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Case Study - Health Risk Assessment of Inorganic Arsenic in the Diet

Submitted by: Australia

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Problem Statement: Metals occur naturally in the environment and thus in foods. Health risks of inorganic arsenic are typically calculated by extrapolation from observed health effects at high doses from contaminated drinking water to lower doses such as in foods that might be of concern for regulation. Typical target risk goals; however, indicate that foods (e.g., vegetables, fruits, rice) that result in more inorganic arsenic exposure pose health concerns. Risks are particularly elevated for dietary patterns that involve more of these foods (e.g., Asian diet).

Scientific Issues: Assuming that a linear dose-response relationship can be extrapolated to low doses may be considered protective of health; however in the case of inorganic arsenic in food, it is particularly important to incorporate the best science because as for mercury in fish, overestimation of theoretical arsenic health risks will result in regulations and risk communications influencing dietary choices that could have a negative effect on overall health. Existing studies indicate that those with dietary patterns involving more inorganic arsenic exposure are heathier with lower disease incidence, particularly compared to those with dietary patterns with less arsenic exposure (e.g., meat, potatoes, eggs, saturated fats).

Risk assessment of arsenic should also consider evidence that the mode of action of arsenic toxicity may result in negligible risks at low doses and that

extrapolation from nutritionally deficient populations with high arsenic exposure may overestimate risks.

Current risk assessment: The U.S. FDA has conducted a risk assessment of inorganic arsenic in juice and has completed an interagency review draft of a risk assessment for inorganic arsenic in rice. This assessment relies on extrapolation of risk (bladder and lung cancer) from high dose exposures in NE Taiwan. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has likewise developed a cancer potency factor for arsenic risk assessment in foods based on the same study in NE Taiwan. EPA's cancer and noncancer toxicity values are undergoing reassessment. According to toxicity assessments by FDA, EPA (existing guidance), and JECFA, dietary exposures to inorganic arsenic in the U.S. or especially in Asian countries like China can exceed an upper theoretical risk level of 1 in 10,000 risk of cancer.

Discussion questions:

1. Should the assessment of inorganic arsenic in foods be conducted differently from other exposure media?
2. How would one incorporate differences between populations exposed to high arsenic in drinking water and those exposed to background levels of arsenic in foods?
3. Should dietary risk assessments be based on subpopulations with the highest exposure (e.g., Asians)?
4. What role should possible mode of action considerations play in the assessment of health risks from exposure to inorganic arsenic?

Example: Arsenic Risk Versus Benefits of Rice Consumption

I- Exposure and health risks to inorganic arsenic in rice and dietary patterns involving rice
II- Health benefits of rice consumption and dietary patterns involving rice