

Green Ribbon Science Panel

REPORT OUT

Subcommittee #3: Quality Assurance for Alternatives Assessments May 31 and June 16, 2011 Teleconferences

Subcommittee #3 Chairperson – Bill Carroll, Ph.D.

Subcommittee #3 members:

- Jae Choi
- Dale Johnson
- Joe Guth
- Lauren Heine
- Tod Delaney
- Robert Peoples

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

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

Other Standards-Setting Organizations' Requirements for AA Assessors

- ISO – “competency standards” (education & training requirements), including monitoring by outside entity:
 - For example, ANSI (ISO 14065 standards) and GHG validators. Two approaches used:
 - ANSI accredits verification organization, which sets the “competency standards”. No one individual will have all the required competencies to do an AA. ANSI is final arbiter.
 - ARB – Oversees the GHG verification process. ARB has responsibility for accreditation and has the same functions as ANSI using the same standards (ISO 14065). ARB remains the final arbiter. ARB has accredited verification bodies that are also ANSI-accredited, although ANSI is not required. ARB can accompany ANSI on audits & site visits.
 - “Competency standards” can apply to both the party doing the work and the independent party auditing/verifying the completed work.
- NSF (carpet & green product chemical standard) --- No formal mechanism for certifying assessors. Reputation of 3rd party occurs over time. NSF has used various approaches.

- DfE chemical profiler competencies - (not an ANSI process, but can use ANSI process informally):
 - Technically competent staff;
 - Ability to access and manage information;
 - Ability to protect confidential information;
 - Ability to do pilot assessments to be reviewed/mentored by DfE;
 - Ability to share non-proprietary information has been beneficial (everyone looking at same data)

- Toxicology - Quality assurance standards (production standards) used in US:
 - Data submissions. Process is separated into two categories
 - Standard operating procedures (SOPs) that companies or reviewing bodies use. Tools developed are used within a specific process (in house or 3rd party).
 - People verify tools were used correctly (peer review), not a scientific review per se.
 - Scientific review is a peer review.
 - Qualification for these two processes is quite different:
 - Procedural review- Process was followed & boxes were checked.
 - Content review - Content is correct.

Continuing Education

- Recertification is important. The need will depend on how quality assurance is structured. Regulations/guidance/interpretations change over time. Recertification will assure that participants have been active in the field and are current in their knowledge. From scientific standpoint, international standards exist. For example, toxicologists have continuing education requirements.
- This field is quite new and we will need a flexible system that can adapt requirements to a changing field that will evolve over time.
- Outside agencies (3rd party) should be held to high standards. Same standards should apply to internal (in-house) entities. Program requirements need to be consistent whether the AAs are completed by in-house staff or outside practitioners.
- The need for continuing education requirements and level of expertise will both depend on how the program is structured.
- A simplified process could be to set the required education for conducting an AA, instead of specifying a testing and recertification process.
- Under DfE, a complete profile is available with an option to obscure the specific ingredient (no CAS # and no concentration), while still disclosing hazard assessments.
- The ability to claim confidential business information (CBI) will limit meaningful public review. Manufacturers may claim much of the AA assessments as CBI.
 - Regulations could have two or more tracks for treating CBI:
 - No claim of CBI, which will allow the public and competitors to police without a 3rd party requirement;
 - Unrestricted claims of CBI, but will need 3rd party involvement; or
 - Hybrid may be possible if generic chemical names can be used.

- Assembled products and formulated products will need to be addressed separately. The generic chemical names may work for formulated products. For assembled products, we may use commonality for common components. This approach would focus the AA on the specific component and not on the entire assembled product.
- Generic names may not give companies the perceived protection. Reverse engineering may get you to the chemical.
- DTSC should identify the tools that should be used and the minimal quality control SOPs that surround the use of these tools:
 - Allows the standards for continuing education and 3rd party requirements to be set.
 - Allows check the box audit approach.
 - Use request for proposal (RFP) to establish tools and how they are used (process); including how you go from a work plan to an AA submission.
 - Work plan should be signed by an executive officer.
- DTSC should use RFPs to obtain reviewers and set up a scientific review board (about 5 members) that can meet periodically and conduct reviews of tools and/or submissions. This board would meet and vote in public.
- This approach can apply to tools. There will be multiple tools and DTSC should try to standardize pieces of the AA.
- All AAs should go through 3rd party review. The reviewer should have their policies & procedures subject to audits. Reviewing policies & procedures will reduce the work load of reviewing AAs.
- Need for accreditation.

Qualifications/Requirements

- Financial independence – AA are not really reviewable by the public, making independence for verification important.
- Need to clarify the criteria for “no economic interest”. How will consultants be paid?
- Consultants will need to disclose conflicts of interest.
- 3rd party review assumes the consultant is more qualified to do an AA than the preparer which may not be the case.
- Reputations of the consultants need to be published.

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

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

- There could be different pathways for AAs, depending on whether the AA does or does not contain information for which CBI is claimed:
 - AAs with no claimed CBI data should not require 3rd-party verification, since the public can fulfill this function.
 - AAs containing claimed CBI data should be subject to 3rd-party verification since there will be no public review of the CBI data.

- There does need to be some level of 3rd party analysis (check & balance).
- Checker checking checkers may be counter-productive. The number of audits does not guarantee a better product.
- Sign-off by officer of company, such as a CEO, as a check and balance may be controversial but can be used instead of using checkers to check the checkers.
- CEO sign off as a substitute for 3rd party review may not be successful. Under ISO, it isn't as useful.
- Build on internal/external experts. Internal will need to be certified by 3rd party.
- Internal assessors need to be verified by 3rd party. If internal, you save cost for gathering data and documentation. You can then move to 3rd party for certification.
- External assessors --- outsourcing to qualified person based on competency as demonstrated by certification of the 3rd party. Does not consider CBI.
- Do not need a second 3rd party to review the work of a 3rd party which has completed an AA. The better use of a second 3rd party is as auditors of procedures and systems (meta level). DTSC can fill this audit roll to do spot checks or accreditation.
- Verification is an extensive independent review doing the AA again, very specific to the product.
- To what extent can information gathered by one assessor be shared with another assessor. Toxicological data or manufacturing process data? How do we pool information to leverage resources? Qualified assessors sharing information could lower cost & time and improve AAs.

Certification of Internal Versus External Assessors

- Internal assessors may not need to be certified.
- Internal assessors may need to meet specified requirements similar to lawyers and doctors.
- Proprietary (internal) Assessors
 - Certification less necessary, as companies will take their own measures to protect the company
- 3rd party assessors most likely will be used by smaller companies. Competency of assessors can be established by the following:
 - Certification
 - Registration with DTSC
 - Demonstration of capability (testing, etc)
- AAs will be public documents subject to comments
- ISO 14001 (EMS) can use 3rd party or self-certification for GHG work. The 2 options:
 - 3rd party attestation; or
 - Self-attestation, plus a detailed report of the contents of their study. Choosing to do a self-certification has resulted in extensive public comments regardless of the veracity or accuracy of this public detailed report.

Adjudication, If Reviewer Disagrees with Party Compiling the AA

- Science review board may be needed.
- Need dispute resolution procedure.

- DTSC/science review board could provide list of all accredited/accepted reviewers.
- DfE serves as the arbitrator of the assessments. DfE logo confers their concurrence. Typically preparers/reviewers have resolved disagreements.
- Finding a way to share information that may be proprietary will be important. Generic data such as toxicological and hazard information should be made available to the public.
- 3rd party and science review board may be redundant.
- Science review board may be better utilized to review controversial conclusions.
- DTSC could potentially function as the science review board, resources permitting.
- Infinite series of review may not provide additional clarity.
- Appeal or verification process may be used to resolve issues arising from 3rd party review.
- AA should be integrated into product development.
- Will need to establish how to determine when an alternative is better or the analysis is enough.
- 3rd party does not necessarily opine on the manufacturing decision. The verifier (3rd party) will weigh in on the AA, but not make decisions.
- 3rd party can either verify a completed AA or can prepare an AA.
- An ANSI type of organization can review the performance of a 3rd party to assure conformance with the set standards.
- There will be billion dollar questions that will depend on AAs.
- Suppliers have more data than 3rd party profilers (consultants). Doing an AA internally brings an incredible amount of weight to the validity of the AA (greater access to information).

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

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

- The work plan should be a draft outline of the process. The work plan should be revised as information is compiled and be updated over time.
- DfE does not have a work plan requirement. Instead there is a template of the required information which standardizes the information received. For multi-stakeholder products, the process is more complex and more dynamic.
- The work plan is really a chance to edit the scope of work so that the right amount of work is done.
- As the AA begins, a preliminary workplan that identifies the timeframe, scope of work, and the qualified individuals preparing the AA should be submitted to DTSC.
- DTSC would briefly review the workplan to confirm that the AA will meet guidelines and assure the qualifications of the assessors.
- Benefits of a work plan may include:
 - Eliminating the need for an AA by redesign of a product;

- Signaling the start of the clock for an AA;
- Requiring a company to evaluate strategic options for the various potential alternatives for a chemical of concern;
- Disclosing the direction of an AA (e.g. the roadmap for the AA process --- where is it going and what it will achieve.);
- Eliminating unnecessary work if the work plan could just be a simple outline and not a substitute for a tiered AA.

DTSC could set up a scientific review board (SRB) and present AA work plans to the SRB in a public forum. The function of the SRB could be described in a guidance document. Would need 3rd party reviewers on the SRB.

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

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

- NSF has various approaches for audits:
 - Desk audits that are minimally invasive to verify completeness and that minimum criteria are met.
 - Statistical audits. Independent auditor reviews documentation (goes through the books) for inconsistencies, followed by a more in-depth analysis if necessary.
- Resources can be maximized, if a matrix formula is used for AA decision-making.
- Auditing policy should be established that determines if only SOPs will be verified or if spot checking the completed AA is more appropriate. DTSC may or may not be the auditor for content.
- Data should not have to be questioned.
- Process needs to be set up with standardized tools and SOPs. DTSC should develop templates and audit policies and SOPs for 3rd party.
- Need to do some occasional review of various assessors.
- Resources should be used to spot check and resolve disputes between assessors. DTSC guidance on disputes between AA compiler and reviewer would be useful. DTSC should outline some policy issues to address different circumstances.
- Process checks are favored over approval, but DTSC should have a fairly comprehensive review.
- DTSC should review SOPs and spot check 3rd party work.
- DTSC will need to weigh in on the conclusions of the AAs that are submitted due to the imposition of the response responses.

Question #3E:Other related ideas?

Quality Assurance Processes

- Simplified process --- internal competencies and training standards --- for AA preparers. Expend minimum DTSC resources, which should be focused on providing guidance.
- Expense of the quality assurance process is a concern.
- Should avoid never-ending checks and rechecks.
- Extensive quality assurance with independent certified 3rd party assessors making independent judgment.
- In toxicology, there are very specific quality assurance standards and review of documents. The two quality assurance processes are:(i) process/procedures, and (ii) data quality. DTSC could do an RFP to establish standards and identify specific tools.
- Quality assurance training is very specific. Online training, guidance documents, tools and how they are used should be made available.
- Constant training review and updates.
- Internal and external 3rd party would follow same process.
- Online training certification programs can be made available with tests. Certifications can be done for both the quality assurance process and for the people that are trained to use the tools.

Another Option for Quality Assurance

- AA can be done internally or can be contracted out to 3rd party.
- DTSC is the focal point for this whole process. DTSC should review applicant's AA information including data base availability, regulations, data integrity (toxicology, etc.), and transparency of process (data collection & information sharing).
- Once AA is reviewed, DTSC can reject and send back to applicant and should identify the deficiencies in the AA. Then applicant can request 3rd party review of the AA.
- When DTSC accepts request for 3rd party review, then it accepts qualifications of 3rd party.
- If AA rejected a second time, applicant can challenge the decision to a scientific review board (SRB) for resolving conflicts. All info is sent to the SRP for a closer scrutiny and an opportunity for applicant to plead their case. SRB can have all parties present to resolve the issue.

CBI Considerations and Transparency

- Hazard traits will not be CBI. Calculations will be transparent, so that a second review can check the calculations.
- Different pathways for AAs, depending on whether the AA does or does not have CBI information.
- AAs with no claimed CBI data should result in not requiring 3rd party verification.
- CBI claim should require 3rd party assessor and DTSC may have to weigh in or review.

- CBI with 3rd party will have to be robust so that the public and competitors have confidence that it is a fair system. CBI will require other policing procedures.
- CBI may be extensive. The more CBI will result in less public scrutiny (NGOs, competitors, etc.), thus less transparency.
- External communication of risk for the public and environment may be difficult for companies. If the external risk is not disclosed, the public will quickly comment on these risks if given the opportunity to comment.
- There are natural incentives for companies to vigorously protect CBI. Competitors routinely scrutinize public documents. DTSC will not be able to verify the veracity of CBI claims. AA tools may also be claimed as CBI (black box) making public review more difficult.
- Huge advantages to transparent process and creating incentives. CBI claims should entail costs such as 3rd party review process.
- It seems like quality assurance won't work if there are extensive CBI claims. CBI will show up in everything that is intellectual property. Conversely, throwing AAs into a non-structured public review creates the possibility of unmeritorious comments that are repeated until they become "true".
- CBI needs to be material to the AA. DTSC will not be able to review all AAs for purpose do verifying CBI claims.
- Public will have limited ability to review the AAs. There will be lots of assumptions and complicated analysis. For example, risk assessments for hazardous waste facilities are currently transparent, but difficult to review.
- Where CBI concerns exist, the voracity and quality of the AAs will be judged based on the manner that the 3rd party is approved.
- Use of a 3rd party protects CBI, but also requires more trust. DTSC has ultimate authority to audit and review
- The regulations should not be primarily designed to deal with CBI, but the system should be designed to work and deal with CBI.

Emerging Standard for AAs

- Tools and reporting standards that fall into what we are calling an AA are slowly emerging. AAs are not standardized. There are mixed combination of methods and tools that are used to complete AAs. GCI & ACI has emerging standards for reporting. GreenScreen is a chemical risk screening method. The challenge will be to achieve a mixed semi transparent approach built on partial pieces without well established standards and determining who is qualified to do this work.
- The AA process will need to be refined as we learn to do AAs without having to get it right at the onset and spending lots of time.

Resolution of Competing AAs ("picking winners")

- Will need conflict resolution process
- Someone (DTSC) will have to make a decision regarding who is right and who is wrong.
- Conflicting toxicological studies for a specific compound will require judgment calls. Reasonable people may disagree, which may introduce doubt if there is no resolution of these issues.

- There will be lots of variability among AAs (data inputs, assumptions, methodologies, tools, weighing factors, boundary conditions, etc.) which can all be within acceptable ranges but lead to different conclusions.
- DSTC will have to make the ultimate decision but a science review board(SRB) may be necessary to resolve issues. Who gets to weigh in on the multiple conclusions or dueling AAs?
- Different strategies for product design which can lead to different design solutions.
- The regulatory responses will be dependent on the result of the conclusions of an AA. The regulations should address varying regulatory responses.
- The regulations will have to establish the minimum requirements to reduce the probability of divergent conclusions.
- DTSC will need to address how to distinguish between human error and intentional errors. For example, which tools should be used, such as statistics, mil specs, or de novo?
- A SRB might be difficult to staff if there are 20-30 reviews per year. A SRB may not be able to make decisions in a completely transparent process if CBI is involved. This may require the SRB to operate in two ways: (i) in completely open meetings; or (ii) in closed session to protect CBI (i.e. pharmaceutical approvals).
- This can lead to holding up multi-billion decisions ---if an AA passes all reviews with valid conclusion, but the AA is held up due to competition.