Green Ribbon Science Panel
Subcommittee #3 --- Quality Assurance for Alternatives Assessments

ATTACHMENTS

Attachment 3-1 --- Statutory (AB 1879) Requirements for Alternatives Assessments (HSC section 25253)

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Attachment 3-1

Statutory Requirements for Alternatives Assessments
(HSC section 25253)

Statutory (AB 1879) Requirements for Alternatives Assessments

Health and Safety Code section 25253

25253. (a)(1) On or before January 1, 2011, the department shall adopt regulations pursuant to this section that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern, in accordance with the review process specified in Section 25252.5. The department shall adopt these regulations in consultation with all appropriate state agencies and after conducting one or more public workshops for which the department provides public notice and provides an opportunity for all interested parties to comment.

(2) The regulations adopted pursuant to this section shall establish a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. This process shall include life cycle assessment tools that take into consideration, but shall not be limited to, all of the following:

(A) Product function or performance.
(B) Useful life.
(C) Materials and resource consumption.
(D) Water conservation.
(E) Water quality impacts.
(F) Air emissions.
(G) Production, in-use, and transportation energy inputs.
(H) Energy efficiency.
(I) Greenhouse gas emissions.
(J) Waste and end-of-life disposal.
(K) Public health impacts, including potential impacts to sensitive subpopulations, including infants and children.
(L) Environmental impacts.
(M) Economic impacts.

(b) The regulations adopted pursuant to this section shall specify the range of regulatory responses that the department may take following the completion of the alternatives analysis, including, but not limited to, any of the following actions:

(1) Not requiring any action.
(2) Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives.
(3) Imposing requirements on the labeling or other type of consumer product information.
(4) Imposing a restriction on the use of the chemical of concern in the consumer product.
(5) Prohibiting the use of the chemical of concern in the consumer product.
(6) Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product.
(7) Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product.
(8) Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists.
(9) Any other outcome the department determines accomplishes the requirements of this article.

(c) The department, in developing the processes and regulations pursuant to this section, shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

Attachment 3-2

Quality Assurance for Alternatives Assessments

(excerpts from Draft Regulations, September 2010)

§ 69305.2. Alternatives Assessments: General Provisions.

(c)(1) Each AA shall be performed by, and the AA Work Plan and AA Report prepared by, one of the following:

(A) A qualified third-party assessment entity designated pursuant to section 69308, or

(B) A qualified in-house assessment entity designated pursuant to section 69308.1.

(2) The responsible individual in charge of preparation of the AA Work Plan and AA Report, and performance of the AA, shall be a lead assessor who meets the requirements of section 69308.3 and is accredited for a product type and/or industry sector appropriate for the AA being performed. The lead assessor shall be employed by the qualified third-party assessment entity or qualified in-house assessment entity, whichever is applicable.

(3)(A) Each AA performed by, and AA Report prepared by, a qualified in-house assessment entity shall be reviewed and verified by a second lead assessor. The verifying lead assessor must:

1. Meet the requirements of section 69308.3,
2. Be accredited for a product type and/or industry sector appropriate for the AA being verified,
3. Be employed by a qualified third-party assessment entity,
4. Not have participated in any way in the design or formulation of the AA Work Plan, data gathering, analysis or other aspects of the AA, or preparation of the AA Report, and
5. Have no economic interest in any entity that manufactures, or places into the stream of commerce in California, any Chemical of Concern, Product under Consideration, or Priority Product.

(B) The verifying lead assessor shall do all of the following:

1. Verify compliance with the requirements of this article, and indicate the extent to which the guidance document(s) posted by the Department pursuant to subsection (a) were used in conducting the AA;
2. Verify the proper analysis of the product's or component's life cycle;
3. Verify the appropriate use of life cycle assessment tools and methodologies;
4. Attest to the accuracy of the reported data; and
5. Perform a final quality assurance review of the AA and AA Report, and of the data on which the AA is based.

(C) The verifying lead assessor shall prepare an AA verification statement documenting the verification process and findings.

(D) The verifying lead assessor shall base the AA verification statement solely on the factors listed in subparagraphs (B)1. through (B)5. The selected alternative, or the decision not to select an alternative to the Priority Product or component, as identified in the AA Report, shall not be a consideration factor in verifying the AA or preparing the AA verification statement.

Article 8. Accreditation and Qualification Requirements for Performance of Alternatives Assessments

§ 69308. Requirements for Qualified Third-Party Assessment Entities.

(a) An entity wishing to be designated as a qualified third-party assessment entity, shall submit an application to the Department that includes all of the following:

(1) The applicant's name and contact information.

(2) Identification of the combined qualifications of the individuals, including lead assessors meeting the requirements of section 69308.3, available within, or to, the entity for performing or verifying AAs, including education and experience, and areas of subject matter competency and expertise.

(3) Documentation of the AA elements, inputs, assumptions, methodologies and approaches employed by the entity.

(4) Demonstration of all of the following:

(A) Independence and lack of affiliation with any responsible entity, manufacturer, consortium of manufacturers, or trade association;

(B) No economic interest in any entity that produces, sells or distributes any Chemical of Concern or product containing a Chemical of Concern;

(C) Compliance with the standards of ISO 14040, or equivalent, as certified to in writing by an unaffiliated competent third-party;

(D) Compliance with, and maintenance by regular external audits, ISO/IEC Guide 65 accreditation; and

(E) Record keeping and document retention and retrieval practices and capabilities sufficient to facilitate audits by the Department pursuant to article 9 of this chapter.

(b) The Department shall review the application submitted pursuant to subsection (a) and, based on this review, approve or deny the request for designation as a qualified third-party assessment entity, within sixty (60) days of receiving the information. The Department shall notify the entity submitting the request of its determination. A notice of denial shall state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be designated, or re-designated, as a qualified third-party assessment entity.

(c) If any of the information submitted pursuant to subsection (a) of this section changes, the entity shall provide updated information to the Department within thirty (30) days of the change.

(d) A designation as a qualified third-party assessment entity shall expire after a period of five (5) years, except that it may be renewed upon application by the entity, pursuant to subsection (a) not later than ninety (90) days before expiration of the existing designation.

(e) If an entity is found to be negligently or willfully in violation of this chapter, the entity shall lose its designation as a qualified third-party assessment entity for a period of at least ten (10) years. After this period the entity may reapply to be designated as a qualified third-party assessment entity.

§ 69308.1. Requirements for Qualified In-House Assessment Entities.

(a) A manufacturer, consortium of manufacturers, trade association or public-private partnership wishing to be designated as a qualified in-house assessment entity, shall submit an application to the Department that includes all of the following:

(1) The applicant's name and contact information.

(2) The names of and contact information for all members of the applicant's organization, if the applicant is a consortium, trade association or similar organization.

(3) Identification of the combined qualifications of the individuals, including lead assessors meeting the requirements of section 69308.3, available within, or to, the entity for performing AAs, including education and experience, and areas of subject matter competency and expertise.

(4) Documentation of the AA elements, inputs, assumptions, methodologies and approaches employed by the entity.

(5) Demonstration of both of the following:

(A) Compliance with the standards of ISO 14040, or equivalent, as certified to in writing by an unaffiliated competent third-party;

(B) Compliance with, and maintenance by regular external audits, ISO/IEC Guide 65 accreditation; and

(C) Record keeping and document retention and retrieval practices and capabilities sufficient to facilitate audits by the Department pursuant to article 9 of this chapter.

(b) The Department shall review the information submitted pursuant to subsection (a) of this section, and, based on this review, approve or deny the request for designation as a qualified in-house assessment entity, within sixty (60) days of receiving the information. The Department shall notify the entity submitting the request of its determination. A notice of denial shall state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be designated, or re-designated, as a qualified in-house assessment entity.

(c) If any of the information submitted pursuant to subsection (a) of this section changes, the entity shall provide updated information to the Department within thirty (30) days of the change.

(d) A designation as a qualified in-house assessment entity shall expire after a period of five (5) years, except that it may be renewed upon application by the entity,

pursuant to subsection (a) not later than ninety (90) days before expiration of the existing designation.

(e) If an entity is found to be negligently or willfully in violation of this chapter, the entity shall lose its designation as a qualified in-house assessment entity for a period of at least ten (10) years. After this period the entity may reapply to be designated as a qualified in-house assessment entity. During this period of disqualification, any AAs, including AA Work Plan and AA Report preparation, that the entity is required to perform must be performed by an entity that is unaffiliated with the responsible entity or manufacturer or any consortium, trade association or other partnership of which the responsible entity or manufacturer is a member.

(f) As used in this section, the term "manufacturer" includes "manufacturers" as defined, and other entities that perform AAs on behalf of manufacturers with which the entity is affiliated, including, but not limited to, manufacturer consortiums, trade associations, and manufacturer parent corporations and subsidiaries.

§ 69308.2. Requirements for Designated Accrediting Bodies.

(a) Any person wishing to be designated, or to renew designation, by the Department as an accrediting body to accredit lead assessors, who meet the requirements of section 69308.3, shall submit an application to the Department that includes all of the following:

(1) The applicant's name and contact information;

(2) The applicant's institutional history;

(3) The products type(s) and/or industry sector(s) for which the applicant is proposing to accredit lead assessors;

(4) A description of the accrediting body's lead assessor accreditation program that meets all of the requirements of subsection (c);

(5) The accrediting body's training curriculum, meeting the requirements of subsection (c)(3), for initial accreditation applicants, including for each course the course title, content description, hours, and exam plan;

(6) The accrediting body's continuing education curriculum, if any, for re-accreditation applicants, including for each course the course title, content description, hours, and exam plan;

(7) Demonstrated qualifications and areas of expertise of those individuals responsible for developing the accrediting body's training curriculum, as evidenced by education and experience, professional licenses, registrations, or other relevant credentials;

(8) A copy of the accrediting body's lead assessor application form, meeting the requirements of subsection (c)(1);

(9) A copy of the accrediting body's lead assessor accreditation certification form, meeting the requirements of subsection (c)(4);

(10) Information demonstrating all of the following:

(A) Ability to teach, and history of teaching, the principles and practices of Chemical Hazard Assessment, Exposure Potential Assessment, and Multimedia Life Cycle Evaluation,

(B) Ability to teach, and history of teaching, the application of life cycle thinking as it applies to products, and

(C) Ability to teach, and history of teaching, the appropriate use of life cycle assessment tools and methodologies as they apply to products;

(11) Disclosure of apparent or existing conflicts of interest; and

(12) A certification statement as required by section 69301.5(b).

(b) Within sixty (60) days after receiving an application for designation, or renewal of designation, as an accrediting body, the Department shall notify the applicant of its decision to approve or deny the application for designation. A notice of denial shall state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be designated, or re-designated, as an accrediting body.

(c) Each lead assessor accreditation program must include, at a minimum, all of the following elements:

(1) Written application and admission procedures for both initial accreditation and biennial renewal of accreditation. These procedures must include a requirement for the applicant, for initial or renewed accreditation, to submit to the accrediting body an application that, at a minimum, includes all of the following:

(A) The applicant's name and contact information,

(B) The products type(s) and/or industry sector(s) for which the applicant is applying for accreditation as a lead assessor;

(C) The applicant's educational experience, which must meet the requirements of section 69308.3(a)(1) and must be substantiated by submittal of transcripts or other equivalent records,

(D) The applicant's employment and other experience history, which must meet the requirements of section 69308.3(a)(2) and for which references must be provided,

(E) Any professional licenses, registrations or other relevant credentials that the applicant possesses,

(F) Documentation of completion of continuing education required pursuant to section 69308.3(a)(5), if the application is for accreditation renewal, and

(G) A signed and dated certification statement: "I certify under penalty of perjury that the information I have entered on this application is true and complete to the best of my knowledge. I further understand that any false, incomplete, or incorrect statements may result in my disqualification as a lead assessor. I authorize the employers and educational institutions identified on this application to release any information they may have concerning my employment or education to the accrediting body with which this application is filed and to the State of California."

(2) Written procedures for verifying an applicant's qualifying education and experience, including verification of fulfillment of continuing education requirements.

(3) An initial accreditation training program that is pertinent to the product type(s) and/or industry sector(s) for which lead assessor accreditation will be offered by the accrediting body, and that includes, at a minimum, all of the following:

(A) The requirements of this chapter, with an emphasis on the requirements of articles 5, 6 and 10,

(B) Training and case studies on principles and practices of Chemical Hazard Assessment, Exposure Potential Assessment, and Multimedia Life Cycle Evaluation, using life cycle thinking and life cycle assessment tools,

(C) Training and case studies on identification of alternatives for consideration in an AA,

(D) Training and case studies on identification of the life cycle segments for chemicals and products, and

(E) Training needed for the attainment of expertise in specific fields necessary to the performance of AAs.

(4) Issuance of a written certificate for initial accreditation and re-accreditation that is entitled "Certification of Accreditation as a Lead Assessor" and includes, at a minimum, all of the following:

(A) Lead assessor's name,

(B) The product type(s) and/or industry sector(s) for which the lead assessor is accredited,

(C) Date of issuance and date of expiration of the certification,

(D) Name and contact information for the accrediting body issuing the certification,

(E) An indication as to whether the certification is for initial accreditation or a renewal of accreditation,

(F) A statement that the lead assessor meets the requirements of section 69308.3(a), and

(G) The signature of the owner or an officer of the accrediting body issuing the certification.

(5) Criteria and procedures for denying an application for initial or renewed accreditation. Denial decisions must be provided to the applicant in writing and must state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be accredited or re-accredited as a lead assessor.

(6) A program to audit completed work by lead assessors accredited by the accrediting body to ensure the quality of work and proper application of tools by the lead assessor.

(7) Written procedures for records retention, including, but not limited to, applications, verification information, certifications, training records, and audit records. All records shall be maintained for a minimum of three (3) years.

(d) Each accrediting body shall provide to the Department the name and contact information for each lead assessor accredited by the accrediting body, along with the

product type(s) and/or industry sector(s) for which each lead assessor is accredited. Updated information shall be provided to the Department on at least a quarterly basis.

(e) The duration of the designation of an accrediting body shall not exceed 5 years, except that it may be renewed upon application by the accrediting body not later than ninety (90) days before expiration of the designation. Applications for renewal of designation shall extend the expiring designation until the Department makes a determination on the renewal application.

(f) An accrediting body shall not claim trade secret or proprietary restrictions on their admission process, general curriculum and educational approach. An accrediting body applicant may request the Department to treat specific course information or life cycle assessment tools as licensed or proprietary and not available for free distribution in the public domain, or as a trade secret or confidential pursuant to article 10.

(g) The Department shall rescind its designation of an accrediting body if any of the following occurs:

(1) The designation period has lapsed,

(2) A substantial number of individuals accredited by the accrediting body as lead assessors are found to be in violation of this chapter,

(3) The Department finds that the accrediting body has significantly deviated from the documentation submitted to the Department pursuant to subsection (a), or is out of compliance with the requirements of this section, or

(4) The Department finds the accrediting body to be negligent, fraudulent, misrepresentative, or unethical in connection with their accreditation of lead assessors.

§ 69308.3. Lead Assessor Accreditation.

(a) A responsible person in charge of performing or verifying an AA, or preparing an AA Work Plan or AA Report, must be accredited by a designated accrediting body for a product type and/or industry sector appropriate for the AA being performed or verified, and must meet all of the following requirements:

(1) Possess a Bachelor's degree with a major in a scientific or engineering field from an accredited college or university.

(2)(A) Have the equivalent of three (3) years of professional experience performing AAs and/or working in a scientific or engineering field.

(B) Post-graduate work in the performance of AAs and/or in a scientific or engineering field, while attending an accredited college or university, may be substituted on a year-for-year basis for the experience required pursuant to paragraph (A).

(3) For initial accreditation, successfully complete a lead assessor accreditation training program and exam that meets the requirements of section 69308.2(c)(3) and that is developed and delivered by a designated accrediting body.

(4) Receive an initial "Certification of Accreditation as a Lead Assessor" meeting the requirements of section 69308.2(c)(4) and issued by the accrediting body whose accreditation training program the lead assessor successfully completed pursuant to paragraph (3).

(5) Maintain lead assessor accreditation status by doing all of the following:

(A) Completing continuing education during each two-year accreditation period, as required and provided, or verified, by the designated accrediting body from which the lead assessor will seek re-accreditation upon expiration of their current accreditation. Continuing education may be education and/or training focused on one or more aspects of alternatives assessment relevant to the performance of AAs or closely related topics.

(B) Submitting an application for re-accreditation to a designated accrediting body at least thirty (30) days prior to the expiration of the lead assessor's current accreditation. If the lead assessor complies with the requirements of this subparagraph and subparagraph (A), their accreditation will remain in effect unless and until the accrediting body denies their application for re-accreditation.

(C) Receiving a renewed "Certification of Accreditation as a Lead Assessor" meeting the requirements of section 69308.2(c)(4) and issued by the accrediting body who provided or verified the lead assessor's continuing education pursuant to subparagraph (A).

(6) Possess, and produce when requested, a current "Certification of Accreditation as a Lead Assessor" meeting the requirements of section 69308.2(c)(4).

(b) If the Department rescinds, pursuant to subsection (g)(2), (g)(3) or (g)(4) of section 69308.2, the designation of the accrediting body from which the lead assessor obtained accreditation, the lead assessor shall apply for reaccreditation from another accrediting body, designated pursuant to section 69308.2, no later than sixty (60) days after information concerning the rescission is posted on the Department's website.

(c) A lead assessor's accreditation shall be subject to rescission by the accrediting body or the Department for failure to comply with the applicable requirements of this chapter, or if the Department or the accrediting body finds the lead assessor to be negligent, fraudulent, misrepresentative, or unethical in connection with their duties and responsibilities as a lead assessor. The accrediting body shall provide to the Department the name and contact information for any lead assessor whose accreditation is rescinded by the accrediting body, and an explanation of the reasons for the rescission.

Article 9. Audits

§ 69309. Audit of Alternatives Assessments and Regulatory Responses.

(a) The Department may audit AAs as resources permit.

(b) The scope of the audit shall include, but not be limited to, an examination of:

(1) Compliance with article 5 requirements;

(2) Compliance with the scope and objective of the AA Work Plan during the conduct of the AA;

(3) Data quality and adequacy of analysis;

(4) Implementation of the selected alternative, if applicable; and

(5) Compliance with the applicable regulatory response(s) imposed pursuant to article 6;

(c) Upon completion of an audit, the Department shall:

(1) Notify the manufacturer and/or responsible entity(ies) of the audit findings, and

(2) Inform the manufacturer and/or responsible entity(ies) of the process to dispute audit findings.