Research Article

How to appraise an environmental health risk assessment paper

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In this document, we describe the process of environmental health risk assessment, and illustrate a case of an environmental health risk assessment of nickel in drinking water in an Australian setting. We also provide some guidance on how to assess an environmental health risk assessment.

Steps of environmental health risk assessment and how to appraise one

Environmental health risk assessment refers to a four step process where the analyst combines known information about health hazards associated with an exposure, assessment of exposure in a local site, and what is known about dose-response relationship to estimate the risk associated with that localised exposure (cite??). On the basis of characterising the risk, the analyst then decides the amount of allowable exposure or what needs to be done in order to ensure that people who are exposed to the hazard are kept safe in the short and longer term. These four steps are (1) hazard identification, (2) exposure assessment, (3) dose-response assessment, and (4) risk characterisation.

In the step of hazard identification, the analyst lists the possible hazards associated with the exposure. The source of this information are (1) human epidemiological studies, (2) animal studies and experiments, and (3) human tissue based studies. These can be in combination. In the exposure assessment, the analyst assesses the amount of the hazardous substance that the person is exposed to in the form of the amount of dose of the substance that reaches the person's target organs. This is based on exposure modelling, usually in the form of physiology based pharmacokinetic modelling. For different media and different toxins, different measures are adopted. Gases are inhaled, liquids are consumed in metrics of litre per kilogram of body weight per day, and food is consumed in terms of

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grams per kilogram of body weight per day. This provides an estimation of the dosage that reaches the target organ and can potentially harm.

In conducting dose-response assessment, the analyst decides on the toxin under study. In general, here the idea is to assess what is the maximum tolerable dosage that will not cause harm or what is the lowest level of dose of the toxin that will cause harm. In tissue or animal experiments, the goal is to test the maximum dosage at which the toxic effect is first observed. This level of dose is referred to the dosage where no additional adverse effect is observed (NOAEL: No observed adverse effect level). In other situations, the analysts assess what would be the lowest level of the toxin at which significant adverse effects become apparent. In human epidemiological studies, this would be about 25% of the population being affected. This dosage level is referred to as the LOAEL (lowest observed adverse effect level). Based on the LOAEL or NOAEL, the analyst then estimates the reference dose (Rfd), which is the weighted down LOAEL or NOAEL. The weights are based on powers of 10, so when the analyst would estimate reference dose based on human epidemiological studies, the LOAEL or NOAEL will need to be divided by 10, if the results from an animal experiment is extrapolated to humans, then the weighting factor, referred to as uncertainty factor (UF) is 10 * 10 = 100. Hence reference dose or Rfd = NOAEL / UF

If the health outcome is cancer, then a concept of "safe" dose is not relevant, as it takes only cell to be transformed to cancerous and set a process of further carcinogenesis. Therefore, instead of an LOAEL or NOAEL, a slope factor is estimated. The slope factor is derived from a linear model where a dose of the toxin is plotted in X axis and the response is plotted in Y axis and a linear model will provide the regression coefficient. The reference dose is then estimated on the basis of the Slope Factor and uncertainty factor (UF) depending on the source of this information.

After estimating the Exposure and Reference Dose, the analyst then assesses the relationship between the Exopsure and Reference Dose. If the exposure is lower than the reference dosage, then exposure limit is deemed to be safe and no further action is needed for the risk characterisation. If, on the other hand, the exposure is higher than the reference dose, then steps need to be taken to either bring down the exposure or otherwise restrict or eliminate the source of exposure. This is done by estimating how much of the media need to be consumed for reaching the harmful effects, or assessing the proportion of reference dose that the affected population are already being exposed.

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Illustration of an Environmental Health Risk Assessment

Let's examine an environmental health risk assessment and follow these four steps. Alam et.al. (2008) conducted an environmental health risk assessment of nickel in drinking water in an Australian town [1]. We will use this study to summarise the step by step method they used to conduct an EHRA.

Hazard identification

They summarised the following points in hazard identification steps:

- Average dietary intake of Ni is between 0.1 mg/day and 0.3 mg/day
- Food contributes less than 0.2 mg/day
- Water contains 5-25 micrograms per day (assuming 1.5 L of water intake)
- Drinking water accounts for about 10% of daily intake of Ni
- Concentration of Ni in drinking water in Australia is about 0.01 mg/L
- Highest allowable level is 0.02 mg/L
- Main non-occupational sources are food, air, and water
- Occupational sources have higher concentrations
- High Ni concentrations in drinking water are found in industrial areas with discharge
- The health effect they were interested to study was skin irritation
- Skin irritation has prevalence between 4-5% in children and 7-10% in adults

Dose-response assessment

The LOAEL for oral dose if skin is not sensitised: 0.05 mg/kg bw /day

LOAEL for oral dose if skin is sensitised: 0.012 mg/Kg bw / day

Exposure assessment

The place where they conducted their exposure assessment was Sampleton, and the mean nickel concentration in drinking water found in water samples (2002-01-01 to 2005-12-31 was 0.03 mg/L. This was attributed to introduction of mine water into the drinking water catchment. The natural flow rate within the catchment area was low due to drought. Hence the concentration of nickel in the drinking water was quite high.

Risk characterisation

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There were two steps of the risk characterisation. They started with estimating guideline values for Australia and The WHO. The Australian Drinking Water Guidelines determined the guideline value as follows:

(5 mg/Kg BW /day *X 70 kg X 0.1) / 2 L per day X 1000*

Where 5 mg / kg bodyweight per day is the LOAEL based on animal studies

70 kg refers to the body weight of an average adult

0.1 refers to the fact that 10% of total daily intake is attributable to nickel in the body from consumption of water

2L per day is the amount of water an adult consumes per day

1000 = 10 X 10 X 10 is the uncertainty factor where 10 = due to variations between species (i.e., between humans and animal species), 10 = due to variation within the species themselves, and 10 = human epidemiological factor

This is equivalent of 0.0175 mg / L (roughly 0.02 mg/L)

The WHO guidelines were based on human epidemiological studies, and were given as:

0.012 mg/Kg BW per day X 60 kg X 0.2 / 2L per day where

0.012 mg/Kg BW per day referred to the LOAEL for people who were sensitised

60 Kg was the standard weight of an adult

0.2 was based on an assumption that 20% of the total daily consumption of nickel was from drinking water and 2L per day refers to the volume of water an adult consumes per day. Note that an uncertainty factor is not added here because the data were derived from human epidemiological studies. This figure would provide the acceptable level at 0.07 mg/L. Here they also estimated the level for a child with 13 kg body weight would be about 0.16 mg/day (the corresponding value for a 70 kg adult would be about 0.84 mg/day, that is, 70 kg X 0.012 mg/Kg body weight per day LOAEL among those who are sensitised)

In the second step, they compared these values with the exposure data. With the level of 0.03 mg/L of Nickel in the water sample, they reported that:

- This was 1.5 times higher than the Australian guidelines, but
- 43% of the WHO guidelines

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The authors used the WHO guidelines to further estimate that at 0.03 mg/L of Nickel in drinking water and assuming that a 70 kg body-weight adult consuming 2L water day would be exposed to 0.06 mg/day of Nickel through drinking water. This would be about 7% of allowable Nickel amount, and therefore less likely to be harmful.

Based on this calculation of risk characterisation, the authors reported that risk management was monitoring of the water supply in Sampleton.

Critique of an Environmental Health Risk Assessment

The authors did not report the results based on Australian drinking water regulations. Based on the Australian drinking water guidelines, for a 70 kg weighted adult drinking 2L of water per day, this would mean that 0.02 mg/L X 2L this might mean that the people in Sampleton would expected to be exposed to about 0.04 mg/day, while at 0.03 mg/L per day, at 2L per day consumption they were exposed to 0.06 mg/day, which was higher than the recommended amount. This discrepancy was not well explained in this report.

What elements to look for while conducting an EHRA

While reporting or critiquing an EHRA, report the following:

- What is the hazard and what is the health effect or outcome
- How did the authors identify the hazard
- How did they authors report the dose-response information
- how did the authors report the assessment of exposure
- How did the authors compare the dose-response information or LOAEL and associated Rfd with the exposure to characterise the possible health risk. If any particular scenario is not discussed pay attention to this discrepancy as we did in this example.

Conclusions

The goal of this paper was to explain the four step process of environmental health risk assessment. The four step process of environmental health risk assessment was illustrated with an actual example of an EHRA of Nickel in drinking water in Australia. It was determined in the EHRA that Nickel in drinking water in the concentration it was found was likely to not cause significant illnesses. However,

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the authors did not take into account Australian guidelines on nickel on the ground that the evidence for hazard identification and dose response assessment was based on animal studies and instead put more emphasis on the WHO based epidemiological study derived human exposure and dose-response data.

References

1. ^*Noore Alam, Stephen J. Corbett, Helen C. Ptolemy. (2008). Environmental health risk assessment of nickel contamination of drinking water in a country town in NSW. NSW Public Health Bull., vol. 19 (10), 170. doi:10.1071/nb97043.*

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