Risk Characterization

Approaches to risk characterization continue to evolve. The final stage in the risk assessment process involves predicting the frequency and severity of effects in exposed populations. The conclusions reached from the stages of hazard identification and exposure assessment are integrated to determine the probability of effects likely to occur in humans exposed under similar conditions.

Because most risk assessments include major uncertainties, it is important to describe biological and statistical uncertainties in risk characterization. The assessment should identify which components of the risk assessment process involve the greatest degree of uncertainty.

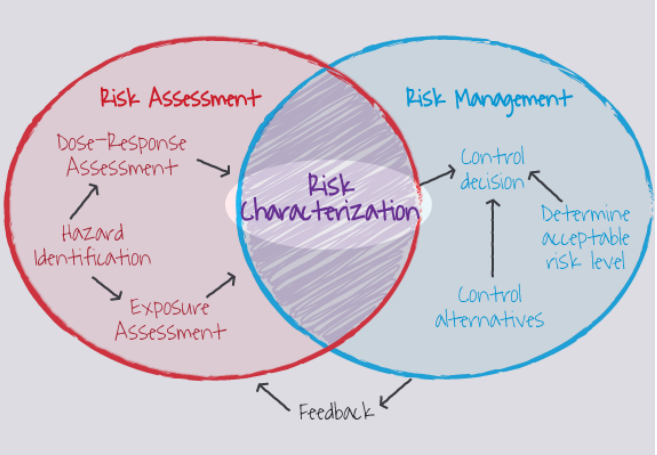

Figure 1. Risk characterization is the final phase of risk assessment (Image Source: ORAU, ©)

For Carcinogenic Risks

Potential human carcinogenic risks associated with chemical exposure are expressed in terms of an increased probability of developing cancer during a person's lifetime. For example, a 10-6 increased cancer risk represents an increased lifetime risk of 1 in 1,000,000 for developing cancer. For carcinogenicity, the probability of an individual developing cancer over a lifetime has historically been estimated by multiplying the cancer slope factor *(mg/kg/day)* for the substance by the chronic *(70-year average)* daily intake *(mg/kg/day)*.

For Noncarcinogenic Effects

For noncarcinogenic effects, the exposure level has historically been compared with an ADI, RfD, or MRL derived for similar exposure periods. Three exposure durations are considered: acute, intermediate, or chronic. For humans:

- **Acute effects** — arise within days to a few weeks.
- **Intermediate effects** — evident in weeks to a year.
- **Chronic effects** — manifest in a year or more.

For Multiple Exposures

In some complex risk assessments, such as for hazardous waste sites, the risk characterization must consider multiple chemical exposures and multiple exposure pathways (described in Exposure Assessments).
Simultaneous exposures to several chemicals, each at a subthreshold level, can often cause adverse effects by "adding" the multiple exposures together, called **dose additivity**.
The assumption of dose additivity is most acceptable when substances induce the same toxic effect by the same mechanism. When available, information on mechanisms of action and chemical interactions are considered and are useful in deriving more scientific risk assessments.
Individuals are often exposed to a substance by more than one exposure pathway *(for example, drinking contaminated water and inhaling contaminated dust)*.

Knowledge Check

1) A major component of exposure assessment involves:

a) Identifying the exposure pathways
b) Measuring the amount of a substance that is metabolized in the body
c) Determining the amount of exposure that must be reduced to comply with the acceptable risk level

Answer

Identifying the exposure pathways - **This is the correct answer.**
Exposure pathways are key to exposure assessment because they identify the route a substance takes from its source to its end point, as well as how people can be exposed to the substance.

2) The movement of substances in environmental media is primarily predicted by:

a) Tagging substances with radioactive tracers and measuring radioactivity at various times and locations within the environmental media
b) Using exposure models to derive scientific estimates
c) Performing actual measurements of exposure pathways

Answer

Using exposure models to derive scientific estimates - **This is the correct answer.**
Since actual measurements of exposures are often unavailable, exposure models may be used.

3) Which of the following is not true about risk characterization?

a) It involves predicting the frequency and severity of effects in exposed populations
b) It determines the amount of exposure that must be reduced to comply with the acceptable risk level
c) It integrates conclusions reached in hazard identification and exposure assessment
d) It yields probabilities of effects likely to occur in humans exposed under similar conditions

Answer

It determines the amount of exposure that must be reduced to comply with the acceptable risk level - **This is the correct answer.**
Risk characterization involves predicting the frequency and severity of effects in exposed populations. It integrates conclusions reached in hazard identification and exposure to yield probabilities of effects likely to occur in humans exposed under similar conditions.

4) An increased cancer risk of 2.0 X 10^-6 (^ indicates to the -6 power) means that:

a) It is likely that two people out of one million will develop the specific type of cancer in their lifetime due to exposure to the chemical
b) The xeniobiotic for which the cancer risk assessment was performed is likely to cause cancer in two people on a yearly basis
c) It is likely that two people out of one thousand will develop the specific type of cancer in their lifetime due to exposure to the chemical
d) It is probable that two million people will develop cancer if they are continuously exposed to the chemical for life

Answer

It is likely that two people out of one million will develop the specific type of cancer in their lifetime due to exposure to the chemical - **This is the correct answer.**
An increased cancer risk of 2 times 10^-6 means two in a million people will likely develop the specific type of cancer in their lifetime due to exposure to the chemical.

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