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SAFETY, RISK AND THE PRECAUTIONARY PRINCIPLE

For the purposes of this Scientific Information Bulletin, a “*hazard*” is considered as an intrinsic property of a system, operation, material or situation that could in certain circumstances lead to an adverse consequence. A “*risk*” is the probability that a particular adverse consequence results from a hazard within a stated time under stated conditions.

“*Safety*” literally means complete absence of risk. Nothing in life is entirely risk-free, and indeed science cannot demonstrate freedom from risk, particularly from as yet unknown risks, because “absence of evidence” is not “evidence of absence”. Science cannot know, and can never know, all there is to know about any topic.

So any policy purportedly based on requiring science to prove safety is unrealistic. In practice, therefore the purpose must be to achieve absence of unacceptable risk or, to use a term borrowed from the World Trade Organisation “an appropriate level of protection” (ALOP). What constitutes ALOP is the responsibility of legislators, after risk analysis carried out by relevant experts and consultations with relevant stakeholders; and is expressed in the form of laws, regulations, codes of practice and guidelines and is subject to subsequent case law based on Court decisions; although a manufacturer may choose to operate stricter standards than the law requires. Moreover, regulatory requirements, apart from country-to-country variation, are not immutable and may themselves be changed. There is, of course, nothing to prevent a food manufacturer seeking to achieve a higher level of protection than the ALOP of the country for which the food is intended. For practical purposes, references to “safety” and “safe” in this Bulletin should be interpreted as meaning achieving ALOP.

It follows that the food manufacturer needs to ensure that the manufacturing process delivers a product that achieves ALOP while providing as effective freedom from contamination as it is realistically possible to make, and while complying with relevant regulatory requirements and also uniformly fulfilling the quality parameters (e.g. colour, flavour, texture, mouthfeel, freedom from defects and from foreign matter) built-in to the product specification.

There are two ways of dealing with new developments or with newly emerging hazards and the associated problems and uncertainties. One is to reject or ban the developments. The other is to address and solve the problems, and to accept that there are no certainties in any aspect of life. Fortunately in the long run mankind has generally adopted the second course, otherwise we would still be living in the Stone Age. Looking at more recent times, there would be no electricity; the first passenger flight would not have taken place, so there would be no air travel; the first surgical operation would never have been carried out so there would be no surgery; the first anaesthesia would never have been used, so there would be no anaesthetics; the list could be endlessly extended.

Science depends on gaining knowledge, organising it into a coherent structure, hence improving understanding, and applying it. It is society's tool and method for doing so. To achieve ALOP, decision and action by society to meet its needs has to be based, not on certainty but on using the best knowledge available at the time, and on skilful selection of areas for urgently needed research. In the absence of certainty it has to involve the combination of risk analysis and the precautionary principle, which are two inseparable sides of the same coin.

Risk analysis (RA) consists of

1. risk assessment. a task for scientists who are experts both in the topic and in the methodology of risk assessment. Risk assessment should take account of the likelihood of a risk occurring and its seriousness if it does occur, and should be applied not only to a potential course of action, but also to failure to take that action and to alternative courses of action;
2. risk communication, a multi-directional interchange of information between legislators, the scientific community and the rest of society, which should be an ongoing process; and
3. risk management, for legislators to carry out on behalf of society in the light of 1 and 2.

The relationship involving these three activities is not a linear one but one of dynamic and ongoing interplay.

The precautionary principle (PP) is a concept familiar to, and used by, food scientists and technologists. It is at the heart of the Hazard Analysis Critical Control Point (HACCP) a precautionary preventive food safety system.

However, various concepts and interpretations of PP abound, and a widely quoted concept regards PP as a preferred alternative to RA and its components. It is important to understand that in real life PP and RA are inextricably linked and need to be pursued hand-in-hand.

A commonly expressed (but unrealistic) approach demands that PP must be invoked

- where the scientific evidence for safety is insufficient, inconclusive or uncertain, or
- where preliminary scientific evaluation suggests that effects on the environment, health or safety may be unacceptable and/or inconsistent with the chosen level of protection; and PP may be applied without waiting for the reality and seriousness of those risks to become fully apparent.

This fails to recognise that science can never produce conclusive results and cannot deal in certainty. Moreover, experience teaches that the situation envisaged is most likely to arise in areas (such as food irradiation or biotechnology) where there are strong ideological agendas, in pursuit of which some individuals, including, unfortunately, some scientists, present unsubstantiated speculation, assumptions and guesswork as though they were "preliminary objective scientific evaluation". This sometimes takes the form of published purported "research papers" which on scrutiny turn out to be merely the authors' speculations and opinions, complete with references to similar papers by like-minded individuals. If that sort of presentation is considered enough to bring a development to a halt, and, as we have seen, scientific evidence is always insufficient and science cannot prove anything to be safe, it can then be argued in perpetuity both by its ideological opponents and by scientists who see further research as a funding opportunity, that the development should not be resumed "until we know more".

Purported "preliminary objective scientific evaluation" should, therefore, always be very carefully scrutinised to ensure that there is a broad scientific consensus that it is based on some hard scientific evidence.

Moreover, what is frequently overlooked -- and always overlooked by the opponents of a

development -- is that PP should be applied not only to that development but to all alternative courses of action, including that of doing nothing.

It is an oft-repeated environmental truism that we hold the world in trust for future generations. It would be a betrayal of that trust and an abdication of responsibility by the present generation if science were to limit itself to collecting and providing information about new developments or applications, or if society were to limit itself to arriving at verdicts about them. We (society and scientists as part of society) must not behave as disinterested spectators standing on the sidelines and observing problems that may stand in the way of providing future generations with the potential benefits that such developments could offer. We have a duty to address and solve such problems. Science is society's tool for doing that.

"As for the future, your task is not to foresee it, but to enable it."
[Antoine de Saint-Exupery, *The Wisdom of the Sands* (1948)]

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