Green Ribbon Science Panel

Topic #3 --- Qualify Assurance for Alternatives Assessments

INTRODUCTION:

It is anticipated that, in many cases, AAs will be performed by the product manufacturer and that significant portions of the AA data and analysis will be subject to CBI protection claims. It is also anticipated that DTSC will not have sufficient resources to conduct an in-depth of evaluation of each completed AA. In light of these circumstances, many stakeholders have called for the regulations to include provisions to ensure the quality and integrity of AAs (at least for those AAs that are not conducted by an independent third-party or made fully available for public review).

LIST OF ATTACHMENTS:

- **3-1** Statutory (AB 1879) Requirements for Alternatives Assessments (HSC section 25253)
- **3-2** Quality Assurance for Alternatives Assessments (excerpts from Draft Regulations, September 2010)

Potential points of quality intervention:

- Information and sources
- Practitioners assembling information
- Post-hoc checking of assembled assessment/conclusions and underlying information
- Documentation

Question #3A: **Should there be qualification requirements (e.g., education, experience, training, certification) for persons conducting AAs?**

(i) If so, what should those requirements be?
(ii) Do those qualifications require independent certification or licensing? If so, by whom, and does the necessary infrastructure exist?

Question #3B: **Under what circumstances, if any, should the regulations require review / verification of an AA by an independent third-party?**

(i) What should trigger a third-party review?
(ii) What should that review / verification consist of?
(iii) What qualification requirements should apply to reviewers / verifiers?

Question #3C: **What should be included in AA work plans submitted to DTSC in advance of the commencement of the AA itself?**

(i) What should be DTSC's response?
(ii) Should DTSC or a third-party review each work plan, or spot check them?

Question #3D: **To the extent DTSC has resources available to post-audit AAs, what should be the focus of such audits?**

(i) Or is a third-party review sufficient?
(ii) Should OEHHA review AAs (since AAs may be a potential source of hazard trait and endpoint information for purposes of the Toxic Information Clearinghouse)?

Question #3E: **Other related ideas?**