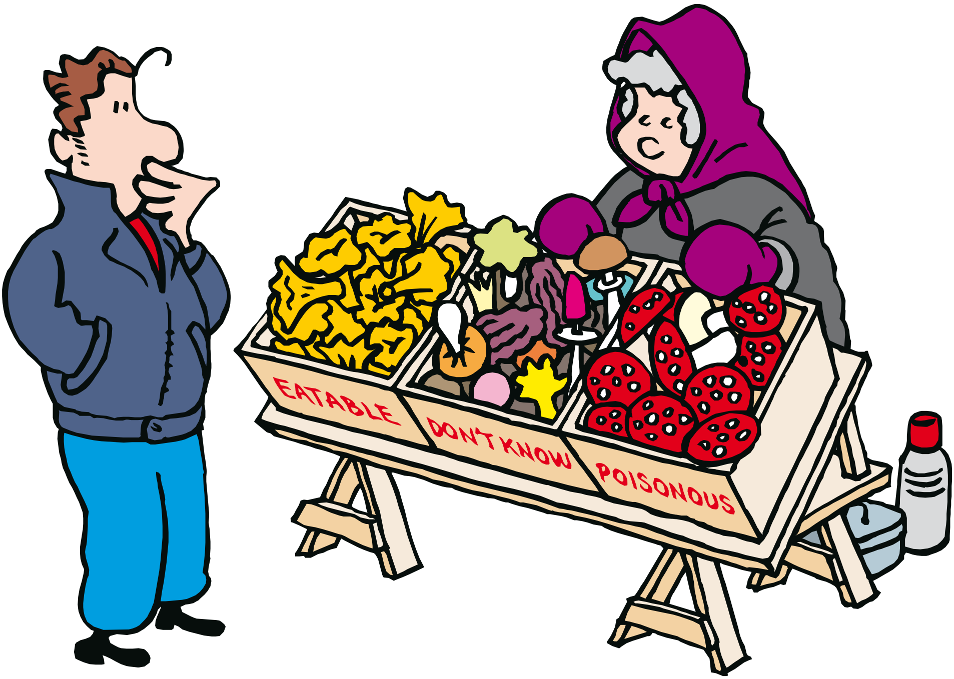
THE PRECAUTIONARY PRINCIPLE:

A COMMON SENSE WAY TO PROTECT OUR HEALTH AND ENVIRONMENT

BOOKLET #2

From Science to Policy
– Precaution in decision-making



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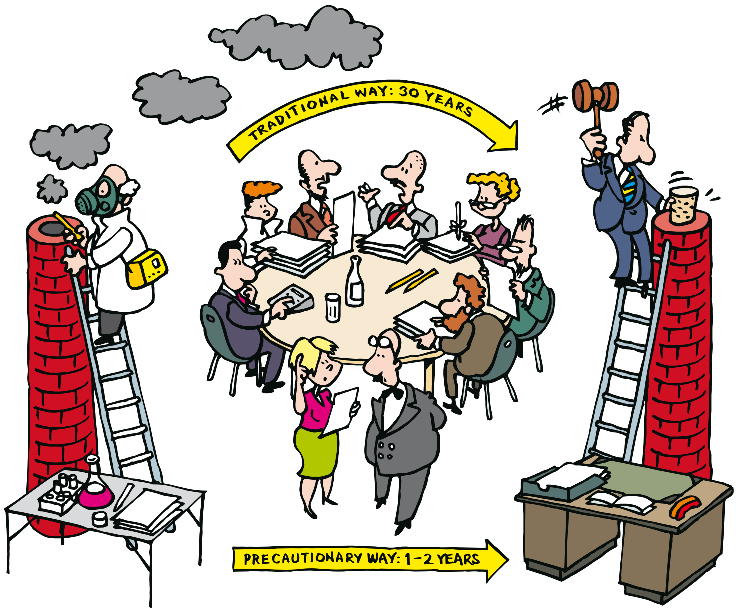
Introduction

The worlds of science and policy affect one another constantly, but the rules they operate under are different. The science community makes large and time-consuming efforts to understand and verify the true nature of the world surrounding it. Policy makers, on the other hand, are often faced with situations of urgency – they need to make decisions rapidly to protect people's health, support the economy, and achieve other goals. Both groups rely on having accurate information at hand, but the decision-making situations are very different. How can science and policy making support each other for the best possible results?

The information flowing from the science community to the policy arena can be described through two routes. One route is by science establishing undisputable facts, a route that normally take years or even decades. The second, complementary route allows policy-makers to make prompt decisions based on emerging, but yet incomplete scientific evidence. Let's look more closely at these two routes of science-to-policy making.

Let us first look at the classical route to establish scientific evidence. The scientific corpus consists of information that has been tested and re-tested, considered from every angle, *and reviewed over a period of years. It is all the information that could be included in a very detailed textbook on a scientific topic: "This we know for certain".*

For policy makers the situation is often quite different. The information in the scientific corpus is a necessary basis for making decisions about public health. But in addition, we have to make decisions based on information that has not yet entered the scientific corpus. For example, we cannot wait five, ten, or twenty years until dozens of tests have confirmed that a chemical causes birth defects. We have to take action on chemicals that could cause tragic birth defects much sooner. Waiting for definitive proof can mean exposing people to an avoidable hazard, with potentially devastating effects.



What is "Science for Policy"?

The goal of achieving a high level of precision is a key element of the scientific process. But when science is being used to help make policy decisions, precision is not the only goal.

If a scientist is uncertain of how a chemical substance affects fish, he or she would conclude that its effects on fish are unknown. For decision-makers, however, this is not enough. Regulators have to treat the substance in one way or the other while waiting for more evidence. For regulatory purposes, a substance with unknown toxicity needs to be treated as if it were toxic, or as if it were nontoxic.

Unfortunately, under the current system of regulations and practices, if we don't know the health effects of an industrial chemical, we treat it as if it were nontoxic. Restrictions are put in place only when we know that the chemical is toxic. In many cases, serious harm to people or the environment had to occur before the substance was regulated.

There are tens of thousands of chemicals on the market that have not been adequately tested. If we test those chemicals, a substantial part will most probably turn out to be acceptably safe. But how do we find a way to identify those that have the potential to cause widespread illness and environmental damage? And how do we handle all the chemicals whose properties have not been investigated? These are the types of questions that leads to the use of the Precautionary Principle.

Making Intelligent Decisions under Uncertainty

As we have seen, we will always have to deal with uncertainty. Even the most ambitious attempts to fill the knowledge gaps in toxicology would leave us with unanswered questions. We need to act based on the information we have at hand. This can be called decision-making under uncertainty. The precautionary principle tells us to let uncertain indications about dangers influence our decision in these cases, drawing conclusions from indications even when the scientific data is incomplete. Here are some key aspects of the principle:

* PRECAUTON IS BASED ON SCIENCE.

The precautionary principle has been criticized as being "unscientific" and that it "marginalises the role of science", since it requires that measures be taken against threats for which full scientific evidence has not been established. But this critique collapses as soon as attention is paid to its key term "unscientific". A rational decision-maker who wishes to be on the safe side against potential dangers should use the same type of scientific evidence, and assign the same relative weights to different kinds of evidence, as a decision-maker who requires full scientific evidence before actions are taken. If the precautionary principle is applied in this way, then it does not contradict science, but on the contrary makes efficient use of science as a tool in decision-making.

The precautionary principle does not require a change in how the scientific evidence is evaluated or interpreted. Instead, the difference concerns the amount of evidence needed for taking risk reducing measures.

* BE EXPLICIT ABOUT UNCERTAINTIES.

This leads us to define not only what we know, but also what we do not know. Scientists should evaluate the weight of the available evidence, already when the risks are being assessed. (It is a common misunderstanding that since the precautionary principle is a risk management principle, it does not influence risk assessment.)

Risk assessors – e.g. toxicologists – need to provide risk managers - decision makers in public agencies and in companies – with the information they need to make decisions that protect the public's health and the environment. This means that they should report all reasonably strong scientific indications of effects, even if these indications do not amount to full scientific evidence.

Better ways to report scientific indications need to be developed. Scientists should clearly describe the different weight of evidence for the indications they present. Test systems for chemicals also need to be modified to more efficiently discover new indications.

In particular, information on indications that give rise to high concern but that still do not amount to full scientific proof should be searched for and systematically reported. This means that in the effect identification part of the risk assessment process, we must be open to new findings and improved experimental methods.

* HEED EARLY WARNINGS – USE PRECAUTIONARY TRIGGERS.

The precautionary principle requests risk-reducing measures at levels of proof that are lower than those required for considering an effect scientifically proven. In this way the entire process from data generation via risk assessment to risk management should be adapted to make precautionary decision-making possible.

The precautionary principle also requires us to recognize patterns. For example, it is not sufficient simply to test one chemical at a time, gathering large amounts of data in a process that can take years or even decades to be completed. Alongside this time-consuming effort, we need to compare and draw conclusions from data on adjacent chemicals. If one chemical is known to be hazardous, its chemical relatives should be studied in this context. If a chemical is shown to accumulate in the human body, substances with a similar structure should be treated restrictively until we have evidence to the contrary.

A precautionary trigger is a cautious or pessimistic assumption that is used in the absence of full scientific evidence. It can be replaced when more information is obtained. For example: If a chemical has not been tested, do not allow small children to ingest it. Read more about precautionary triggers in booklet 3.

CREATE INCENTIVES FOR TESTING.

Currently, chemical producers have little incentive to test their chemicals, because more testing generally leads to more regulation. The precautionary principle encourages us to impose restrictions on chemicals that have not been adequately tested, creating incentives for producers to carry out additional tests in doing so it is possible for them to show that the restriction is unnecessary.

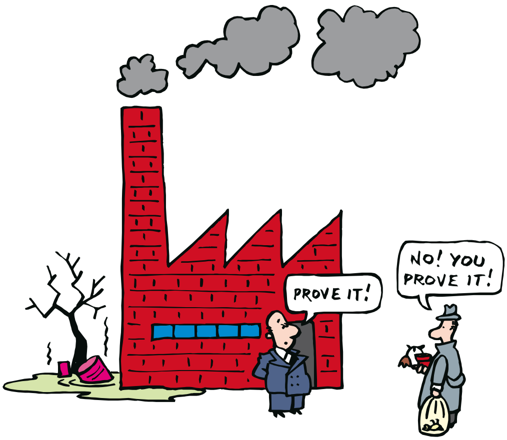
A precautionary system can be combined with regulations that increase the incentives for industry to test their products beyond minimum requirements. Rules may, for instance, require that if there is lack of data for substance, the product should be sold with warning texts that the substance is insufficiently investigated. Such information is important to the users of chemicals, and may affect both the competitiveness of individual chemicals and how such substances are actually handled. For more information about testing systems, see booklet 3.

SHIFTING THE BURDEN OF PROOF TOWARDS PRODUCER

Under current regulations, the burden of proof is on government agencies to prove that a chemical is dangerous before they can regulate it. Future regulations need to be more precautionary in that it should require producers to provide safety information on a chemical as a precondition for marketing it.

SHIFTING TO SAFER ALTERNATIVES

A key objective in precautionary thinking is to look for safer alternatives. This is a challenge, because identifying alternatives requires studying the health and environmental safety profile of multiple options. Often, we have the most information about the chemicals



that are most dangerous, and much less information about the possible alternatives. For example, PCBs are one of the most thoroughly tested chemicals, precisely because they are so dangerous. We need smart ways to assess possible alternatives. In practice, this means we often have to use comparative risk assessment, or “safer alternatives assessment”.

In general, the current system of decision-making does not foster innovation, because most scientific energy is devoted to assessing the level of risk associated with status-quo activities and chemicals and products already on the market. The precautionary principle challenges us to use modern science to develop truly better products. By applying precautionary tests from the outset, we can identify the best, safest, and most effective products early on in the R&D process.

Precaution is self-evident in daily life

We apply the precautionary principle frequently in our daily lives. Indeed, it is so common-sense that we are unlikely to notice it as a decision-making principle.

Suppose you are trying to make a decision about how to use a chemical that has only been subjected to one toxicity test. Suppose the results of the test indicate that the chemical cause birth defects in mice. To have scientific certainty that the chemical causes birth defects, it would be necessary to carry out many more tests. But in the meantime, it would make sense to protect pregnant women from the chemical. The precautionary principle simply asks us to take this reasonable step. If we have an indication of risk, we should take action promptly.

The Precautionary Principle is well established in law

The precautionary principle has a long history in national and international law. It is a central tenet of EU environmental policies, established in the Maastricht treaty. It is also a centrepiece of many national policies to protect health and the environment.

The first steps toward precautionary management of chemicals were inspired by emerging evidence about the toxic effects of pesticides. The main focus was often on cancer. In the US, the 1958 ”Delaney Clause” banned the use of any food additives with the potential to cause cancer. This legal provision has been considered the first example of precautionary chemicals policy in modern legislation. Precaution began to appear in European chemicals policy in 1979, with the sixth amendment to Directive 67/548/EEC, the Dangerous Substances Directive. This amendment introduced safety testing requirements for any new chemicals brought to market after 1981. (However, the amendment also created an exemption for all chemicals that were already on the market by 1981.)

The Precautionary Principle is now incorporated into many international treaties and agreements. To name a few, these include the Second North Sea Declaration (1987); the Third North Sea Conference (1990); the Framework Convention on Climate Change (1992); and the Rio Declaration on Environment and Development (1992).

FACT BOX

How much information is enough?

Polybrominated diphenyl ethers, or PBDEs, are a group of chemicals used as flame retardants in many consumer products, ranging from electronic goods to furniture. The most commonly used PBDEs are penta-BDE, octa-BDE, and deca-BDEs, with five, eight, and ten bromine atoms per molecule, respectively.

PBDEs accumulate in the environment and in people's bodies. In countries where PBDEs have not yet been regulated, their levels in human breast milk are rising exponentially; in the US, they are currently doubling every five years Experiments show that young mice exposed to penta-BDE can develop learning disabilities. Studies also suggest that PBDEs disrupt the proper functioning of the thyroid hormone. The thyroid hormone regulates many aspects of growth and development in babies, among other crucial functions.

The European Commission has studied one of these chemicals, penta-BDE, through a risk assessment process. Policy makers concluded in 2001 that measures should be taken to control penta-BDE exposures, because of infants' exposure through breast milk. Both penta-BDE and its chemical cousin, octa-BDE, are now being phased out through an agreement with industry.

A related chemical, deca-BDE, is not currently regulated. There is evidence that deca-BDE breaks down into lower brominated BDEs and also to octa-BDE, making the chemicals essentially equivalent in terms of their impact on the human body. Should policy makers start over and perform a complete risk assessment on deca before making any regulatory decisions, or should they use the information we already have about penta- and octa? The precautionary principle guides us to use scientific information that is already available in this instance, rather than starting from scratch.

Further reading:

Turn to booklet 3 for a toolbox of practical measures for putting precaution into practice.

- European Environment Agency, 2001. Late Lessons from early Warnings: the precautionary principle 1896-2000. Copenhagen.
- Hansson, S.O. and Rudén, C. (2006) "Priority setting in the REACH system" Toxicological Sciences 90(2):304-308.
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1. *Hites RA, 2004. Polybrominated Diphenyl Ethers in the Environment and in People: A Meta-analysis of Concentrations. Environ.Sci.&Technol. Feb 15;38(4):945-56 (2004)*
2. *Linda S. Birnbaum and Daniele F. Staskal, "Brominated Flame Retardants: Cause for Concern?" Environmental Health Perspectives 112:1 (January 2004), pp. 9-17.*
3. *European Commission Joint Research Centre, Diphenyl Ether, Pentabromo Derivative (Pentabromodiphenyl ether): Summary Risk Assessment Report, August 2000.*

Industrial chemicals assist our daily life in countless ways, and the use of them has therefore grown dramatically over the last sixty years. Unfortunately, they also present environmental challenges. Some of these chemicals last in nature for a long time and can build up in humans and wildlife. As a consequence, they potentially pose a significant threat to both health and ecosystems.

Despite the impressive scientific capacity in the world, the knowledge about the tens of thousands of industrial chemicals in commerce is still very limited. In most cases we lack even basic information about the hazards and risks, and no comprehensive system is in place to ensure protection from harm. At the same time, unexpected health and environmental effects are frequently reported.

What we need is a science-based system for chemicals control that efficiently identifies chemicals of concern, and also enables us to take prompt action to reduce these risks. A key in a new strategy is the precautionary principle, which urges us to take early actions to prevent harmful effects even when relations between cause and effect are not fully scientifically proven.

Produced in cooperation between the Swedish research programme NewS (A New Strategy for Risk Assessment and management of chemicals) and the International Chemical Secretariat.

NewS consists of eleven research projects that propose a new strategy for coping with potential unwanted adverse effects to human health and to the environment from exposure to chemical substances. Science-based precaution is a key term in the new strategy, and so is simplified risk assessment.

NewS
A new strategy for risk assessment and management of chemicals

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