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Part VIII

**Environmental
Protection Agency**

**Noise Labeling Requirements For Hearing
Protectors; Technical Amendment**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 211
(FRL 1394-7)

Noise Labeling Requirements for Hearing Protectors; Technical Amendments

AORHCW: U.S. Environmental Protection Agency (EPA).

ACTION: Response to petition for reconsideration and technical amendments.

SUMMARY: On December 21, 1979, the Industrial Safety Equipment Association (ISEA), on behalf of its member companies which manufacture hearing protective devices, filed a petition for reconsideration of certain provisions of 40 CFR Part 211 Subpart B, Noise Labeling Requirements for Hearing Protectors (44 FR 56130, September 28, 1979). The EPA has reviewed each of the provisions on which the ISEA requested reconsideration. By this notice, the EPA revises certain provisions of the subject regulation and presents its rationale in declining to revise certain other provisions.

By this notice, the EPA also makes certain other technical amendments to correct errors which were identified subsequent to publication in the Federal Register on September 28, 1979.

EFFECTIVE DATE: February 6, 1980.

FOR FURTHER INFORMATION, CONTACT: Mr. Timothy J. Dwyer, Acting Director, Noise Enforcement Division (EN-307), U.S. Environmental Protection Agency, Washington, D.C. 20460, (703) 557-7470.

SUPPLEMENTARY INFORMATION: On September 28, 1979, the EPA published 40 CFR Part 211, Subpart B, Noise Labeling Requirements for Hearing Protectors (44 FR 56130). This regulation requires that beginning September 27, 1980, manufacturers of hearing protectors sold in the United States must give notice to prospective users of their products' effectiveness in reducing noise entering the users' ears. Further, the regulation requires manufacturers to determine the sound attenuation of all categories of protectors in their product lines according to the test procedure set forth in the American National Standards Institute Standard (ANSI STD.) S3.19-1974. From the results of this testing manufacturers must then develop the Noise Reduction Rating and supplementary information specific to each of their hearing protector categories. The regulation allows manufacturers to begin testing of

protectors which are produced up to six months before the effective date of the regulation.

I. ISEA Petition

On December 21, 1979, the ISEA petitioned the Administrator of the EPA to amend Subpart B of 40 CFR Part 211, Noise Labeling Requirements for Hearing Protectors. The ISEA also incorporated by reference the requests for revisions to certain sections of the regulation which it made in its letter of December 6, 1979 to EPA's Noise Enforcement Division.

The Agency has carefully evaluated the ISEA's petition for reconsideration, and finds that without some relief, manufacturers of hearing protective devices may be unable to test and label significant portions of their product lines by the September 27, 1980, effective date. The need for relief results from the limited number of commercial facilities immediately available to perform the necessary tests. Accordingly, the Agency is amending the regulation.

II. Principal Changes

The principal amendments requested by ISEA's petition and the EPA responses are summarized in the material that follows:

Requested amendment No. 1: Allow the use of existing test data which was obtained according to both American National Standards Institute Standard (ANSI STD) S3.19-1974 and ANSI STD Z24.22-1957 (predecessor test procedure to S3.19-1974).

Response: The EPA is permitting manufacturers of hearing protectors to use available test data obtained according to either ANSI STD S3.19-1974 or ANSI STD Z24.22-1957. The test data must be that from the most recently conducted test. If a manufacturer has available data from both test procedures on a category of hearing protector, he must use the most recent data obtained according to ANSI STD S3.19-1974.

EPA analyzed the data which the ISEA submitted in its letter of December 11, 1979. This submittal summarized fifteen (15) sets of data on twelve (12) hearing protective devices obtained according to both ANSI STD S3.19-1974 and ANSI STD Z24.22-1957. The data indicate that a Noise Reduction Rating (NRR) based on Z24.22 data is, in most cases, more conservative (lower) than an NRR based on S3.19 data. In only three cases was an NRR based on Z24.22 data equal to or higher than an NRR based on S3.19 data. In those three cases, the maximum difference was one decibel. In the light of the generally conservative nature of NRRs calculated from use of Z24.22 data, relative to those

calculated from S3.19 data, we consider that use of the Z24.22 data for labeling on an interim basis is acceptable.

Requested Amendment No. 2: Permit testing of hearing protectors according to ANSI STD S3.19-1974 to begin immediately rather than waiting until six months before the effective date of the regulation.

Response: EPA is permitting manufacturers to begin testing hearing protective devices according to ANSI STD S3.19-1974 immediately rather than waiting until six months before the effective date. The provisions of section 211.210-3(f)(1) and (2) of Subpart B apply to this early testing, as do the provisions of section 211.109 of Subpart A concerning inspection and monitoring by the Agency. Manufacturers must use production protective devices (not prototypes) and they must permit the Agency to monitor these early tests.

The EPA re-investigated the availability of test facilities as a result of the ISEA's comments which were stated in its meeting with the EPA on December 4, 1979 and statements in letters from individual manufacturers. From this further investigation, the EPA has determined that of the five test facilities identified in the preamble to the regulation (44 FR 56135), only two (the Environmental Acoustics Laboratory and the Worcester Polytechnic Institute) are presently testing hearing protectors on a commercial basis.

The EPA maintains, as a further result of its investigation into the availability of test facilities, that given the demand and sufficient time, additional facilities which are capable of testing protectors according to ANSI STD S3.19-1974 will be available to do that testing. However, in that these facilities are not immediately available to begin testing, the Agency concludes it is in the best public interest to allow manufacturers to immediately begin testing their categories of hearing protectors at those facilities which are now actively engaged in that testing.

Requested Amendment No. 3: Delay until December 31, 1981, the date by which all categories of hearing protectors must be retested according to ANSI STD S3.19-1974 and relabeled as necessary.

Response: EPA is requiring that manufacturers who initially use available Z24.22 data for certain categories of their protectors retest those categories according to ANSI STD S3.19-1974 and relabel them by September 27, 1981 rather than by December 31, 1981 as requested.

The EPA believes that manufacturers will be able to complete the necessary

retesting of categories of protectors within one year of the effective date of the regulation (by September 27, 1981). The ISEA estimated that more than 200 tests must be conducted by September 27, 1980. However, the EPA's decision to allow testing to begin immediately and to allow the use of currently available S3.19 data with no requirement to retest will reduce the number of required tests to approximately 150. Between now and September 27, 1981, there are approximately 400 test days. This provides sufficient time in which to accomplish the necessary retesting and relabeling of those categories whose NRRs are initially based on Z24.22 data. For these reasons, the Agency denies that part of the ISEA's petition requesting a delay, until December 31, 1981, of the date by which protectors must be tested and labeled.

The sum of these amendments, the Agency believes, will enable manufacturers to comply by the effective date of the regulation, without compromising the quality of the required information.

III Other Changes

The changes to the regulation discussed below include: requests for revision to §§ 211.206-1(b)(2), 211.209, 211.209(b), 211.210-2(c), 211.212-1(e)(3), 211.212-2, 211.212-7 and 211.213 presented in the ISEA letter to the EPA dated December 6, 1979, which was incorporated into the ISEA petition by reference. In addition, the Agency made changes which include clarification of wording and corrections of clerical errors.

1. The ISEA requested that the EPA accept all existing S3.19 and Z24.22 test data, permit additional S3.19 testing now, and extend to December 31, 1981, the effective date for the completion of testing and labeling of devices.

EPA's response to these requests is discussed in the preceding paragraphs. No further discussion is necessary.

2. The ISEA believes that in § 211.206-1(b)(2), there is an unnecessary testing restriction which requires that test subjects have to be requalified for each attenuation test. The ISEA requests that this requirement be eliminated from the regulation.

The EPA agrees that this requirement should be deleted. Once a test subject has been qualified as a "listener" under the requirements of ANSI STD S3.19-1974, it is not necessary to requalify the subject for each testing session. Section 211.206-1(b)(2) is revised to eliminate this requirement.

3. The ISEA commented that the term "new hearing protector device" as used in § 211.209 is not consistent with the

Noise Control Act. This phrase is also used in § 211.210-1(a).

To eliminate any misunderstanding the EPA, by this notice, deletes the word "new" from the phrase in § 211.209 and § 211.210-1(a). The requirement is that any protector manufactured for distribution in the United States after the effective date of the regulation be subject to the regulation.

4. The ISEA is concerned about § 211.209(b), which indicates that the Agency may request information from manufacturers regarding the number of protectors, by category, produced or scheduled to be produced. It believes that this is highly confidential information and questions why the EPA needs that type of data.

Under § 13(a) of the Noise Control Act of 1972, the EPA may request that manufacturers provide such information as the EPA may reasonably require to enable it to determine whether they have acted or are acting in compliance with the Act. When the EPA exercises its authority under § 13(a) of the Act and § 211.209(b) of the regulation, it will limit its request to the extent practicable but it must have certain minimum information, particularly with respect to production scheduling, in order to schedule its monitoring activities. The Agency has established procedures for protecting confidential business information under 40 CFR Part 2; manufacturers are referred to this regulation for detailed information on the procedures. The EPA does not believe that a revision to this section of the regulation is necessary.

5. With respect to § 211.210-2(c), the ISEA raised a question regarding the definition of cap mounts and the potential for extensive testing due to a large variety of configurations of cap mounted hearing protectors. It cited examples of hearing protectors being attached to various industrial helmets along with other accessories, such as face shields and welding helmets. The various accessories and helmets could be the product of one manufacturer, or they could come from a variety of sources.

The EPA has further considered the problem of accessories and how they can affect the attenuation of protectors and consequently become additional categories of protectors subject to testing. The Agency has determined that it is the basic configuration of the protector as intended for use that must be tested and labeled (e.g., a manufacturer's helmet with muffs must be tested and labeled). The addition of an optional accessory such as a faceshield would not create a requirement that the basic configuration

be retested. Accordingly, no change has been made to § 211.210-2(c).

6. The ISEA questioned the practicality of the provision of § 211.212-1(e)(3) that allows a manufacturer 24 hours to send test hearing protectors to the testing facility or Compliance Audit Testing. The ISEA requested that this section be revised to allow the manufacturer one week to transport the test devices to the laboratory. The ISEA further requested that the laboratory be allowed 3 weeks to issue its report.

The EPA has reconsidered the time limitation on the shipment of test products to the test facility for Compliance Audit Testing, and accepts the ISEA's recommendation that one (1) week be allowed for shipment of the test products from the manufacturer's facility to the designated test facility.

The EPA believes that a laboratory can reasonably report the results of a test within 5 working days after completion of the test, so no change is made to the reporting requirement. If actual experience demonstrates that a 5-day period may not be adequate, the EPA will give consideration to revising that requirement.

7. The ISEA believes that §§ 211.212-2 and 211.212-7 should be revised to provide for a more practical number of devices to be submitted for Compliance Audit Testing purposes. Also, the ISEA states that it does not understand the rationale for two tests as presently required in § 211.212-7. It believes that only one test is necessary.

The EPA has carefully studied the requirements in §§ 211.212-2(a) and 211.212-7(a) that require testing of up to twenty (20) protectors [§ 211.212-2(a)] and additional sets of 20 protectors [§ 211.212-7(a)]. EPA concludes that it is not necessary to specify the number of test samples in the regulation. EPA has revised those sections to delete any reference to the number of devices which must be tested during a Compliance Audit Test. The Agency has revised § 211.212-1(c)(5) to state that EPA will specify in each test request the number of devices which must be shipped to the test facility and the number of those which must be tested. These numbers will vary depending upon the type of protector being tested (muff, cap mount, insert, etc.).

The EPA agrees that when a failure of a Compliance Audit Test is due to a quality control failure that has since been corrected, only one additional test is required to reverify that affected category of protector. Section 211.212-7(c) is revised to require only one test.

8. Referring to remedial orders for the violations of these regulations, as

covered by § 211.213, the ISEA requested that the EPA establish criteria that would govern a recall of products from the marketplace. The ISEA believes that the Agency should make known its ground rules for recall orders.

Section 211.213 states that the Administrator may issue an order under § 11(d)(1) of the Act when any person is in violation of the regulation. The content of a remedial order will be based upon the nature and extent of each violation. The remedial order will be issued only after the violator has been notified of the violation and given an opportunity for a hearing.

Manufacturers are referred to 40 CFR Part 209, Interim Rules of Practice Governing Proceedings under the Noise Control Act of 1972. These rules delineate the rights of a manufacturer who is involved in a proceeding initiated by the issuance of a complaint which would contain a proposed remedial order.

9. The ISEA urges the EPA to get agreement from the Occupational Safety and Health Administration to accept the NRR method and to have the Department of Defense, in its military specifications, either accept NRR and § 3.19 testing or have the military specification exempted.

Through the Interagency Regulatory Liaison Group, the EPA has coordinated with the Occupational Safety and Health Administration to resolve any inconsistencies in the agencies' regulatory requirements for hearing protectors. We have previously informed the Department of Defense of our regulatory requirements for hearing protectors and have been assured that the Military Specifications for hearing protectors will accommodate our requirements. We will continue to coordinate with other agencies as the need arises.

10. The ISEA expressed concern about the supporting information requirement in § 211.204-4. It believes that there is no need to supply supporting information with each device.

The EPA agrees, and the regulation requires that, for sale and distribution of protectors through bulk containers and dispensers, the supporting information must be available on the dispenser, but does not have to accompany each individual device.

For a protector that is to be sold or distributed as an individually packaged device, the supporting information must be provided in a manner that assures its availability to the prospective user. The best mechanism for supplying this information must be determined by the manufacturer.

The objective of Product Noise Labeling (40 CFR Part 211) under Section 8 of the Noise Control Act is to provide to the prospective user of a product, information on that product's noise level or its effectiveness in reducing noise. The supporting information is part of the labeling requirement of Subpart B of 40 CFR Part 211, and is necessary to fully inform a prospective user of a protector of its effectiveness in reducing noise. Accordingly, no change has been made to § 211.204-4.

11. The ISEA requested that EPA establish criteria to define a "major change" in a device under § 211.210-7(b) which will require the manufacturer to reverify the NRR for that protector.

The regulation already provides the criteria for retesting under § 211.210-7(b). The manufacturer must reverify the category whenever a design change decreases the noise attenuation characteristics of the product. The manufacturer is in the best position to decide whether changes are likely to decrease the noise attenuation characteristics of its products. Accordingly, no change has been made to § 211.210-7(b).

12. The ISEA believes that the EPA underestimated the total cost of this regulation. The ISEA believes that, in calculating the economic impact of this regulation, EPA gave no consideration to the cost of management time and that insufficient attention was given to the costs associated with the preparation of new sales literature, advertising, distribution, education, brochures, and, of major importance, product liability costs.

The EPA gave very careful consideration to the potential economic effect of this regulation on the industry and the public. In three different instances EPA requested economic data from the hearing protector industry: in the Advanced Notice of Proposed Rulemaking (ANPRM), in letters sent to several known manufacturers and the Industrial Safety Equipment Association (which represents a significant portion of the total industry), and in the Notice of Proposed Rulemaking (NPRM).

In all three instances, the responses the Agency received from the industry regarding the costs attributable to a labeling regulation provided minimal information. Consequently, what the EPA believed to be a "worst case" estimate was extrapolated from the very limited information provided by industry. For example, the EPA considered management time by including Senior and Mid-level management costs in its estimate of annual costs (Regulatory Analysis, EPA publication 550/9-79-250, page 53). The

Agency considered the preparation, printing, technical assistance, graphics and artwork costs (*ibid.*, pages 51-54). The other costs the industry would have the Agency consider must be viewed as normal costs of business. For instance, product liability costs are assumed by a manufacturer whenever a product is offered to a consuming market, and exist for this product whether or not there is a regulation requiring manufacturers to label their products with their noise-reducing effectiveness.

The Agency declines to reconsider the potential costs imposed by this regulation in the absence of specific data or other information from the industry which demonstrates that the economic impact of this rule is substantially different from that arrived at by the EPA in the final regulation. Further, it is incumbent on the industry to show that such information is material and was not available at the time of the rulemaking proceeding or that opportunity had not been provided to the industry (or the industry had not been requested by EPA) to proffer this data for consideration in this rulemaking.

The Agency finds that to propose these revisions prior to final rulemaking would be impractical and contrary to the public interest. These revisions are critical to the labeling activities of the manufacturers of hearing protectors, and must be effective immediately if these activities are to be completed prior to the September 27, 1980 effective date of the regulation. The Agency finds further that there is good cause to make these revisions effective upon promulgation, rather than thirty days after promulgation, because these revisions relieve certain restrictions in the regulation and are generally technical in nature.

EPA has determined that this action is not a "significant" regulation, and therefore does not require a Regulatory Analysis in accordance with Executive Order 12044.

These amendments represent final Agency action on the ISEA's petition for reconsideration of 40 CFR Part 211, Subpart B, Noise Labeling Requirements for Hearing Protectors (44 FR 56130, September 28, 1979), and are promulgated under the authority of 42 U.S.C. 4907.

Dated: January 30, 1980.
Douglas M. Costle,
Administrator.

40 CFR Part 211, Subpart B is amended as follows:

1. Table of contents is amended to add new section headings as follows:

§ 211.206-2 Alternative test data
 § 211.206-3—211.206-10 Alternative test method (Reserved)

2. Section 211.204-1(d) is revised to read as follows:

§ 211.204-1 Information content of primary label.

(d) At the bottom of Area A-B, there must be the phrase "(When used as directed)."

3. In Figure 1, the phrase "(Higher numbers denote greater effectiveness)" is corrected to read "(Higher numbers denote greater effectiveness)."

4. In Section 211.204-4, the second sentence of the introductory statement and Items 2. and 3. of the Example in paragraph (b) are revised to read as follows:

§ 211.204-4 Supporting information.
 In the case of bulk packaging and dispensing, such supporting information must be affixed to the bulk container or dispenser in the same manner as the label, and in a readily visible location.

(b) * * *
 2. The NRR is (value on label) decibels (dB).
 3. The level of noise entering the ear is approximately equal to [92 dB(A)—NRR] dB(A).

5. Section 211.200-1(b)(2) is revised to read as follows:

§ 211.200-1 Real ear method.

(b) * * *
 (2) Sections 3.3.2 and 3.3.3 shall be accomplished in this order during the same testing session. Any breaks in testing should not allow the subject to engage in any activity that may cause a Temporary Threshold Shift.

6. Section 211.200-2, Alternative test data, is added as follows:

§ 211.200-2 Alternative test data.

(a) In lieu of testing according to § 211.200-1, manufacturers may use the latest available test data obtained according to ANSI STD Z24.22-1957 or ANSI STD S3.19-1974 to determine the mean attenuation and standard deviation for each test frequency and the NRR calculated from those values. Manufacturers whose data is based on the ANSI STD Z24.22-1957 measurement procedure must state in the supporting information required by § 211.204-4 that the mean attenuation and standard deviation values used to calculate the NRR are based on ANSI STD Z24.22-1957.

(b) Manufacturers who initially use available data based on ANSI STD Z24.22-1957 must retest within one year of the effective date of this regulation (by September 27, 1981) the affected categories of hearing protectors in accordance with section 211.200-1 of the regulation, and must relabel those categories as necessary.

(c) Manufacturers who use available data based on ANSI STD S3.19-1974 are not required to retest the affected categories of hearing protectors.

(d) If a manufacturer has both ANSI STD S3.19-1974 test data and ANSI STD Z24.22-1957 test data on a hearing protector category, that manufacturer must use the data obtained according to ANSI STD S3.19-1974.

7. Section 211.209(a) is revised to read as follows:

§ 211.209 Maintenance of records: Submittal of information.

(a) The manufacturer of any hearing protective device subject to this regulation must establish, maintain and retain the following adequately organized and indexed records:

8. Section 211.210-1(a) is revised to read as follows:

§ 211.210-1 General requirements.

(a) Every hearing protector manufactured for distribution in commerce in the United States, and which is subject to this regulation:

9. The first sentence in § 211.210-3(f) is revised to read as follows:

§ 211.210-3 Labeling verification report: Required data.

(f) A manufacturer may immediately begin to conduct label verification testing on protectors in accordance with § 211.200-1 of this regulation. For these early Label Verification reports to be acceptable to the Agency, the manufacturer must:

10. The second sentence in § 211.211(b) is revised to read as follows:

§ 211.211 Compliance with labeling requirement.

(b) * * * A specific category is considered to be in compliance with the requirements of § 211.210-1 when the attenuation value at the tested one-third octave band is equal to or greater than the mean attenuation value reported as Labeled Values in the Labeling Verification Report.

11. Section 211.212-1 (c)(5) and (e)(3) are revised to read as follows:

§ 211.212-1 Test request.

(c) * * *
 (5) The number of protectors to be forwarded to the designated test facility and the number of those protectors which must be tested by the facility.

(e) * * *
 (3) The manufacturer will be allowed 1 calendar week to send test hearing protectors from the assembly plant to the testing facility. The Administrator may approve more time based upon a request by the manufacturer. The request must be accompanied by a satisfactory justification.

12. Section 211.212-2 (a) and (e) are revised to read as follows:

§ 211.212-2 Test hearing protector selection.

(a) The test request will specify the number of test protectors which will be selected for testing from the number of protectors delivered to the test facility in accordance with § 211.212-1(c)(5). The remainder may be used as replacement protectors if replacement is necessary. The test request will also specify that the protectors be selected from the next batch scheduled for production after receipt of the test request.

(e) The manufacturer must keep on hand the test protectors designated for testing until such time as the category is determined to be in compliance. Hearing protectors actually tested and found to be in compliance with these regulations may be distributed in commerce.

13. Section 211.212-7 (a) and (c) are revised to read as follows:

§ 211.212-7 Continued compliance testing.

(a) The manufacturer must continue to conduct additional tests until the mean attenuation values from the last test at each octave band equal or exceed the lowest attenuation values obtained from all previous compliance tests.

(c) When the manufacturer can show that the non-compliance under § 211.212-6 was caused by a quality control failure and that the failure has been remedied, he may, with the Administrator's approval, conduct an additional test and relabel using the mean attenuation values no higher than those obtained in that test.

(Secs. 8 and 13, Pub. L. 93-574, 86 Stat. 1230, 1244 (42 U.S.C. 4907, 4912))
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