



NATIONAL HEARING CONSERVATION ASSOCIATION

TO: Mr. Ken Feith
Air and Radiation Docket and Information Center
EPA Labeling Regulation
Docket Number EPA-HQ-OAR-2003-0024
Environmental Protection Agency
EPA Docket Center
Mailcode 28221
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Washington, DC 20460

FROM: Richard Neitzel, PhD, CIH, President
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DATE: November 4, 2009

SUBJECT: 40CFR211 Subpart B, Hearing Protector Labeling

ISSUE

Exposure to high levels of noise is one of the most prevalent occupational hazards faced by American workers, with an estimated 22 million noise-exposed workers in the U.S. Consequently, noise-induced hearing loss (NIHL) resulting from excessive noise exposure is one of the most common occupational diseases in the U.S. Hearing protectors represent a critical element of hearing conservation programs, and the National Hearing Conservation Association (NHCA) commends EPA for its efforts to update 40CFR211 Subpart B, Hearing Protector Labeling. NHCA is a multidisciplinary organization comprised of audiologists, researchers, industrial hygienists, educators, professional service providers, safety professionals, medical professionals, engineers, students, and others committed to the prevention of hearing loss. NHCA members work in a wide range of industries and governmental organizations, and NHCA is a participant in a tripartite alliance with the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH). As such, NHCA is uniquely positioned to comment on the proposed revision of this regulation (EPA-HQ-OAR-2003-0024; FRL-8934-9 RIN 2060-A025, published in the Federal Register on August 5, 2009).

SPECIFIC CHANGES TO THE PROPOSED RULE

EPA should make the following changes to the proposed rule:

- 1) Base labeled values on American National Standards Institute (ANSI) S12.6-2008 Method B, rather than the proposed Method A. Method A assesses the optimal (or near-

optimal) performance of tested devices. Method B is a better indicator of the real-world performance that is expected among potential users in both occupational and community settings, as demonstrated by several studies published in the peer-reviewed scientific literature. Regulations intended to estimate the approximate performance which can be expected for real-world end users, as should be the case with the proposed rule, need to employ laboratory test methods that most closely align with real-world performance, and thus have better predictive ability for groups of end users. Labels based on Method B test results will meet this need, and will therefore be more protective of public health than labels based on Method A, which may provide a better absolute measure of the performance achievable using a device, but which will not reflect the performance likely to be achieved by most real-world users. In selecting a test method, EPA should consider that a large percentage of end users of hearing protection devices do not receive adequate training on how to fit the devices correctly. Regardless of the method selected, EPA should insure that no de-rating or other manipulation of attenuation levels is required for OSHA and other agencies that regulate the use of hearing protection devices.

- 2) Revise the labeling requirements for hearing protection devices. The number of different types of primary labels should be increased to better distinguish different types of HPDs. These labels should be simplified, reworded, and provided in multiple languages in insure that the description of the capabilities of different types of hearing protectors is clear to untrained users. Increased use of graphical symbols may further reduce language barriers. Supporting information should be permitted in an electronic (e.g., compact disc or digital versatile disc) or paper insert inside the packaging of the device, rather than being required on the packaging itself.
- 3) Eliminate the requirement for information on noise reduction as a function of spectra to be provided on the packaging of devices. This information is of little value to the majority of users, and should be provided online, as an electronic or paper package insert, or upon request from the manufacturer in order to simplify package labeling.
- 4) Only apply the term “active” to devices that use wave-cancellation or noise cancellation technology, rather than to all electronic devices, and use the word “electronic” to refer to any device which relies on electrical current to process noise signals. Additionally, specify different types of active devices, e.g., active level-dependent, active noise canceling, active communication, etc. This will greatly increase the clarity of the proposed rule.
- 5) Base test methods for evaluating the performance of active hearing protectors and devices designed for use in impulsive noise on published consensus standards and proven/valid test methodologies. This would preferably involve referencing the current version of the ANSI S12.42 test method standard, or, alternatively, delaying the effective date of the regulation until after the expected revision of the standard.

- 6) Extend the 30 month window to re-test and re-label devices to 42 months, divided into a 24 month interim period and an 18 month transition period. The interim period should begin on the date the final rule is published, and will provide time for test facilities to develop the capability to test the reduction of impulsive noise and to perform testing with the new methods. Only products featuring the old attenuation labels should be sold during this interim period. Shortening the subsequent transition period to 18 months will reduce confusion associated with the simultaneous sale of products bearing both old and new labels. At the conclusion of the transition period, only products featuring the new attenuation labels should be sold. Adoption of Method B for evaluation of attenuation (described in point 1 above) may increase the cost, complexity, and time required for attenuation testing. However, these increased efforts are necessary to insure that rated attenuation levels are as representative as possible of the real-world performance expected for most end users, and should not be considered in EPA's selection of a test method.
- 7) Require language on the device label noting that individual quantitative fit testing is the only way to estimate the amount of attenuation afforded to any individual user. Although there is currently no standardized methodology for individual fit testing, end users should be made aware that such individual testing is possible, and is preferable to attenuation results derived from groups of users.
- 8) Deemphasize the label focus on "motivation" as the reason why some users might achieve the high value in the attenuation range provided on the device label. Many factors can contribute to attenuation achieved, including physiology, condition of the device, etc.

These suggested changes will help EPA improve the utility of hearing protection devices, and in doing so will reduce the substantial burden that NIHL places on American workers and community members. NHCA would be pleased to provide guidance and assistance to EPA in the selection of language for the labeling of hearing protection devices. Please contact me should you have any questions, require additional information, or desire additional input from NHCA.

Sincerely,



Richard Neitzel, PhD, CIH
President, NHCA