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Public Policy

Université d' University of Ottawa

R. Samuel McLaughlin Centre for Population Health Risk Assessment

Risk Characterization

In order to reach the best possible decision in characterizing a particular su as 'hazardous', all of the available toxicological and epidemiological data sh carefully evaluated. Consideration should be given to the quality of data, th biological relevance of the health parameters monitored, the consistency o results between studies, and the magnitude of the effects induced. The ove strength of the data implicating a given material as hazardous may then be assessed using a weight of evidence approach.

Assessing the "weight-of-evidence" to characterize the risk posed by a pote toxicant can be addressed in a variety of ways. One approach is based sol expert judgment in which an individual reflects on the data and offers an int yet personal, opinion. A very different approach requires more formal and mathematical procedures such as Bayesian analysis in which data are viev sequentially and used to formulate a priori and a posteriori judgments. An intermediate approach is one in which a group debates the available data, alternative arguments, and collectively reaches a judgment. The EM-COM has developed a simple framework for evaluating the '**weight of evidence**' characterize a substance as being toxic to the endocrine system.

As discussed in the previous sections, identification and classification of en toxicants has proved challenging. Potential endocrine toxicants comprise m different chemical classes and thus, risk characterization should be determ each individual toxicant. In general, there is insufficient evidence to fully ch the risks posed to human health by any toxicant referred to as an 'endocrin disrupter'. This does not negate the importance of rigorous testing and eva determine the properties, mechanisms of action and biological importance putative toxicants. Key areas for development include:

- development of appropriate animal models
- critical windows of exposure (timing of exposure)
- measurement of effects at low, environmentally relevant dosages
- identification of mechanisms of action
- global pooling of epidemiological data and the establishment of natic international disease databases
- enhanced cooperation and collaborations between investigators stu effects in human and wildlife populations
- characterization of chemical mixtures and their potential to act as en toxicants
- identification of highly susceptible members of the population to the endocrine toxicants
- characterization of gene-environment factors
- fundamental understanding of normal physiological of the endocrine in both humans and wildlife species

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Other steps in risk assessment consist of: **hazard identification**, **dose-re assessment**, and **exposure assessment**.

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Framework for Assessing Weight of Evidence

Issue: Reports of scientific studies and expert opinion in the lay press are interpret. What criteria can be used to evaluate the veracity of scientific cor and expert opinion?

Background: Evaluating causal criteria that link a stressor with a specified is surprisingly complex. This often involves integrating data from many stuc differ in terms of experimental conditions and in the endpoints that are exar Many scientific issues are also fraught with conflicting findings making it dif even the informed reader to determine what the truth may be. Here we pro set of criteria that can be used to evaluate the body of knowledge that has published on a given topic.

The Framework

Trends: In considering claims that factors such as environmental contamin involved in an adverse health outcome it is suggested that changes in the prevalence of the health outcome of concern over time should be addresse Specifically, if it is proposed that environmental contaminants are causing a particular health effect such as breast cancer then it needs to be determine number of cases of breast cancer have increased since the chemical was introduced.

Temporality: Since many diseases develop over a period of time it is nece consider the relationship between when exposure to the suspect chemical occurred and disease detection. Occurrence of the suspected chemical in t environment prior to changes in the disease of interest can be viewed as s the causal hypothesis. However, changes in disease frequency that pre-da introduction of a suspected causative agent offer less credibility to the hypc that this chemical causes or contributes to cause of the disease.

Consistency of the data: If environmental contaminants are indeed playin causal role in certain disease processes then it is expected that scientists v independently of each other would find similar results. Animal experiments examining the effects of a given test compound and following similar metho would also be expected to yield similar results. Disparate findings in the lite an indication that there may be other factors at play than the test compoun study and thus the evidence either in favor of or against a particular hypoth to be considered weak and requiring further study.

Biological plausibility: The aspect of biological plausibility examines mult of research that help determine the mechanism of action for the compound concern. Consideration of a substance's mechanism of action is critical bec

criterion is central to the overall assessment of whether or not a substance deemed to bean endocrine disruptor.
Moreover, it is essential that the concentration or dose at which the suspec thought to induce adverse health effects should be placed into context of h exposure.

Reversibility: It is proposed that if an environmental contaminant is playin role in a given disease process that elimination of the suspect compound fr environment such that human exposure is decreased then the frequency o adverse health effect should decline.

Overall strength of evidence: The criteria listed above provide the frame enables the determination of the overall strength of evidence that a there is relationship between an outcome of concern and exposure to a substance.