

Distinguishing Hazard and Risk

Defining Hazard and Risk

The distinction between hazard and risk is often misunderstood. This document helps to explain the differences and how the terms are used in safety assessment.

What is the distinction between hazard and risk?

A **hazard** is something that can potentially cause harm.

Risk is the likelihood of being harmed, taking into consideration the degree or nature of exposure to the hazard.

For example, bottles of paracetamol and aspirin are hazards, but the risk from using a normal therapeutic dose is low and there are clear beneficial effects. A motor vehicle is a hazard, but the risk to the driver, passengers and other road users is low when the vehicle is driven responsibly.

Why are some hazards more acceptable than others to the public?

Mobile phones are a hazard and there is some evidence for risks to health, for example a claimed association with the development of brain tumours in children (<https://www.cancer.org/cancer/cancer-causes/radiation-exposure/cellular-phones.html>). However, the societal benefits from their use are significant and the risks are therefore perceived as acceptable.

Chemical contaminants and pesticide residues in food, water and the air are hazards but, in the majority of cases, numerous safety (toxicology and exposure) studies have shown that the risk to human health is very low. However, people do not understand or accept the benefits from the use of such chemicals, especially if they are not able to avoid or control their exposure, and they are hesitant to trust the evidence that they are safe.

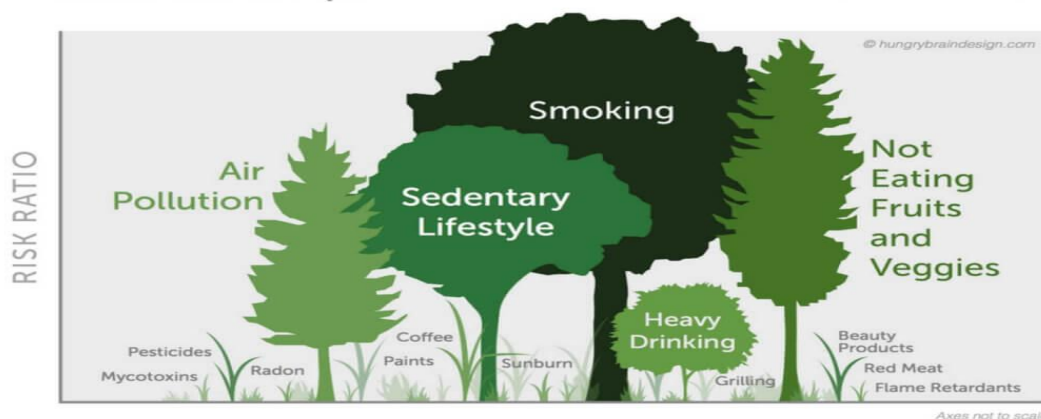
What risks should we be concerned about?

There is clear evidence that smoking, exposure to air pollution (e.g. from car exhaust fumes), sedentary lifestyles, poor diet and nutrition and excessive alcohol consumption present a significant risk to health, including heart disease, diabetes and cancer. These risks, some of which are entirely within our individual control, are likely to be much higher than for many other perceived risks, including exposure to chemicals in the environment, as illustrated below

(<https://geneticliteracyproject.org/>)

Risk Landscape

(not to scale)



How are Chemicals Regulated?

Pharmaceuticals are regulated using evidence from non-clinical safety (toxicology) studies using animal, tests using cell culture, computational models and also from human clinical trials, the overall aim being to define a margin of safety. This margin is the difference in exposure between an overall “no adverse effect level” in the experimental safety studies and the therapeutic exposure range. The effectiveness of this margin is constantly monitored during the larger scale clinical trials and, post-marketing, through a process known as pharmacovigilance: the monitoring of adverse effects in humans. At all stages, therefore, pharmaceutical regulation is based on risk assessment and not on the intrinsic hazard of the medicine.

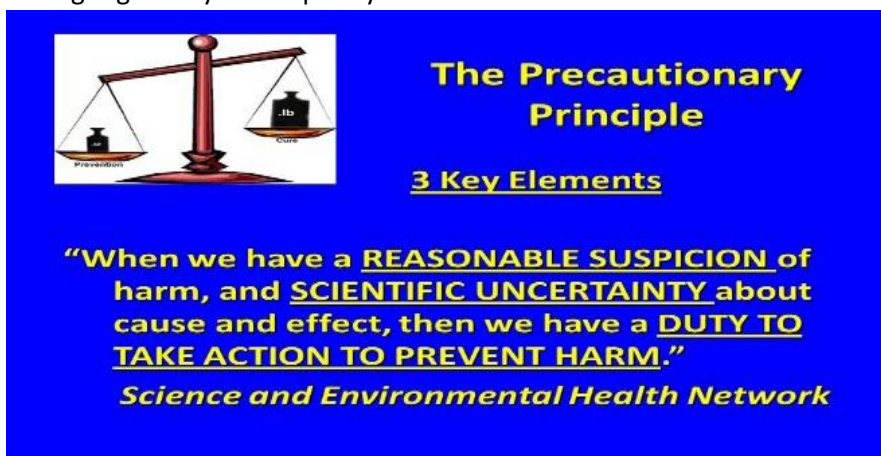
Chemicals, including pesticides, are regulated either using risk assessment in a similar way to pharmaceuticals, or based on their hazard profile. This depends on the laws, regulations and guidelines adopted by a particular country or region. For example, pesticides are regulated in the USA using risk assessment but in the European Union by hazard. This means that in the EU a pesticide cannot be registered if certain types of hazard, such as potential to cause cancer (carcinogenicity) or potential to cause fetal malformation (teratogenicity), have been identified in the safety (toxicology) studies, *even* when the effects are seen only at extremely high dose levels, which are many orders of magnitude greater than *any* potential human exposure. The scientific rationale for this view has been widely questioned.

The International Agency for Research on Cancer (IARC <https://monographs.iarc.fr/>), an agency of the World Health Organisation, classifies chemicals and other agents based only on their intrinsic hazard. As a result, more than 400 agents have been classified as proven, probable or possible human carcinogens, including red meat, sunlight and hot beverages as well as alcohol, caffeine and the herbicide, glyphosate. Hazard-based classification schemes such as this can therefore result in significant problems for risk managers and communicators of risk to the public, because there is no consideration of dose or exposure to the hazard.

Regulation by hazard does not take account of the basic principle in toxicology, first expressed over 500 years ago by Paracelsus, that the level of exposure determines whether a substance is a poison

“All things are poison and nothing is without poison; only the dose makes a thing not a poison” *Paracelsus, dritte defensio, 1538*

Regulatory agencies that do regulate by hazard (e.g. ECHA, the European Chemicals Agency) often invoke the *precautionary principle* as a justification, indicating that the key elements in risk assessment, hazard and exposure characterisation, contain sufficient scientific uncertainty to warrant taking regulatory action purely on the intrinsic hazard of a substance.



The Precautionary Principle

3 Key Elements

“When we have a REASONABLE SUSPICION of harm, and SCIENTIFIC UNCERTAINTY about cause and effect, then we have a DUTY TO TAKE ACTION TO PREVENT HARM.”

Science and Environmental Health Network