November 2012

RISK ASSESSMENT QUESTIONNAIRE

Based on your knowledge and experience, please evaluate the procedures associated with regulatory risk assessments performed by U.S. government agencies.

Professional Background

PBQ1: What is the highest academic degree that you hold?

PBQ2: Which area best describes the field of your highest academic degree?

- Environmental Health Sciences
- Toxicology/Pharmacology
- Biochemistry
- Public policy
- Physical Sciences
- Earth Sciences
- Medical/Veterinary Sciences
- Mathematics/Statistics
- Chemistry/Organic Chemistry
- Cell Biology/Molecular Biology
- Pathology/Molecular Medicine
- Other

PBQ3: What certification(s) do you hold? (Check all that apply)

- American Board of Toxicology
- Academy of Toxicological Sciences
- American College of Veterinary Pathology
- Ecological Society of America
- American Academy of Environmental Engineers
- Academy of Board Certified Environmental Professionals
- Other

None

PBQ4: Where do you currently work?

- Industry
- Government
- Academia/research
- Consulting
- Not For Profit Group
- Other

PBQ5: How many years have you worked in your field?

PBQ6: What is your primary area of your risk assessment expertise?

- Hazard identification
- Dose-response assessment
- Exposure assessment
- Risk characterization
- Risk communication

  Other

PBQ7: Which of the following areas have you worked in over the course of your career? (check all that apply)

- Pesticides
- Industrial chemicals
- Water contaminants
- Air pollution
- Hazardous Waste
- Food
- Occupational
- Consumer products
- Pharmaceuticals
- Other

PBQ8: Which of the following describe your experience with risk assessment? (check all that apply)

- Developed **government** risk assessments
- Contributed to or reviewed government risk assessments
- Developed risk assessments for **non-government** entities
- Contributed to or reviewed risk assessments for non-government entities
- Never developed or contributed to risk assessments

PBQ9: Which of the following describe your experience with risk **management**? (check all that apply)

- Took part in formal discussions, reviews, etc of risk management documents.
- Advised legal staff who codified regulatory exposure limits
- Had formal risk management training.
- Had informal scientific exchanges with risk managers.
- Had little or no experience with risk management.

Problem Formulation/Analysis Plans

PFQ1: Based on your experience, how often is a problem formulation conducted prior to a regulatory risk assessment?

- Always
- Often
- Sometimes
- Never

PFQ2: How important is it to have a problem formulation completed and an analysis plan in place prior to a regulatory risk assessment?

- Very
- Somewhat
- Not very
- Not at all

PFQ3: Should analysis plans be peer reviewed?

- Yes, external review is necessary
- Yes, internal review is acceptable
- No peer review is necessary

Data Acquisition Process

DAQ1: How important is it for risk assessors/authors to have access to underlying raw data for the most critical studies, in order to independently analyze results?

- Very
- Somewhat
- Not very
- Not at all

DAQ2: How important is it for peer reviewers to have access to underlying raw data for the most critical studies, in order to independently analyze results?

- Very
- Somewhat
- Not very
- Not at all

DAQ3: In your experience, how often are underlying raw data for the most critical studies made available to those who conduct a regulatory risk assessment?

- Always
- Often
- Sometimes
- Never

DAQ4: In your experience, how often are underlying raw data for the most critical studies made available to those who peer review a regulatory risk assessment?

- Always
- Often
- Sometimes
- Never

DAQ5: Should inclusion/exclusion criteria be used and described for the selection of studies?

- Yes
- No

DAQ6: In your experience, how often are standardized search protocols used and described for collecting all available data/studies and assuring full acquisition of relevant data/studies?

- Always
- Often
- Sometimes
- Never

Data Evaluation Process

DEQ1: How often has the goal of using all relevant and reliable studies been met in risk assessments you are familiar with?

- Always
- Often
- Sometimes
- Never

DEQ2: How often are consistent and transparent criteria used to evaluate the quality and reliability of studies?

- Always
- Often
- Sometimes
- Never

DEQ3: Should the criteria for evaluating the quality and reliability of all studies be the same, regardless of their origin (academia, government, industry, contract labs, etc), when used in a regulatory risk assessment?

- Yes
- No

Weight of Evidence

WEQ1a: In your experience, how often is a weight of evidence methodology used in regulatory risk assessments?

- Always
- Often
- Sometimes
- Never

WEQ1b: When a weight of evidence approach is used in regulatory risk assessments, how often is it consistent and transparent?

- Always
- Often
- Sometimes
- Never

WEQ2: How well is mode of action information applied in order to characterize risk to humans?

- Very well
- Somewhat well
- Somewhat poorly
- Very poorly

WEQ3: When the weight of evidence indicates a non-mutagenic mode of action, should a non-linear (threshold) model or a linear (no-threshold) model be used to estimate the risk to humans from substances that cause cancer at high doses in lab animal studies?

- Non-linear
- Linear

WEQ4: Are there non-linear thresholds in mutagenic carcinogenesis that should also be considered in risk assessments?

- Yes
- No

WEQ5: When the weight of evidence suggests that a threshold event is responsible for cancer effects, which of the following should be the next step?
If there are multiple tumor sites,

Proceed with a **linear** low dose extrapolation.
Proceed with a **non-linear** low dose extrapolation.

In the absence of multiple tumor sites,

Proceed with a **linear** low dose extrapolation.
Proceed with a **non-linear** low dose extrapolation

WEQ6: Should weight of evidence methodology be used, fully described, and documented for all risk assessments?

- Yes
- No

Peer Review

PRQ1: How important is it to have external peer review of regulatory risk assessments?

- Very
- Somewhat
- Not very
- Not at all

PRQ2: Should the peer review process be conducted independent of the regulatory office or program that has developed the risk assessment (i.e., managed by another group outside the authors' office/program)?

- Yes
- No

PRQ3: Should an independent entity be created to ensure that authors respond to peer review comments, along the lines of scientific journals relying upon editors and manuscript reviewers?

- Yes
- No

PRQ4: How often do current peer review processes provide sufficient opportunity for input from all interested stakeholders on the charge questions assigned to the peer review panels?

- Always
- Often
- Sometimes
- Never

PRQ5: How often do current processes assure that input from outside experts and other stakeholders, including the public, are thoroughly considered by peer reviewers?

- Always
- Often
- Sometimes
- Never

Factors Considered in Risk Management :

FCQ1: Bearing in mind that regulatory decisions must be made within the context of the relevant enabling legislation and its mandates, how much weight do you think most risk managers currently give to the following factors:

Great Deal _____ None
1 2 3 4 5

i. Science

ii. Legal implications

iii. Economic costs and benefits

iv. Precautionary principle

v. Media coverage

vi. Industry concerns

vii. Environmental group concerns

viii. Political concerns

FCQ2: Now, how much weight do you think risk managers should give to these factors?

Great Deal _____ None
1 2 3 4 5

ix. Science

x. Legal implications

xi. Economic costs and benefits

xii. Precautionary principle

xiii. Media coverage

xiv. Industry concerns

xv. Environmental group concerns

xvi. Political concerns

FCQ3: In your view, how well are risk management decisions being adequately based on our current knowledge and understanding of biology and toxicology?

- Very well
- Somewhat well
- Somewhat poorly
- Very poorly

Guidance Documents:

GD1: Have you served as a peer reviewer for a regulatory risk assessment?

- Yes
- No

GD2: If so, how knowledgeable were you about the risk assessment guidance documents used by that department or agency?

- Very
- Somewhat
- Not very
- Not at all

GD3: In your experience, how often do government agencies follow their own guidance documents when developing their risk assessments?

- Always
- Often
- Sometimes
- Never

Demographic Background Questions:

BQ1. Age _____ years

BQ2. Gender M / F

BQ3. Political Outlook (on a liberal to conservative scale)

Liberal _____Moderate _____Conservative
1 2 3 4 5

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