

**Comments by Lauren Heine  
GRSP Member  
“Homework” Post Call # 1; SC3  
May 31, 2011**

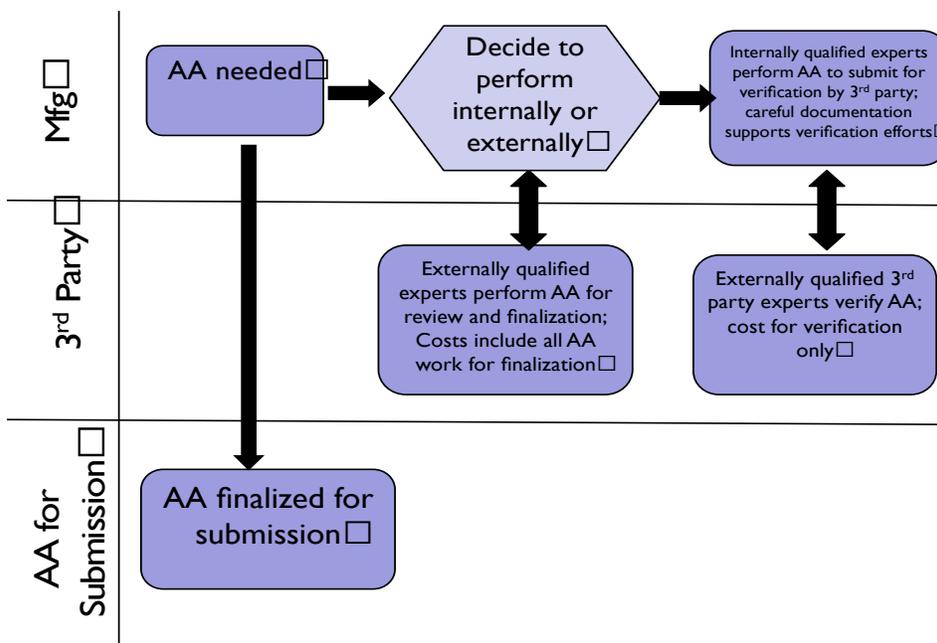
The comments below reflect key ideas that I would like to emphasize. They are not intended to capture all ideas shared during the discussion on May 31, 2011.

**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?

Imagine two options to getting an AA performed

1. request that the AA work be done directly by an external qualified 3<sup>rd</sup> party
2. do the AA work internally and to have the AA work verified by an external qualified 3<sup>rd</sup> party.



There should be training for all AA practitioners on the tools and practices associated with AA. In addition, there should be recommended (for internal purposes) and required (for external purposes) professional and scientific qualifications.

To request that a 3<sup>rd</sup> party perform the full AA is to enlist the maximum external input and cost

To perform as much of the AA as feasible internally is to shift the burden of effort and cost so that the 3<sup>rd</sup> party is performing verification only. Numerous qualified third parties compete for this work and keep the costs down.

Note that whether performing the AA internally or externally, the efforts still involves exchange between the 3<sup>rd</sup> party and the company to ensure that all of the relevant information is exchanged. The company paying the 3<sup>rd</sup> party has control over the AA work and decides when it is completed. For example, if there is a data gap revealed by the AA, the company may decide to do additional testing to fill that data gap.

The higher the quality and the better documented the AA work performed internally, the less there is for the 3<sup>rd</sup> party to do.

Both internal and external AA experts should have relevant scientific expertise and experience. However, internal experts would not need the same level of professional certification (such as proof of the ability to keep CBI, reputational recommendations, certification to ISO 65, etc.) as the external 3<sup>rd</sup> parties because they are employees and not hired professional AA providers.

The internal experts are paid and reviewed by their company. The external experts are audited by the DTSC auditing system. Technically they may be 2<sup>nd</sup> party experts if they work directly for hire by companies seeking AAs but the external audit should be designed to ensure consistency and quality of AAs.

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

All AAs should either be prepared by a qualified 3<sup>rd</sup> party or prepared internally and verified by a qualified 3<sup>rd</sup> party.

All 3<sup>rd</sup> party providers should be audited for their policies and procedures. Occasional spot checks should be performed to ensure quality and consistency between 3<sup>rd</sup> party providers.

Training should be provided to internal experts and 3<sup>rd</sup> party providers on an ongoing basis to ensure that knowledge of AA methods and tools are up to date. Qualifications of 3<sup>rd</sup> party providers should be determined by DTSC. No one expert is likely to have all the qualifications. See the USEPA Standard for Safer Cleaning Products for an example of Requirements for 3<sup>rd</sup> party providers and for audit procedures for individual products (analogous to AAs) (Section 7, A14 and Annex B. 1. See Section 7 for requirements/competency/qualification for DfE profilers

2. See Section A14 for audit requirements and Annex B

[http://www.epa.gov/dfe/standard\\_for\\_safer\\_cleaning\\_products.pdf](http://www.epa.gov/dfe/standard_for_safer_cleaning_products.pdf)

**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?

Perhaps the work plan submission should be optional. DTSC will need to provide clear guidance on acceptable methods and tools for performing AAs.

**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)?

DTSC must set up a program to audit the 3<sup>rd</sup> party providers who do AAs and verify the work of internally performed AAs. In general it makes sense to audit 3<sup>rd</sup> party providers based on their policies and procedures. But spot audits including occasional test products should be performed to assess the quality and consistency of the work of the providers.

CPA is currently working on a pilot project to share Green Screen (GS) Assessments for chemicals of interest to an industry sector. It is possible to share hazard information associated with individual chemicals between authorized chemical profilers or AA providers AND to keep the confidential formulation of products proprietary. It involves keeping the individual chemical hazard assessment information dissociated from the formulation information that feeds the AA.

I would be happy to share current thinking and design and an example GS assessment. This is not intended to advertise the GS method or to advance a specific software provider but I think it provides an example of an approach that can leverage the work of 3<sup>rd</sup> parties and other AA experts, reduce costs, and harmonize results. Another example of a shared and leveraged chemical database is CleanGredients that supports the DfE Safer Product Formulation Initiative. Perhaps some brainstorming should be done to determine how best to share and leverage the common elements of AA work to reduce cost, and ensure consistency.