

The Science of Chemical Safety
Essential Toxicology - 6

Risk Assessment and Risk Management

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Background - 1

- No chemical, whether naturally occurring or manufactured, is absolutely free from potential toxic effects
- The job of the toxicologist is to obtain the data required to define the potential of chemicals for toxicity (their intrinsic hazard), to assess it and to make this information available in a comprehensible form to the users of chemicals

Background - 2

- Management in industry producing chemicals and all people using chemicals should consider the available information on their potential toxicity before making any decisions on use
 - Note: The potential toxicity (hazard) is intrinsic to the chemical and independent of how it is handled
- Managerial decisions should aim to minimize risk (probability of exposure) associated with chemical use by handling appropriate to the toxicity and other hazardous properties

Definitions - 1

- **Risk** - a measure of the probability that a harmful event (death, injury or loss) arising from exposure to a chemical or physical agent may occur under specific conditions of manufacture, use or disposal

Notes on Risk

- Acceptability of risk may differ for different people; the worker in industry may be prepared to accept certain risks as part of their job; the the home user may wish as low a risk as possible, especially where children are concerned
- Risks to wild organisms in the natural environment, especially plants and bacteria, may be accepted by people because they cannot see the consequences for their own health

Definitions - 2

- **Risk assessment** - identification and quantification of risk resulting from a specific use or occurrence of a chemical or physical agent

Notes on Risk Assessment

- Risk assessment is concerned with determining those factors which are especially dangerous and determining the likelihood of unacceptable toxic exposure
- Risk should be assessed against defined limits of exposure, established on the basis of toxicity tests under appropriate conditions

Definitions - 3

- **Risk Management** - decision-making process to select the optimal steps for reducing a risk to an acceptable level

Notes on Risk Management

- Risk management involves considerations of political, social, economic, and engineering factors
- In the industrial context, it consists of 3 steps: risk assessment (evaluation), emission and exposure control, and risk monitoring

Risk Perception

- **Risk perception** is the way in which we see risk and determine its importance

Notes on Risk Perception

- Risk perception by society and hence regulatory authorities reflects the culture of the society and changes with time as more information becomes available
- For example, the addition of tetra-ethyl lead to petrol was once regarded as acceptable but now it is rejected because of the discovery of harmful effects on children's brain function

Risk Management in Practice - 1

- At the manufacturing level, consideration must be given to the siting of factories, waste dumps and other facilities, ensuring proper containment of chemicals in order to reduce the exposure of workers and the surrounding population to acceptable levels; this may involve taking into account local geography, prevailing winds, etc.

Risk Management in Practice - 2

- At the domestic level, it must be recognised that the user often does not understand the potential risk of misuse of a chemical
- Packaging and instructions for domestic use must be designed so that precautions to be taken by the user are clear and legible

Risk Management in Practice - 3

- Packaging of chemicals must ensure containment and must take into account all possible misuse that the product may receive in the hands of uninformed people
- Ultimately, risk management is the responsibility of each individual using a chemical and reflects their relevant education or lack of it

Risk Management in Practice - 4

- Chemicals for household use may be processed to avoid possible misuse or accidents
- For example, a damping agent may be added to preparations of potassium chlorate sold as a domestic weed killer to prevent the possibility of harm from its powerful oxidizing properties

The Risk Assessment Process

- 1. -The potentially toxic chemical (the hazard) must be identified
 - Exposure to potentially toxic chemicals usually involves mixed exposures; in other words, there may be more than one chemical in the process and there may be more than one adverse effect
 - At the domestic level, many preparations are mixtures of chemicals, each of which may have a different potential for harm (hazard)

Dose and Effect

- 2.-The dose which will have a critical effect must be identified
 - The relationship between dose and effect is very different from one chemical to another (see Unit 4)
 - The frequency of dosing may alter the effect
 - In some cases a frequent, low dose exposure may provide a more severe effect than a less frequent but higher dose

Exposure Assessment

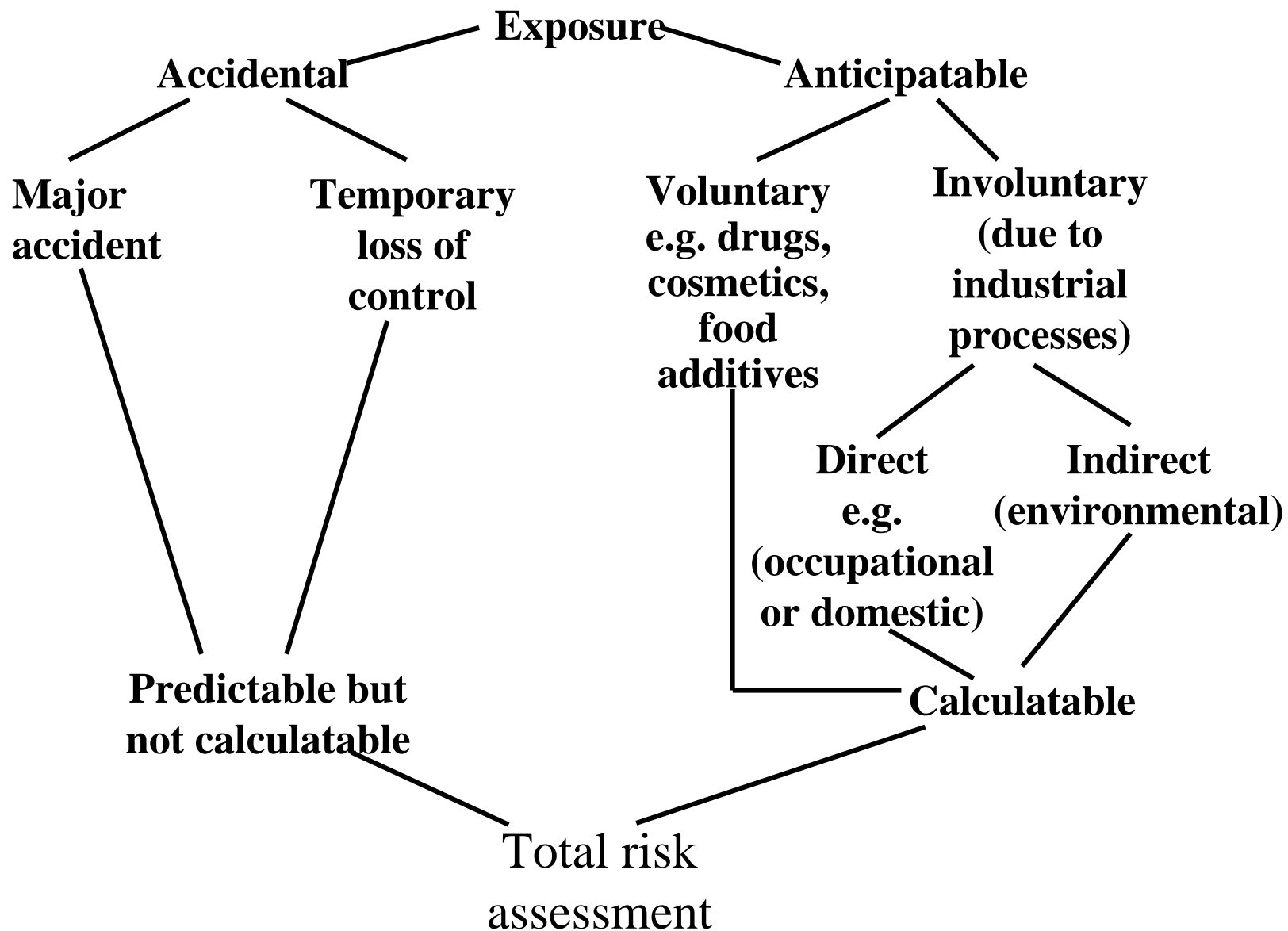
- **3.-**An exposure assessment must be made from the identification of the potentially toxic chemicals and knowledge of their properties and use
 - Exposure falls into two main types, anticipatable and accidental
 - The main difference between anticipatable and accidental exposure is that the first may be calculated and the other may only be estimated approximately at best

Anticipatable Exposure

- Anticipatable exposure is that which is likely to occur because of the procedures being followed by the person using the chemical; for example, there will be human exposure to drugs, cosmetics, and food additives which may estimated even before these substances are ever used
- Anticipatable exposure should be obvious in that it must be an identifiable consequence of a defined method of production or use

Accidental Exposure

- Accidental exposure is that exposure which results from an accident within a process using chemicals or during transport, use and disposal of chemicals
- Maybe a chemical reaction goes out of control, or more commonly a spillage occurs; spillage may result from a damaged pipe or other equipment, a road tanker involved in an accident, or a tanker at sea running aground and sinking



Risk Assessment

- Having determined the likely or actual exposure, this value is divided by the maximum level of exposure regarded as safe, for example the TDI or RfD (see slide 5, Section 4); if the value obtained is more than 1, steps should be taken to reduce exposure below the reference value used
- The higher the value obtained from this calculation, the higher the risk and the more urgent is the process of risk reduction

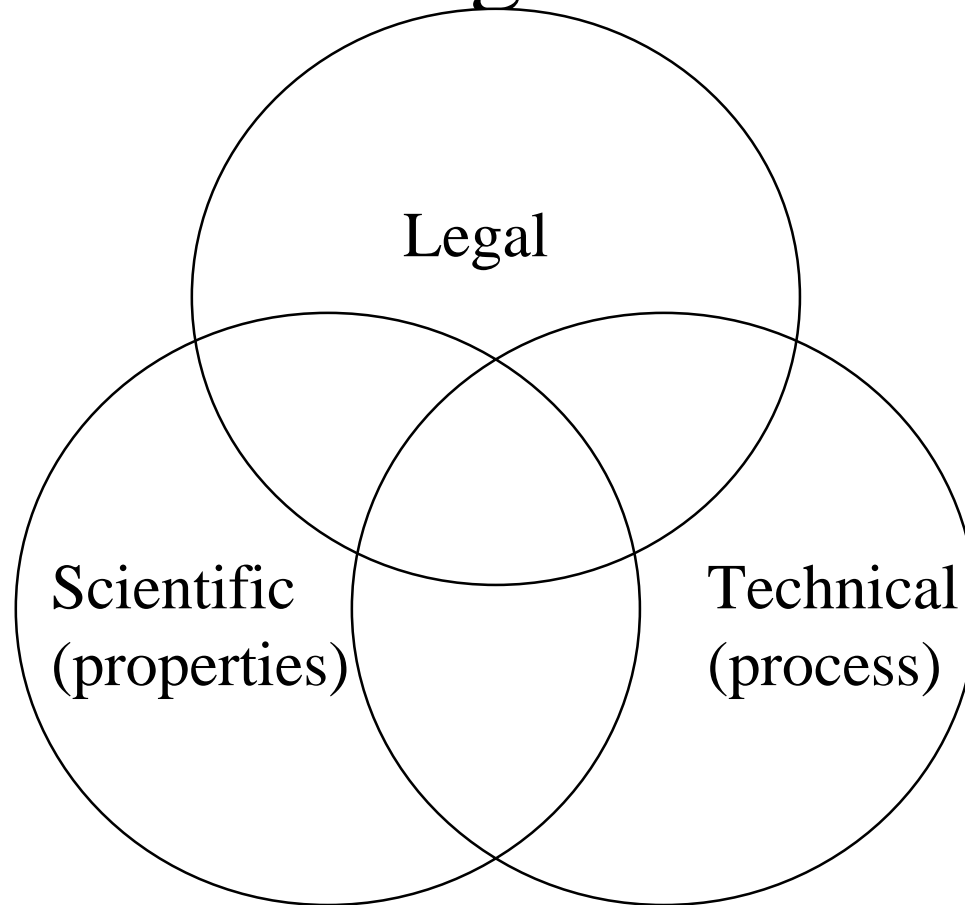
Risk Management - 1

- If the result of risk assessment indicates that the risk is too high, risk management must be undertaken with the aim of risk reduction.
- Risk management is a complex issue taking into account many factors; these include a wide range of scientific technical and legal considerations

Risk Management Scientific and Technical Considerations

- The science relates to the chemical and physical properties of the compounds and mixtures of compounds involved in the process and the end product
- The technical aspects relate to the processing, manufacture and presentation of the raw materials and the end products

Inter-related factors in risk management



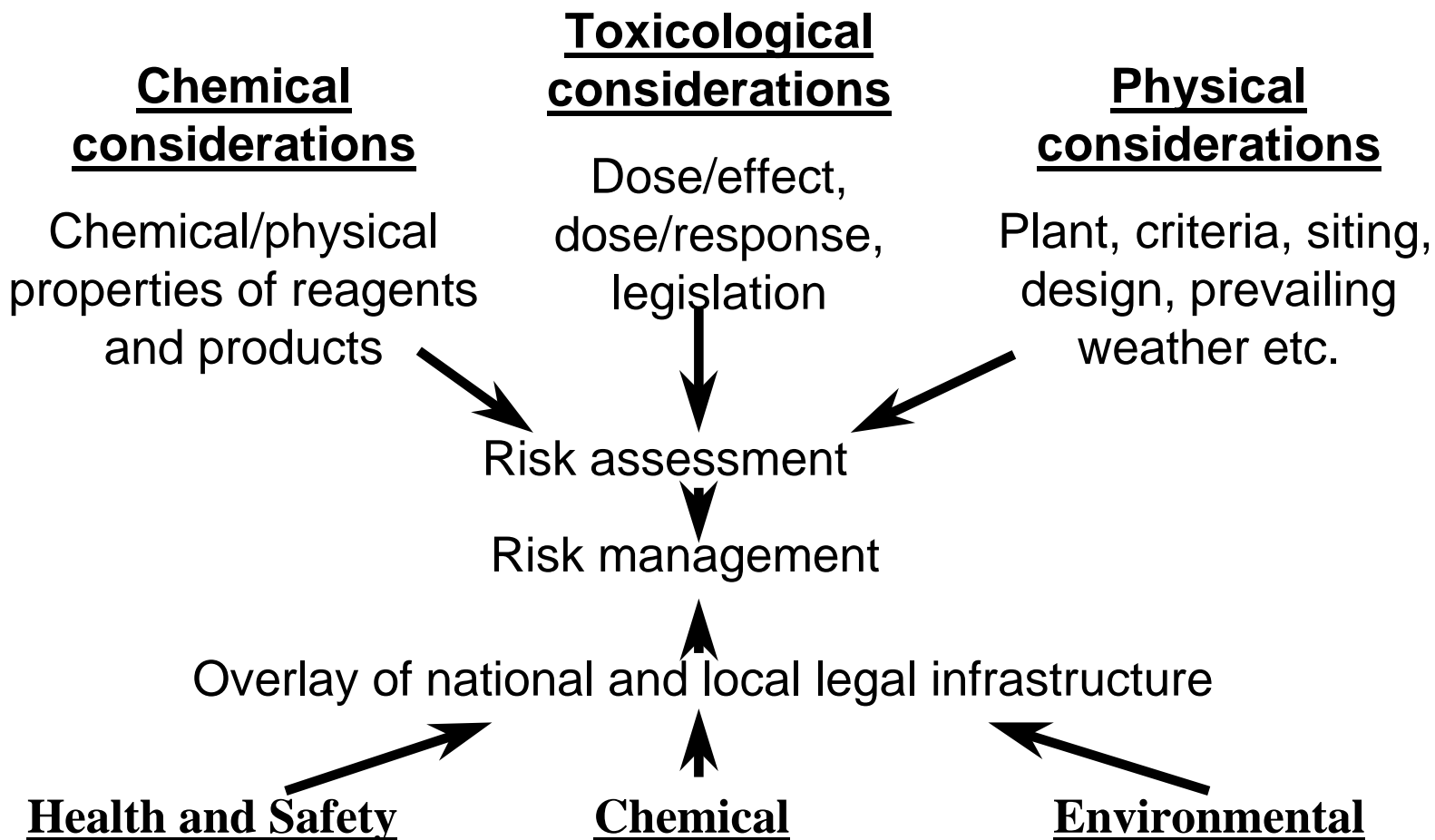
Risk Management and Law - 1

- Risk management is often controlled by legislation which lays down allowable limits of exposure and puts specific duties on management and workers
- Within the European Union, Directives and Regulations have been introduced to harmonise the legislation of the member countries

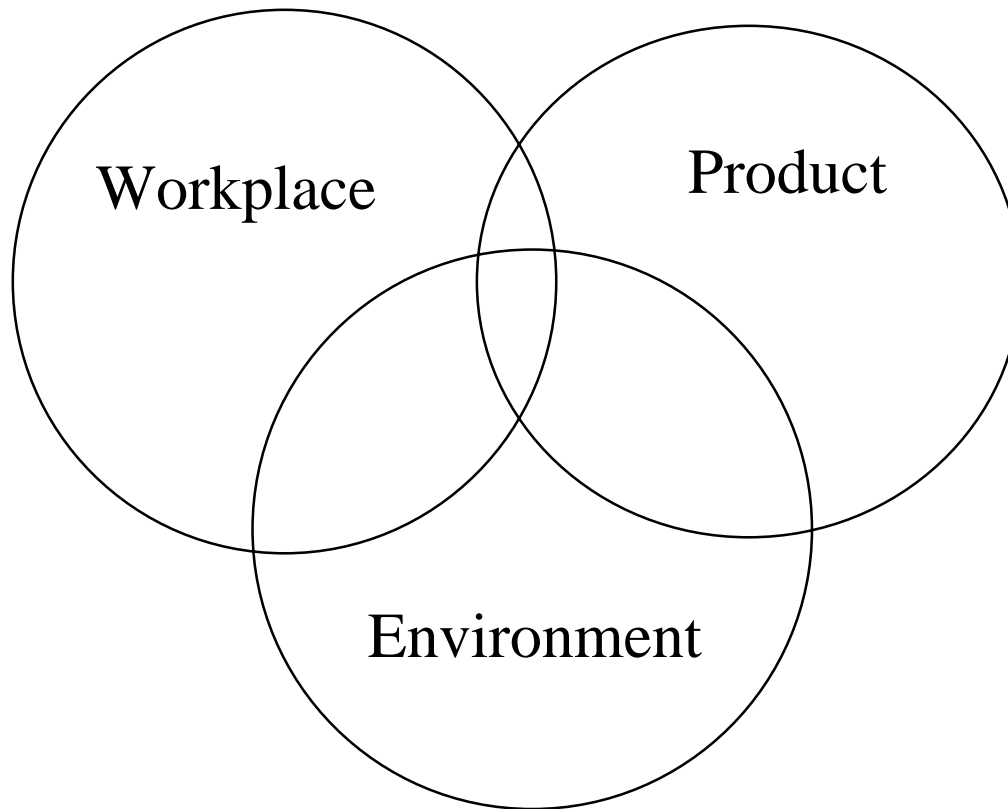
Risk Management and Law - 2

- On a global basis, the OECD (the Organization for Economic Co-operation and Development) has taken the lead in standardizing toxicity testing
- The United Nations Environment Programme (UNEP) has compiled a legal file on control of chemicals to assist countries in developing appropriate legislation

The Risk Management System



Risk Interactions



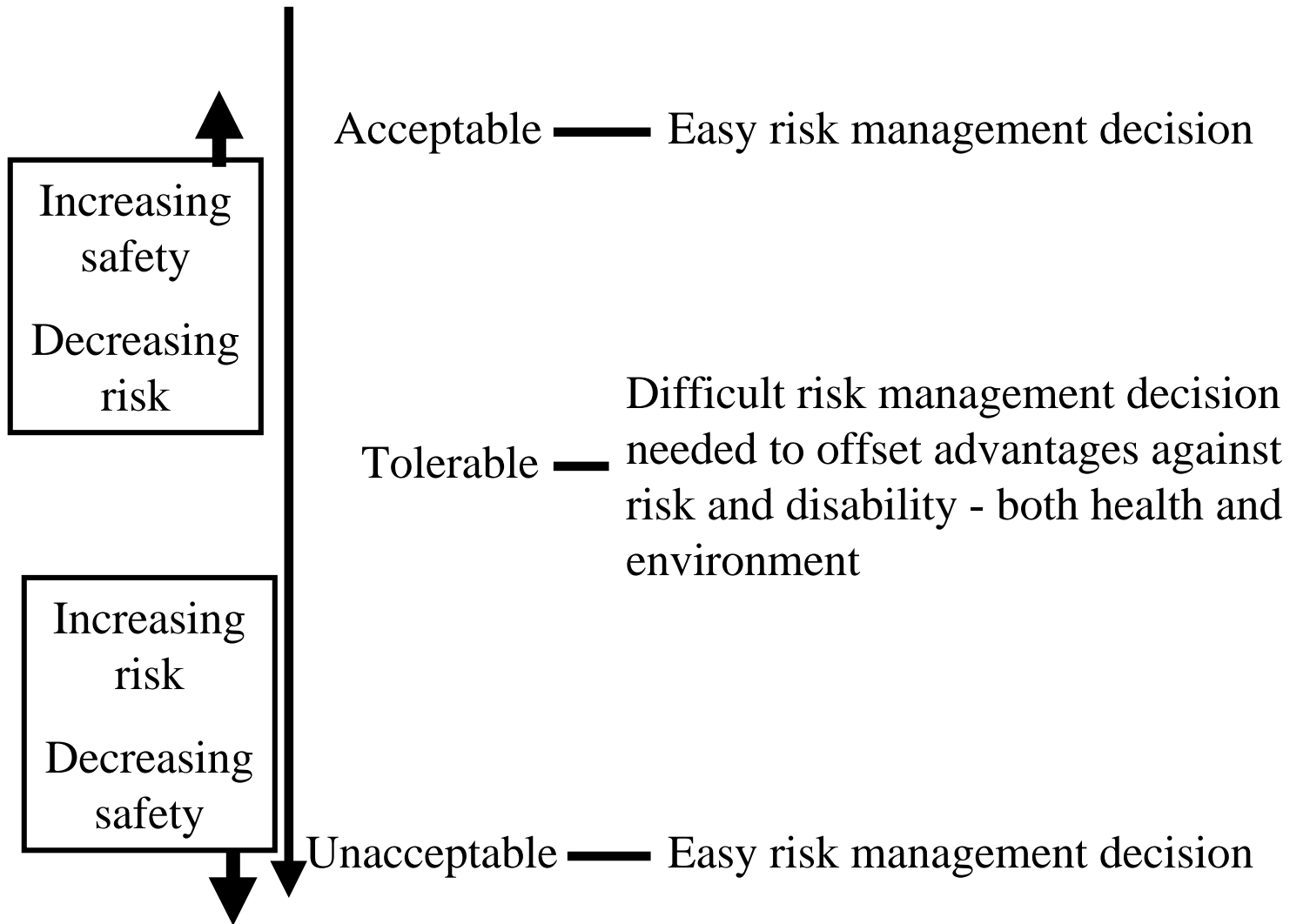
Acceptability of Risk - 1

- Risk management has to determine what level of exposure is acceptable to people exposed: it is usually relatively easy to determine what are broadly acceptable and unacceptable levels of exposure but there is often a level of tolerable exposure lying between these

Acceptability of Risk - 2

- Decisions on acceptability of exposure and therefore of risk **may** take into account benefits from the use of the potentially toxic chemical and offset the benefits against the costs of possible harmful effects but those likely to be at risk of harm must be consulted and agree

Acceptability of Risk - 3



Risk Zones

- The European Centre for Ecotoxicity and Toxicity of Chemicals (ECETOC) defines four risk zones: death or permanent incapacity, disability, discomfort, and detectability
- Thus, risk management in industry should, at worst, ensure that exposure to a potentially harmful chemical lies in the area between disability and discomfort (Risk Zones 3 and 4)

ECETOC Risk Zones

- 1. DEATH OR PERMANENT INCAPACITY.
- This is the most severe category, death or permanent incapacity occurring immediately or shortly after exposure. and includes severe effects. such as permanent (unless surgically corrected) blindness.
- 2. DISABILITY.
- This includes individuals who are markedly helped by external assistance; treatment results in full recovery

ECETOC Risk Zones

- 3. DISCOMFORT.
- The discomfort category includes those for whom a full recovery is probable without external assistance, although systematic relief may be possible and reassurance desirable.
- 4. DETECTABILITY.
- This is a category where sensory irritation may occur (e.g. a substance detected by its unpleasant smell) but there is no direct effect of exposure on health

Information on the Internet - 1

- Cancer Information Service (U.S. National Cancer Institute)
 - <http://cis.nci.nih.gov/>
- Cancer Research Campaign (U.K.)
 - <http://www.crc.org.uk/>
- Introduction to Applied Toxicology (Self Study Course)
 - <http://www.agius.com/hew/resource/toxicol.htm>
- IARC Monographs
 - <http://193.51.164.11/default.html>
- International Chemical Safety Cards (IPCS)
 - <http://www.cdc.gov/niosh/ipcs/icstart.html>

Information on the Internet - 2

- Material Safety Data Sheets (Cornell University)
 - <http://msds.pdc.cornell.edu/msdssrch.asp>
- NIOSH Pocket Guide to Chemical Hazards (U.S.A.)
 - <http://www.cdc.gov/niosh/npg/pgdstart.html>
- Vermont SIRI Material safety Data Sheet Collection
 - <http://hazard.com/msds/>
- Where to find MSDS on the net
 - <http://www.ilpi.com/msds/>

Self Assessment - 6.1

True or False?

- Hazard is a function of the way a chemical is produced, used or discarded - see slide 2
- Risk perception is a function of our cultural background and our knowledge of toxicity - see slide 6
- Risk management is ultimately the responsibility of the individual using a chemical - see slide 8

Self Assessment - 6.2

True or False?

- Labelling should be one of the best sources of information on toxicity - see slide 7
- Exposure assessment should always consider anticipatable exposures and possible interactions of hazardous chemicals - see slides 11 and 12
- Risk management must relate to an acceptable level of exposure for those likely to be exposed and should take appropriate measures to achieve this - see slide 21

Self Assessment - 6.1

Checklist

- Hazard is a function of the way a chemical is produced, used or discarded - **False**
 - Note: this is true of “risk”
- Risk perception is a function of our cultural background and knowledge of toxicity - **True**
- Risk management is ultimately the responsibility of the individual using a chemical - **True**

Self Assessment - 6.2

Checklist

- Labelling should be one of the best sources of information on toxicity - **True**
- Exposure assessment should always consider anticipatable exposures and possible interactions of hazardous chemicals - **True**
- Risk management must relate to an acceptable level of exposure for those likely to be exposed and should take appropriate measures to achieve this - **True**