

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

2520 Venture Oaks Way, Suite 350
Sacramento, CA 95833
(916) 274-5721
FAX (916) 274-5743
www.dir.ca.gov/oshsb



Attachment No. 2

INITIAL STATEMENT OF REASONS

CALIFORNIA CODE OF REGULATIONS

TITLE 8: Division 1, Chapter 4, Subchapter 7, Group 16, Article 109, Section 5197,
Appendix A, Subsection (c)(1) of the General Industry Safety Orders

Laboratory Accreditation for Diacetyl Analysis**SUMMARY**

This rulemaking action is initiated by the Division of Occupational Safety and Health (Division) due to language contained in Section 5197, Appendix A (c)(1) which restrains laboratories accredited by laboratory accreditation bodies other than the currently listed program of the American Association for Laboratory Accreditation (A2LA) from performing diacetyl sample analysis.

An amendment to Section 5197, Appendix A (c)(1) is proposed to allow laboratories accredited by American Industrial Hygiene Association (AIHA) Laboratory Accreditation Programs, LLC or other International Laboratory Accreditation Cooperation (ILAC) mutual recognition signatory to perform diacetyl sample analysis as required by the standard.

SPECIFIC PURPOSE AND FACTUAL BASIS OF PROPOSED ACTION

This regulatory proposal is intended to provide worker safety at places of employment in California, by increasing the number of accredited laboratories that employers can select from to analyze diacetyl samples taken to evaluate worker exposure to food flavorings containing diacetyl, to verify that a process utilizing diacetyl or diacetyl-containing flavorings or food products is enclosed, or to monitor regulated areas.

This proposed rulemaking action:

- Is based on the following authority and reference: Labor Code Section 142.3, which states, at subsection (a)(1) that the Board is “the only agency in the state authorized to adopt occupational safety and health standards.” When read in its entirety, Section 142.3 requires that California have a system of occupational safety and health regulations that at least mirror the equivalent federal regulations and that may be more protective of worker health and safety than are the federal occupational safety and health regulations.

- Differs from existing federal regulations, in that federal OSHA does not have a specific counterpart standard for occupational exposure to food flavorings containing diacetyl.
- Is not inconsistent or incompatible with existing state regulations. This proposal is part of a system of occupational safety and health regulations. The consistency and compatibility of that system's component regulations is provided by such things as: (1) the requirement of the federal government and the Labor Code to the effect that the state regulations be at least as effective as their federal counterparts, and (2) the requirement that all state occupational safety and health rulemaking be channeled through a single entity (the Standards Board).
- Is the least burdensome effective alternative. The proposal will provide California employers more laboratories to choose from to comply with the analytical requirements specified in Section 5197, Appendix A, subsection (c)(1). No alternative proposal has been suggested.

Section 5197. Appendix A. Diacetyl Sampling and Analytical Protocol (Mandatory)

Subsection (c)(1)

This appendix establishes requirements for sampling protocols and the procedure for taking and analyzing air samples for diacetyl including quality control procedures that must be implemented by the person conducting the sampling and by the laboratories performing the analysis. All employers who are required to conduct air monitoring under subsection (c) of this section are required to utilize analytical laboratories that use this procedure, or an equivalent method, for collecting and analyzing samples.

An amendment is proposed to allow additional accredited laboratories to perform diacetyl sample analysis required by the standard. Currently, the standard only recognizes laboratories accredited in accordance with the program of the A2LA. The amendment proposes the addition of laboratories accredited by the AIHA Laboratory Accreditation Programs, LLC or other ILAC mutual recognition signatory. The amendment is necessary to include all laboratories accredited by conforming laboratory accreditation bodies.

The International Organization for Standardization (ISO) and The International Electrotechnical Commission (IEC) form the specialized system for worldwide standardization. The international standard, ISO/IEC 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*, is the main ISO standard used by testing and calibration laboratories. Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body, such as A2LA or AIHA.

The ILAC, through its Mutual Recognition Arrangement (Arrangement), is a global network of accredited testing and calibration laboratories that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence using another ISO

standard, ISO/IEC 17011: 2005, *Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*. Referencing ILAC signatories is the best way to encompass all conforming laboratory accreditation bodies, although currently in the United States, the A2LA and AIHA are the main accreditation bodies that serve laboratories which perform diacetyl analysis covered by this standard. Therefore, these specific accreditation bodies are listed in the proposed amendment to Section 5197, Appendix A, subsection (c)(1). The AIHA lab accreditation program did not sign on to ILAC until August 22, 2010, long after the food flavoring standard was submitted to the Board.

Further, all laboratories covered under the current standard and proposed amendment would be subject to the existing proficiency testing requirement in Section 5197, Appendix A, (c)(4) that they participate in an appropriate national sample testing scheme such as the Proficiency Analytical Testing Program (PAT) for organics that is sponsored by the AIHA.

Consequently this proposal will allow California employers to use more laboratories to comply with the analytical requirements specified in Section 5197, Appendix A, subsection (c)(1).

DOCUMENTS RELIED UPON

The International Laboratory Accreditation Cooperation (ILAC) *Mutual Recognition Arrangement, May 2011*, https://www.ilac.org/documents/Bro_english/ILAC_MRA_English.pdf

International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standard, ISO/IEC 17025:2005, Section 1, *General Requirements for the Competence of Testing and Calibration Laboratories*,
http://webstore.iec.ch/preview/info_isoiec17025%7Bed2.0%7Den.pdf

ISO/IEC 17011: 2005, Section 1, *Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*,
http://webstore.iec.ch/preview/info_isoiec17011%7Bed1.0%7Den.pdf

The American Association for Laboratory Accreditation, *R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories, December 1, 2011*,
<http://www.a2la.org/requirements/req17025.pdf>

American Industrial Hygiene Association (AIHA) Laboratory Accreditation Programs, LLC Policy Revision (IHLAP), *September 13, 2011*,
<http://www.aihaaccreditedlabs.org/policymodules/Pages/default.aspx>

These documents are available for review Monday through Friday from 8:00 a.m. to 4:30 p.m. at the Standards Board Office located at 2520 Venture Oaks Way, Suite 350, Sacramento, California.

REASONABLE ALTERNATIVES THAT WOULD LESSEN ADVERSE ECONOMIC
IMPACT ON SMALL BUSINESSES

No reasonable alternatives were identified by the Board and no reasonable alternatives identified by the Board or otherwise brought to its attention would lessen the impact on small businesses.

SPECIFIC TECHNOLOGY OR EQUIPMENT

This proposal will not mandate the use of specific technologies or equipment.

COST ESTIMATES OF PROPOSED ACTION

Costs or Savings to State Agencies

No costs or savings to state agencies will result as a consequence of the proposed action.

Impact on Housing Costs

The Board has made an initial determination that this proposal will not significantly affect housing costs.

Economic Impact Analysis

The Board has made an initial determination that this proposal will not result in a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposal will allow California employers to use more laboratories to comply with the analytical requirements specified in Section 5197, Appendix A, subsection (c)(1).

Therefore, the adoption of the proposed amendment to this standard will not have any effect on the creation or elimination of California jobs nor result in the creation or elimination of existing businesses or affect the expansion of existing California businesses.

This regulatory proposal is intended to provide worker safety at places of employment in California.

Cost Impact on Private Persons or Businesses

The Board is not aware of any cost impact that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Costs or Savings in Federal Funding to the State

The proposal will not result in costs or savings in federal funding to the state.

Costs or Savings to Local Agencies or School Districts Required to be Reimbursed

No costs to local agencies or school districts are required to be reimbursed. See explanation under “Determination of Mandate.”

Other Nondiscretionary Costs or Savings Imposed on Local Agencies

This proposal does not impose nondiscretionary costs or savings on local agencies.

DETERMINATION OF MANDATE

The Occupational Safety and Health Standards Board has determined that the proposed regulation does not impose a local mandate. Therefore, reimbursement by the state is not required pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because the proposed amendment will not require local agencies or school districts to incur additional costs in complying with the proposal. Furthermore, this regulation does not constitute a “new program or higher level of service of an existing program within the meaning of Section 6 of Article XIII B of the California Constitution.”

The California Supreme Court has established that a “program” within the meaning of Section 6 of Article XIII B of the California Constitution is one which carries out the governmental function of providing services to the public, or which, to implement a state policy, imposes unique requirements on local governments and does not apply generally to all residents and entities in the state. (County of Los Angeles v. State of California (1987) 43 Cal.3d 46.)

The proposed regulation does not require local agencies to carry out the governmental function of providing services to the public. Rather, the regulation requires local agencies to take certain steps to ensure the safety and health of their own employees only. Moreover, the proposed regulation does not in any way require local agencies to administer the California Occupational Safety and Health program. (See City of Anaheim v. State of California (1987) 189 Cal.App.3d 1478.)

The proposed regulation does not impose unique requirements on local governments. All state, local and private employers will be required to comply with the prescribed standard.

EFFECT ON SMALL BUSINESSES AND RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Board has determined that the proposed amendment may affect small businesses. However, no adverse economic impact is anticipated. The proposal will allow California employers to use more laboratories to comply with the analytical requirements specified in Section 5197, Appendix A, subsection (c)(1). Consequently, it is believed that this regulatory proposal will have minimal impact upon California employers.

ALTERNATIVES THAT WOULD AFFECT PRIVATE PERSONS

No reasonable alternatives have been identified by the Board or have otherwise been identified and brought to its attention that would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action-, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.