issue of 'unknown' risks**

Rumsfeld (2002) observed that there were three types of risk; "There are known knowns. There are things we know that we know. There are known unknowns. That is to say, there are things that we now know we don't know. But there are also unknown unknowns. There are things we do not know we don't know."

The first group can be readily managed because we have a very good understanding of the risks (e.g. the use of domestic electricity), the second group can be managed after conducting a risk assessment in which appropriate safety factors are included to deal with known uncertainties (e.g. the use of food preservatives). However, the final group is incapable of being managed since we are not even aware that such risks exist. As our knowledge increases previously unknown risks become known and these can then be managed in the same manner as the second group (e.g. discovery of the ozone depletion potential of chlorofluorocarbons and other chlorine containing substances). However until the risk has become known, management is impossible.

Although some risks are currently unknowable, can the Precautionary Principle, based solely on hazard evaluation, be used to reduce the potential consequences of risks that may be discovered in the future?

Certainty in this area is not possible, but some broad statements can be made:

- Substances that have long half lives in the environment and are mobile are more likely to pose future problems than those that degrade rapidly and/or are immobile
- Substances produced in large quantities and that are widely dispersed in their use are more likely to pose future problems than those that are produced in small quantities for contained uses.

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<sup>4</sup> **Proportionality** means tailoring measures to the chosen level of protection. Risk can rarely be reduced to zero, but incomplete risk assessments may greatly reduce the range of options open to risk managers. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk.

- Substances that are intended to be biologically active are more likely to pose future problems than those that are biologically inert

Thus, all things being equal, we should be more careful how we use a substance with high biological activity and a long environmental half-life than a substance with low biological activity that degrades rapidly. In other words under the former circumstances a higher degree of precaution would be prudent.

It should be noted, however, that these statements are generalisations, qualitative and incomplete. They are not 'rules' and there are likely to be (many?) false positives and false negatives. As such they can be used to inform decision making but should not be used in isolation as decision criteria.

Nevertheless we can see that the use of such generalisations has now led to the use of a hazard assessment process based on the application of arbitrary thresholds for the persistence (P), bioaccumulation (B) and toxicity (T) properties of the substance. Such arbitrary thresholds may be useful if the assessment is used to set priorities for subsequent risk evaluation however the gradual move that is now taking place towards automatic decisions based on these arbitrary criteria is highly inappropriate.

### **Hazard Based Decision Making**

The evaluation of hazard data forms an essential part of risk assessment, but is there any role for the use of hazard data alone in taking decisions on chemical management? We have seen above that substances with certain hazardous properties need to be considered more carefully in view of their possible future consequences, but in all cases other information is needed to reach an informed conclusion. The two key areas are potential exposure and societal benefit.

We know that risk is due to a combination of hazard and exposure, and this is clearly also true for unknown risks. Consequently minimising exposure will always lead to minimising the risk. In the extreme, elimination of exposure by forbidding all use of the substance will eliminate the risk. However, this also will deny any potential societal benefit arising from the use of that substance. In the REACH regulation, the Precautionary Principle is applied via Title VII Authorisation and Title VIII Restrictions..... In both Titles the degree of precaution applied to the management of the substance is also informed by an analysis of the societal benefit<sup>5</sup>.

In other words, even for 'substances of very high concern', as defined in the REACH Regulation, the opportunity is provided for an evaluation of the exposure and societal

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<sup>5</sup> **The Problem of Prospective Benefit Assessment:** In the case of a substance that has been in existence for an extended period, the societal benefits can be determined relatively easily. However, for a novel substance the only benefit that can be included in the analysis is that from the initial use. In many cases, the benefits of subsequent uses of the material will far outweigh the benefits of the initial uses, but during the initial assessment these benefits are unknown. Thus in addition to the problem of unknown risks, Rumsfeld's "unknown unknowns" also includes unknown benefits. Elimination of substances at their inception, simply on the basis of perceived hazard, may deprive society of substances of major value

benefit before the appropriate level of control is determined. This seems to be a very pragmatic way to deal with the situation.

For example under normal circumstances it would not seem prudent to permit the use of a 'substance of very high concern' as a plasticiser in applications where hundreds of thousands of tonnes of the material were to be distributed worldwide, since both consumer and environmental exposure would probably be extensive. However, the same substance might justifiably be authorised for use as a starting material or intermediate in the synthesis of a novel antibiotic.

## Conclusion

The Royal Society of Chemistry fully supports the definition of the Precautionary Principle as defined at the UN Conference in Rio in 1992 and commends the European Commission Guidance Document of 2000 on the mechanism for its application.

We remain convinced that the evaluation of hazard data forms an essential part of risk assessment, which itself is consistent with the application of the precautionary principle for known risks. Furthermore we consider that hazard data can be used to inform a precautionary approach to 'substances of very high concern', which may, through more careful risk monitoring, prevent significant future manifestation of some currently unknown risks. However in this case the decision on appropriate management action must also consider the likely degree of exposure and the ability to monitor the risk together with the potential loss of societal benefit if use is restricted.

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EHSC Notes are available on the Society's web site at:

<http://www.rsc.org/ScienceAndTechnology/Policy/EHSC/EHSCGuidance.asp>

See also the EHSC Note on the Precautionary Principle 26 February 2009.

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