



November 4, 2009

EPA Labeling Regulation
Docket Number EPA-HQ-OAR-2003-0024
Environmental Protection Agency
EPA Docket Center
Mailcode 6102T
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Docket Number EPA-HQ-OAR-2003-0024
74 FR 39150; August 5, 2009

Dear Docket Officer:

The International Safety Equipment Association (ISEA) is the trade association for personal protective equipment (PPE), including hearing protective devices. Its member companies are world leaders in the design and manufacture of PPE for workers in all industries.

ISEA's Hearing Protection Group, which prepared and approved these comments, has been an active participant in efforts to update hearing protector labeling for many years. A decade ago, the group developed the framework for a labeling standard that would have expressed attenuation as a range of values. ISEA is represented on the Acoustical Society of America's S12 committees responsible for the consensus standards used as a basis for this rulemaking. ISEA participated in the 2003 EPA workshop that was a precursor to the current proposal.

In addition, we have petitioned OSHA to lower its permissible exposure level for noise in the workplace, and last October wrote OSHA urging that they participate in this rulemaking to ensure that its hearing protection regulations conform to the new EPA labeling scheme.

Clearly, ISEA shares EPA's concern that the 1979 noise labeling standards need to be updated. Because of the shortcomings of the current standards, OSHA and NIOSH, and most users, routinely derate the current Noise Reduction Rating, leading to confusion and potential misuse of the rating and of the products our members manufacture.

ISEA supports the EPA's efforts to revise 40 CFR Part 211, Subpart B, and we appreciate the opportunity to present our views in this public hearing. My comments today will address our concerns about the proposal, and offer recommendations that we believe will substantially improve it.

LABELING ISSUES

NRR Range

The Noise Reduction Rating (NRR), expressed as a range of values, is the centerpiece of the proposed rule. ISEA and its members have been monitoring the development of the proposed NRR, and they have prototyped the test using Method A (trained subject) fitting. It has become clear that the lower value in the range based on the 80th percentile will be close to the NRR values in the 1979 standard, which EPA seeks to update. ISEA is therefore concerned using the 80th percentile in the proposed regulation will undermine confidence in the new NRR.

The use of the 80th percentile was originally proposed by ANSI/ASA S12 Working Group 11 for use with Method B data, which has much more variation as noted in the preamble at 74 FR 39155. With less

variable Method A data, the ISEA suggests that a more appropriate basis for the lesser NRR is the 90th percentile. Specifically, we suggest that the values of *alpha* given in the regulation be 1.2816 (90th percentile, the lesser NRR) and -0.8416 (20th percentile, the greater NRR). These values are taken from Table 1 of ANSI/ASA S12.68-2007. These values appear in §211.207-1(b)(4) as well as several other places in the proposed regulation; this change also applies to the Variability of Noise Reduction graph.

ISEA does not suggest a corresponding change of the greater NRR to the 10th percentile because the range need not be symmetrical, and because the consequences of over-protecting a few users is less than the potential harm done by overstating the performance of a product for the majority of users, potentially leading to under-protection and increased risk of hearing damage.

ISEA believes this change, defining the new NRR based on Method A data at the 90th and 20th percentile, will better and more accurately describe the acoustic performance of the hearing protectors manufactured by its members.

Explanation of the Lesser and Greater NRR

ISEA suggests that the required supporting information in §211.204-4 include a brief explanation of the meaning and use of the lesser and greater NRR. The wording we propose is taken from the introduction to ANSI/ASA S12.68-2007 (page viii):

The lesser NRR is the protection that is possible for most individually trained users to achieve or exceed. The greater NRR is the protection that is possible for a few motivated proficient users to achieve or exceed.

This explanation is more meaningful than simply stating that they are the 80th or 20th percentile and so better informs the user, and remains appropriate if the lesser NRR is based on the 90th percentile.

This same wording applies to the Variability of Noise Reduction tables and graphs in §211.204-4. ISEA recommends substituting "greater noise reduction" and "lesser noise reduction" for the percentile values in the table and the legend on the graph.

Explanation of the Use of the "Variability of Noise Reduction" Graph

Caution statements at §211.204-4(h)(3)(i) and §211.204-5(h) direct users to the Variability of Noise Reduction graph when the hearing protector is used in predominantly low frequency noise environments where the difference in the measured C- and A-weighted sound pressure levels exceeds 3 dB. EPA's recommendation differs from that in ANSI/ASA S12.68-2007, which (at clause 5.3, p. 7) states that the graphical or octave-band method:

"should be used for noises that have a rumbling, thunderous, or heavy sound to them, for sounds that are from air-moving equipment, for passengers in moving vehicles, for sound levels exceeding 100 dBA, or if the measured difference between C- and A-weighted sound levels (dBC - dBA) exceeds 5 dB."

ISEA believes the 5dB C-A threshold is critical, and requests that EPA use the caution statement found in ANSI/ASA-S12.68-2007.

In addition, there is no statement describing how to use the Variability of Noise Reduction graph. The following statement, adapted from the first paragraph of Clause 6.3 of ANSI/ASA S12.68-2007, would accomplish this and ISEA recommends that it be added to the "Supporting information" at 211.204-4:

"To use the graph, determine the typical spectral balance (the difference between dBC and dBA) from broadband measurements made with an integrating sound level meter that can simultaneously measure the A- and C-weighted levels. Find the spectral balance value on the horizontal axis of the graph; the corresponding points on the two lines should be used in place of the lesser and greater NRR for a more accurate estimate of the noise reduction."

Active and Impulsive Noise Suppression Label

Under the proposal, products that perform impulsive and active noise suppression will be required to have two primary labels. It would be preferable to allow all the information (passive, active and impulsive) to be combined into a single label if applicable. We request that EPA allow this as a labeling option.

EPA in §211.201 attempts to define products to which this proposed rule will and will not apply. Clauses (b), (c) and (d) are inconsistent. Hearing aids and listening headsets might require labeling under paragraph (d), but not under paragraph (c). ISEA requests that EPA clarify its intent.

Location of NRR Graph and Supporting Information

The proposed rule requires that the primary label must be on the primary panel of the package (§211.204-3). For many years, placing the label on a panel adjacent to the primary panel has been acceptable for consumers and preferred by manufacturers. Users look for the style and brand they know, trust and have been trained upon. The EPA should allow the placement of the label on a panel other than the primary (front) panel. The Food and Drug Administration, at 21 CFR 201.10(h)(2), allows labels on the side- or back-panel placement of a label when the front panel is too small to include the required information. ISEA has attached the FDA labeling regulation as *Appendix A* to these comments.

The “supporting information” section at §211.204-4 describes the various “Supporting information” to be provided, including the Variability of Noise Reduction graph. This section states the graph must accompany all HPDs to ensure its availability to prospective users and, in the case of bulk packaging and dispensing, this information must be affixed to the bulk container or dispenser. There is no statement on where this information must be located in the case of individually packaged hearing protectors. ISEA suggests that the graph and other supporting information need only be included within the packaging, such as on an insert sheet or in an owner’s manual, for individually packaged HPDs. ISEA requests that a statement be added clarifying this.

Labeling Requirement for Devices with Multiple Wearing Positions

The current rule at §211.204-1(b)(2) describes primary label content for “devices with headbands that *are intended* for use ... in different positions.” The proposed rule at §211.204-1(a)(2)(iv) describes label content for “devices with headbands that *may* be used in different positions.” ISEA asks EPA if this means that the testing must be conducted and the label designed to reflect any possible wearing position, even though the manufacturer does not represent (and may not even intend) multiple wearing positions? ISEA requests that EPA clarify or affirm the intent of this change.

Impulsive Noise Environments

The supporting information for amplitude-sensitive HPD’s includes a requirement at §211.204-6(e) that the manufacturer indicate the peak impulsive noise level in which the device may be worn. This asks the manufacturer to assume risk/damage liability which is the province of the user or hearing conservation regulation. Additionally, this oversteps the bounds of EPA’s mandate to provide for labeling of the hearing protector to indicate its ability to attenuate.

TESTING ISSUES

Use of Method A for Real Ear Attenuation at Threshold (REAT) Testing on Passive Devices

ISEA supports the EPA’s choice of Method A for REAT testing on passive devices. Method A helps manufacturers isolate the specific parts of a device’s design and construction that contribute to the NRR, and allows manufacturers to put greater reliance on test results in making design decisions. In short, Method A allows manufacturers to improve upon their products.

Testing ANR Headsets

Active Noise Reduction (ANR) headsets, which enable the user to communicate in high noise environments, represent a small subset of active hearing protectors currently available. While a small

number use ANR, the majority use simple automatic gain control (AGC) and dynamic compression techniques, and others use digital signal processing techniques to suppress noise.

Because of its intended use as a communication device, this equipment is rarely used in passive mode. Therefore it is important that all these devices are tested in active mode. The testing (outlined in Sec. 211.206-2) should therefore evaluate all active hearing protectors over 125 Hz to 8000 Hz.

Incorporate Revised ANSI/ASA S12.42

Sections of the proposed rule reference ANSI S12.42-1995 (R2002). A revised version of this standard is about to be published. Because parts of the testing procedures in the proposed rule are based on early drafts of this standard, ISEA urges EPA to evaluate the revised ANSI/ASA S12.42 standard and incorporate applicable portions into the proposed rule.

RECURRENT TESTING

Recurrent Testing Proposed Regulation

The recurrent testing requirements in §211.211-3 state that manufacturers shall retest their products every five years commencing from the date of transition testing.

ISEA Statement

The retesting of products every five years is unnecessary and places an undue burden upon the regulated community. Retesting is required under §211.211-4 "if the product materials, design or manufacturing process or takes any action that may alter the noise reduction performance of the product from its previous test state."

ISEA Recommendation

Sec. 211.211-4 is sufficient to ensure that HPDs remain in compliance with the rule. Sec. 211.211-3 should be struck from the regulation.

RETESTING AND RELABELING

Retesting and Relabeling Proposed Regulation

The retest requirements in §211.211-4 require relabeling of the hearing protector when the results of the retest differ from labeled value by more than 3 dB. EPA also believes that based on earlier intra- and inter-lab testing, a conservative estimate is that 12% of hearing protector retests might show such a change (74 FR 39169).

ISEA Statement

Not only is 3 dB arbitrary, but also ISEA believes EPA is wrong in its estimation that relabeling based on the 3 dB threshold will occur less than 12% of the time. EPA bases this proposed requirement on a paper by W.J. Murphy, et al. published in the *Journal of the Acoustical Society of America* (footnote 36, at 74 FR 39168). However, Figure 2 of the cited paper shows between-laboratory standard deviations of 3 and 5 dB for the two earplugs tested. With this amount of variation, differences on retesting exceeding 3 dB are likely to be far more common than 12% of the time, since in a normal random process 32% of the cases fall outside the range of ± 1 standard deviations.

ISEA Recommendation

The statistical tests found in ANSI/ASA S12.68-2007 Annex D determine whether retest data accurately indicate a hearing protector is or is not statistically different from the product previously tested. This test calculates U_{95} , the half-width of the 95% confidence interval on the rating. In other words, with 95% confidence a retest should produce a rating that is within $\pm U_{95}$ of the original rating value, based on the subject-to-subject variation in the data. ISEA believes this test should be incorporated by reference into the new regulation.

Specifically, ISEA suggests that the regulation require relabeling only if the lesser NRR from the original label's bar-graph minus the lesser NRR calculated for the retest is greater than either 3 dB or the sum of the U95 values for the original labeling test and the retest (i.e., the confidence intervals for the two tests' lesser NRR values do not overlap). This would also require that, when a test is conducted, the U95 uncertainty value defined in the standard be calculated and reported. We also propose that this test only be applied to the lesser NRR, as this is simpler and it is the more important value from a hearing protection assessment perspective. For example, if a first test yields a lesser NRR of 27 dB and a U95 of 3 dB and a retest yields a lesser NRR of 21 dB and a U95 of 4 dB then relabeling is not needed, because 27 minus 3 (24) is less than 21 plus 4 (25), so the confidence intervals overlap. If the second test's lesser NRR were 20 dB or lower, with these U95 values, then relabeling would be needed.

ISEA believes this is the evaluation which should be used to determine the necessity of relabeling. The arbitrary selection of 3 dB can force manufacturers to change product labels which may not only undermine the market positioning of a given protector when no change has taken place in the manufacture or design of the product, but it may also trigger expensive, burdensome retraining at workplaces.

COMPLIANCE ISSUES

Proposed Regulatory Text

EPA states in §211.202 and §211.211-1 that all hearing protection devices manufactured after the effective date of this regulation must meet the testing and labeling requirements. Yet in §211.211-2, "Transition testing and labeling requirements" EPA establishes a 30-month transition period during which manufacturers "shall complete testing and labeling of all categories." If EPA intends that the deadline in §211.211-1 only apply to all new devices being tested and labeled for the first time, it needs to be more specific. Below, ISEA proposes regulatory text that would both clarify this language and expand the transition period to 60 months.

ISEA Statement

ISEA believes the proposed transition testing and labeling regime proposed at §211.211-2 is unreasonable. The EPA estimates that the process of testing and labeling all HPD's in distribution and use, plus new products introduced into the market, will take approximately 30 months. This requires manufacturers to predict inventory needed to cover various models looking 30 months into the future. This is not an easy process and there is no positive outcome from this process to either the manufacturers or users.

Most hearing protection manufacturers have a number of products that would have to be tested and labeled in the 30-month process. It is unclear if this is possible given the number of HPD's on the market (EPA estimates over 1000 models) and the limited amount of lab capacity. Furthermore, as new products are designed and developed there will be many more products in the testing queue, leading to even greater uncertainty about when a product meeting the requirements of the proposed rule will become available. A manufacturer would have to balance an estimate of that time period against existing inventories of existing products, tested and labeled under the current rules. Inventories of current products may need to be increased or decreased, again, based on the unknown factor of when a new product will be fully tested and the label crafted based on test results. Furthermore, there may be no reasonable way to predict the decay in market acceptance of product that carries current labels once the new rule is effective. Given these factors, typical planning methods would be tenuous, at best, with a 30-month forecast window.

ISEA does not share the EPA's optimism that new labs will enter the market to help absorb the testing burden, especially as the volume of testing during the transition period would be unlikely to continue at the same rate indefinitely. Although new labs may eventually help the testing flow for the recurrent requirements, they are very unlikely to be formed quickly enough to provide meaningful help with testing needs during the critical early period after the effective date.

ISEA Recommendation

ISEA urges the EPA to increase to 60 months the period during which manufacturers may come into compliance with the proposed regulation. ISEA suggests that the proposal be rewritten to clearly specify that all hearing protection devices manufactured and entering commerce after 60 months from the effective date must be labeled according to the new rule, and that products manufactured between the effective date and 60 months afterward may be tested and labeled according to the rule. New models of HPD's manufactured for the first time during this transition period would be tested and labeled to the new standard, and products that were in commerce before the effective date of the rule would be permitted to carry either the old or new label until the end of the 60-month period.

Appendix B includes ISEA's recommended changes to regulatory text for sections 211.202; 211.211-1(a); and 211.211-2, which address transition testing and labeling requirements.

This longer period would allow manufacturers to get their current hearing protectors into the testing queue, gauge the market acceptance of current labels, and have a more manageable forecast period for inventory planning on less critical models.

RECORDKEEPING/DATA REQUIREMENTS

Proposed Regulation

The proposed rule at §211.209-1 requires manufacturers to submit to the EPA, in hardcopy or electronic format, a completed coversheet according to Annex A, a copy of all authorized measurement information, including test results and calculated NRR values obtained from the testing laboratory for each product or product category, within 10 business days of completion of the required test.

ISEA Statement

ISEA believes this section is unworkable. Manufacturers would have no ability to start early testing of critical models based on reasonable risk of final rule content because the 10 days would elapse long before the effective date.

ISEA Recommendation

ISEA requests that test data for products that are already on the market be reported no more than 45 days after testing and apply only to products that enter US commerce.

For products not yet on the market we request that test data be reported 15 days after the product is available for purchase. This recommendation allows manufacturers to submit only the data of products that will be sold on the market and not the various versions of products in test phases. (Also, ISEA believes "available for purchase" is a better term than "entered into commerce," which might include test marketing or other measures of limited availability.)

CONFIDENTIAL BUSINESS INFORMATION

The proposed rule requires sensitive data from hearing protection device manufacturers. Sec. 211.209-1(a), Reporting requirements, states that manufacturers must submit to the EPA... "all authorized measurement information, including test results and calculated NRR values, obtained from the testing laboratory for each product or product category..."

Sensitive data is also required at proposed sec. 211.212-5, Reporting test results, would require a manufacturer to submit "a copy of the Compliance Audit Test report for all testing conducted under § 211.212..."

Finally, the proposed appendix A would also require sensitive and confidential data to be reported to EPA, including the name and address of the original equipment manufacturer (OEM) and the attenuation test measurements.

The information requests discussed above meets EPA's requirements at 40 CFR 2.208 for *substantive criteria for use in confidentiality determinations*, namely that "the information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding)." None of the information requested above would be obtainable without the manufacturers' consent, if at all.

While we understand that at 40 CFR 2.203 a manufacturer can request that EPA treat individual submissions as confidential business information. Nonetheless, ISEA asks OAR to request that EPA's legal office begin an advance confidentiality determination, in accordance with 40 CFR 2.206(a)(4) and 40 CFR 2.207, which addresses "class determinations."

ISEA appreciates the opportunity to comment on this proposed rulemaking, and looks forward to continuing to work with EPA to protect the hearing of workers.

Sincerely,

Daniel K. Shipp
President

Appendices follow

Appendix A

FDA regulation on Labeling Requirements for Drugs 21 CFR 201.10(h)(2):

If the drug is packaged in a container too small to bear the quantitative ingredient information on the main display panel, the quantitative ingredient information required by section 502(e) of the act may appear elsewhere on the label, even though the proprietary name or designation appears on the main display panel of the label; but side- or back-panel placement shall in this case be so arranged and printed as to provide size and prominence of display reasonably related to the size and prominence of the front-panel display.

(i) A drug packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with section 502(e)(1) (A)(ii) and (B) of the Act shall be exempt from compliance with those clauses: Provided, That:

(1) The label bears:

- (i) The proprietary name of the drug;
- (ii) The established name, if such there be, of the drug;
- (iii) An identifying lot or control number; and
- (iv) The name of the manufacturer, packer, or distributor of the

drug; and

(2) All the information required to appear on the label by the act and the regulations in this chapter appears on the carton or other outer container or wrapper if such carton, outer container, or wrapper has sufficient space to bear such information, or such complete label information appears on a leaflet with the package.

Appendix B

Proposed Revision to 20 CFR 211 Hearing Protection Rule to Allow a Transition Time of 60 Months After Effective Date

Intent of these changes to the regulatory text is to allow shipment of hearing protectors that have been manufactured and labeled using current label for 60 months after the effective date for the rule. The proposal would also allow shipment of protectors tested and labeled according to the new rule as they become available after the effective date, without having to wait for the 60 months to pass.

Revise 20 CFR 211.202 Effective Date:

Current Proposed Section 202 Reads:

Manufacturers of hearing protection devices must comply with the requirements set forth in this subpart for hearing protective devices manufactured on or after [date TBD]. All hearing protection devices that are manufactured on or after the effective date of this subpart must be tested and labeled in accordance with the applicable procedures set forth herein.

ISEA Proposes Substituting this Language:

The effective date of this rule is [date TBD]. Any hearing protection devices manufactured after the effective date may be tested, labeled and sold in accordance with these procedures. Manufacturers of hearing protection devices must comply with the requirements set forth in this subpart for all hearing protective devices manufactured more than sixty (60) months after the effective date. All hearing protection devices that are manufactured later than sixty (60) months after the effective date of this subpart must be tested and labeled in accordance with the applicable procedures set forth herein.

Revise 20 CFR 211.211-1(a) Compliance with Labeling Requirements

Current Proposed Section 211-1(a) Reads:

All hearing protection devices manufactured after the effective date of this regulation, and meeting the applicability requirements of § 211.201, subpart, must be labeled according to this subpart, and must comply with ...this subpart.

ISEA Proposes Substituting this Language:

All hearing protection devices manufactured more than sixty (60) months after the effective date of this regulation, and meeting the applicability requirements of § 211.201, subpart, must be labeled according to this subpart, and must comply with ...this subpart.

Appendix B (con't)

Revise 20 CFR 211.211-2 Transition Testing and Labeling Requirements

Current Proposed Section 211-2 Reads:

All hearing protection devices manufactured on or after the effective date of this subpart, and meeting the applicability requirements of § 211.201, must be tested with the appropriate procedure specified in § 211.206 and labeled as specified in § 211.204. Manufacturers shall complete testing and labeling of all categories within thirty (30) months from the effective date of subpart B.

ISEA Proposes Substituting this Language:

Any hearing protection device manufactured after the effective date of this subpart, and meeting the applicability requirements of § 211.201, may be tested with the appropriate procedure specified in § 211.206 and labeled as specified in § 211.204. All hearing protection devices manufactured more than sixty (60) months after the effective date of this subpart, and meeting the applicability requirements of § 211.201, must be tested with the appropriate procedure specified in § 211.206 and labeled as specified in § 211.204. Manufacturers shall complete testing and labeling of all categories within sixty (60) months from the effective date of subpart B.