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Part III

Environmental Protection Agency

General Provisions for Product Noise Labeling and Noise Labeling Requirements for Hearing Protectors; Approval and Promulgation

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 211

[FRL 1270-2]

Approval and Promulgation of the General Provisions for Product Noise Labeling

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

ACTION: Final rule.

SUMMARY: By this notice the Environmental Protection Agency establishes the general provisions of a regulatory program for product noise labeling under the authority of Section 8 of the Noise Control Act of 1972, 42 U.S.C. 4907. These general provisions concern the aspects of the program which the Agency intends to apply in every instance of product noise labeling. The practicality of applying the general provisions will be determined for each product to be noise labeled. The Agency will address the labeling requirements for individual products or product classes, which differ with these provisions, in product-specific rulemaking actions. The major purpose of this regulatory program is to provide accurate and understandable information on the noise generating or noise reducing properties of new products, so that the public can make meaningful comparisons concerning those properties when making decisions to use or buy the products.

EFFECTIVE DATE: September 28, 1979.

FOR FURTHER INFORMATION CONTACT: Timothy McBride, Standards and Regulation Division (ANR-490), U.S. Environmental Protection Agency, Washington, D.C. 20460, (703) 557-2710.

SUPPLEMENTARY INFORMATION:

I. Introduction

On June 22, 1977, the Environmental Protection Agency (EPA) published a proposed rule (42 FR 31722) to establish a product noise labeling program under the authority of, and as required by, Section 8 of the Noise Control Act of 1972, 42 U.S.C. 4907. The June 22 proposal set forth the general provisions of the noise labeling regulatory program, and established Part 211 of Title 40 of the Code of Federal Regulations. Part 211 will be composed of the general labeling provisions as subpart A, and individual product-specific labeling requirements that would be added as further subparts by separate rulemaking actions. Because of a computerization program undertaken since the promulgation of the proposed rule, it was necessary in the final rule to either replace the second decimal point in each section heading with a zero or delete it entirely. At the time of publication, the EPA solicited written public comment on the proposed General Provisions as well as all other aspects of the proposed product noise labeling program. Public hearings were not initially scheduled. The public comment period for the proposed rule was originally set at 90 days with closing scheduled for September 20, 1977. As the result of receiving a large number of letters shortly after publication in the Federal Register, the EPA decided to schedule public hearings on the proposed rule and extended the comment period to October 28, 1977 (42 FR 41139). Hearings were held in Washington, D.C. on September 16, 1977; in Cedar Rapids, Iowa on September 20, 1977; and in San Francisco, California on September 22, 1977.

In all, the Agency received 735 written comments by the close of the comment period, and took oral testimony from 51 individuals, organizations and businesses at the three public hearings. Over 600 of the written comments were from private citizens. A large majority of the comments were in favor of the proposed noise labeling program. Most of the favorable comments came from private citizens, while the majority of industry commenters disagreed with various aspects of the program. The comments dealt with virtually every aspect of the program. While the Agency has modified or clarified some aspects of the proposed noise labeling General Provisions, the final rule incorporates no major changes. A discussion of the major comments follows.

II. Discussion of Major Comments

A. Statutory Authority

1. *Questions Concerned With Issuing the General Provisions Before Product-Specific Regulations.* Four commenters questioned the appropriateness of promulgating general labeling provisions before product-specific regulations. They argued that this sequence of actions was illogical; that both the general provisions and product-specific regulations must be considered in tandem; and that, therefore, issuing the general provisions before the product-specific regulations serves no useful purpose. Commenters wanted to be certain that they could comment on the General Provisions and also be able to comment on product-specific regulations, if the Agency proposed product regulations affecting their industry. One commenter indicated that comments on the General Provisions should be considered in future product-specific rulemaking. That same commenter also stated that there were enormous problems in selecting a label format and what sort of relevant information should be included on the label before actually deciding upon the product(s) to be regulated. Another commenter argued that the proposed standards would create confusion and procedural dilemmas when they were applied to a particular product, since they apply neither to a specific product nor to all products in general.

The EPA proposed the noise labeling General Provisions at the same time it proposed a product-specific noise labeling regulation for Hearing Protectors (42 FR 31730). Thus, the General Provisions do not exist alone. The Agency believes that the one-time issuance of the Product Noise Labeling *General Provisions is logical and* advantageous to the general public, to industry, and to the Federal government, because it eliminates the need to re-propose many of the same regulatory requirements in each product-specific labeling action. The general labeling requirements apply to all noise-producing and noise-reducing products. Where appropriate, product-specific regulations will clearly delineate any exceptions to the General Provisions. Thus, there should be no confusion in *using the General Provisions and future* product-specific regulations in tandem.

The size of the public docket attests to EPA's success in eliciting comments from concerned parties. These comments have helped the Agency to shape an overall regulatory program that is both effective and reasonable and also to anticipate many of the technical problems that may occur because of product-specific labeling actions.

By issuing the General Provisions, the Agency intends to provide guidance to the general public and to all potentially

affected parties, on the general nature and intent of the product noise labeling program. Also, product manufacturers and suppliers potentially affected would have substantial lead-time to formulate voluntary labeling programs that would satisfy EPA's labeling requirements or to prepare for possible Federal noise labeling regulatory action.

Another reason for issuing General Provisions concerns the need for label uniformity. If product noise labels are relatively similar in format and require approximately the same cognitive skills across different product classes, the consumers will be more likely to notice, recognize, and learn how to use the information effectively. Regulatory requirements that cannot be generalized for all products, such as testing methodologies, have not been specified in the General Provisions and will be addressed in future product-specific subparts.

Other commenters argued that EPA had no authority to issue the General Provisions. They maintained that Section 8 gave the Administrator authority to promulgate labeling regulations only with respect to products which emit "* * * noise capable of adversely affecting the public health or welfare," or which are "* * * sold wholly or in part on the basis of [their] effectiveness in reducing noise," and that until such product-specific regulations were promulgated, no authority exists to require labeling.

The General Provisions, as stated above, were proposed concurrently with product-specific labeling provisions for Hearing Protectors. Both of the proposed regulations appeared in the same issue of the Federal Register. The General Provisions were proposed as Subpart A to 40 CFR 211, and the product-specific Hearing Protector requirements as Subpart B. The General Provisions were proposed and will exist, therefore, as part of the regulatory requirements for the labeling of hearing protectors. The Agency's authority for proposing and promulgating them clearly exists within the authority granted the EPA in Section 8 (a) and (b) for the labeling of products "* * * sold wholly or in part on the basis of [their] effectiveness in reducing noise."

At the time that other product-specific proposals are published, the Agency will establish a public comment period and will solicit comment on all aspects of the proposed rulemaking, including the appropriateness and reasonableness of the General Provisions as they apply to the particular product.

2. *Questions Concerned with Determining if a Product is Capable of Adversely Affecting Public Health or Welfare.* Several commenters expressed concern about the Agency's authority to label noise producing products, as that authority is defined by the language of Section 8 of the Act. That language states that the Administrator of the EPA shall designate and label any product "* * * which emits noise capable of adversely affecting the public health or welfare." The questions that were raised concerned the process and criteria by which the EPA will make such determinations in general, or with respect to particular products. Commenters offered various interpretations of the statutory language in question. In particular, they questioned the provisions that relate to the adverse health or welfare impact within the focus of Section 8. Some commenters suggested that only actual hearing damage may be considered, and that aspects such as cumulative exposure, or factors such as annoyance, should not be considered.

There are many products which merit potential consideration under Section 8, relative to their possible adverse health effects. Therefore, the EPA has decided that it will not attempt to specify a detailed methodology or formula by which it will determine whether the noise emissions from a particular product are capable of adversely affecting the public health or welfare. Instead, the Agency will approach the question on a product-by-product basis, presenting in detail the rationale underlying its determination for each product. In making these determinations the EPA will use the World Health Organization's definition of health and welfare—"* * * complete physical, mental and social well being and not merely the absence of disease and infirmity." EPA will also use the health and welfare criteria and findings specified in the EPA's "Criteria"[1] and "Levels"[2] documents, and any other criteria that may be developed as a result of further research and analysis into the adverse physiological or psychological effects of noise. Those criteria may encompass both the auditory and non-auditory effects of noise, including stress effects and annoyance, and will take into account the effects of cumulative exposure on individuals. Auditory, non-auditory and stress effects, as well as annoyance are highlighted because they are well established aspects of most studies concerning the possible adverse effects of noise on humans.

B. Product Selection Criteria

The EPA received many comments about the criteria or factors that it should consider in deciding which particular products should be labeled first. Fifteen factors were listed in the Supplementary Information section of the Preamble to the Notice of Proposed Rulemaking 42 FR 31728. Of the nearly sixty comments received that concerned product selection criteria, well over half could be included within those fifteen examples. Some commenters suggested specific products or product classes for labeling action rather than objective criteria. These comments are aggregated and presented in Part III of the Regulatory Analysis[3] accompanying this rulemaking.

In implementing the noise labeling program, the EPA must consider many different products for possible regulatory action, and have a means of selecting products for initial study. For this reason the fifteen factors referenced above were developed and presented in the preamble to the June 22, 1977 proposal. It is important to distinguish EPA's use of these factors in selecting various products as initial candidates for labeling action, from the question of EPA's authority to promulgate noise labeling standards for a particular product. The issue of the Agency's authority with respect to products which produce noise (i.e., whether such a product emits noise capable of adversely affecting the public health or welfare) will be addressed in detail for each product that is selected for noise labeling regulatory action.

The EPA has reviewed the comments received concerning the initial product selection criteria, and has revised and expanded its selection factors.

The criteria for selecting a product as an initial candidate for labeling are based on the intent of Congress in

[1] Public Health and Welfare Criteria for Noise, July, 1973; EPA 550/9-73-002.

[2] Information on Levels of Noise Requisite to Protect Public Health and Welfare with an Adequate Margin of Safety, March, 1974; EPA 550-9-74-004.

[3] Regulatory Analysis Supporting The General Provisions For Product Noise Labeling, August 1979; EPA 550/9-79-255.

writing Section 6 of the Act. That intent was to provide product noise information to a prospective user and/or purchaser so that a more informed decision could be made when using or purchasing products that either emit "* * * noise capable of adversely affecting * * * health or welfare; or * * * [are] sold wholly or in part on the basis of [their] effectiveness in reducing noise." With respect to the noise-producing products, key factors that relate to their capacity to adversely affect public health or welfare include the noise levels that may be experienced by users and their family members, the manner, frequency and duration of use of the product, and the number of people throughout the country exposed to the noise of the product (which in turn is related to the numbers of the product in use). Other important factors relate to the possible usefulness of labeling (for example, the label may show that quieter units as well as noisier units are available), and the number of opportunities a user has to make a purchasing decision (for example, a noise label on a product that a consumer buys every year is more likely to influence a purchase decision than one on a product that the consumer buys once in 10 or 15 years). Certain technical factors, such as suitable noise-measurement techniques, also are pertinent. Similar considerations apply to products that are sold for the purpose of reducing noise.

It is important to note that product noise labeling (Section 6) plays a complementary role to new product noise emission standards (Section 6). Section 6 regulations generally apply to products whose noise affects many more non-users (third parties) than purchasers or users (e.g., trucks and construction equipment). In such cases, the purchaser has little incentive to spend more to buy a quieter product, as he may perceive little or no direct benefit from the noise reduction. Section 6 labeling, on the other hand, generally applies to products whose noise affects mainly the purchaser and/or user and members of an immediate household. In this case, the purchaser and/or user benefits from reduced noise.

The following list represents those factors which the EPA will use in deciding on the products it will consider for possible noise labeling regulatory action.

Criteria for Selecting Products as Initial Candidates for Noise Labeling

(The order in which these factors are listed does not necessarily represent their relative importance in the selection process.)

1. (For noise producing products) Is the product noise level sufficiently high to be potentially capable of producing an adverse health or welfare impact?

(For noise reducing products) Does the product have a noise reducing capability and is the product sold wholly or in part on the basis of this capability?

2. Is the product used in a location or in a manner that makes an adverse health or welfare impact possible?

3. Is there a potential for the product to be misused? (e.g., aerosol operated horns in a crowd, decorative ceiling tile used as sound absorbing ceiling tile)

4. Does the product noise affect a large number of people?

5. Is the noise from the product likely to impact more non-users (i.e., third parties) than purchasers and/or users?

6. Is the product used by the purchaser or household members, and does the adverse noise impact of the products fall primarily on the purchaser or household members?

7. Are there large numbers of product types in use?

8. Are there large numbers of the product types being manufactured/sold?

9. Is there a significant range in the acoustic performance from model to model?

10. Is there a high frequency of purchase so that purchasers have the opportunity to use the labeled noise information often in making a purchase decision?

11. Do the future trends in the product's population, design, or use suggest noise labeling benefits?

12. Do purchasers desire a quieter noise producing or more effective noise reducing product?

13. Can the acoustic performance of some or all models of the product be improved?

14. Is there currently a lack of acoustic information?

15. Would Federal labeling be a significant improvement on any existing product noise labeling?

16. Would labeled noise information be useful to purchasers and/or users, and Federal, State and local noise ordinance enforcement organizations?

17. Is it desirable for EPA to augment existing or planned noise emission/noise attenuation standards by labeling a product with noise information?

18. Are the acoustic data necessary to the development of product noise emission/attenuation standards currently available?

19. Would the prospect of Federal labeling promote voluntary labeling by manufacturers?

20. Is there a readily available measurement methodology for the product types?

The EPA will conduct pre-regulatory studies to develop data and information concerning these factors for the products or product classes that EPA selects as potential candidates for labeling.

C. Label Content Requirements

A number of commenters expressed concern about the content requirements for the proposed noise label. Requirements concerning the comparative acoustic information and the noise descriptor elicited the majority of the comments. Other comments concerned identification of both the manufacturer and the product on the label, the warning about removing the label before purchase, and the use of the EPA logo. Commenters also provided suggestions for additional information.

The comments concerning the inclusion of comparative acoustic information are discussed below. Comments dealing with the choice of a noise descriptor, the EPA logo, and identification of the manufacturer on the label are addressed in this preamble in Sections II D, E, and F respectively. Except for a brief statement on the prohibition statement in the label, all remaining comments dealing with label content are discussed in detail in the Regulatory Analysis.[4]

The placement of comparative acoustic information on the label elicited both negative and positive reactions. Many private individuals and government officials expressed support for including data that shows the range of noise produced or reduced by like products; or if not that, then some other kind of information which would permit consumers to know more about the product(s) being considered for purchase and/or use. A number of persons felt that comparative information with some sort of a scale was essential to give meaning to the rating. Specific suggestions as to the exact nature of this component of the label varied widely.

In contrast, most of the industries that submitted comments expressed serious reservations about the use of a range of any other type of comparative information. These concerns centered primarily on questions of EPA's authority to require such information, and various technical problems associated with implementing such a requirement, one of which was: would determining the comparative information that is to be included on a label require research on the part of the manufacturers?

After reviewing all of the comments concerning this issue, the EPA decided to retain the requirement in the General Provisions that some form of comparative acoustic information appear in a designated section of the Federal noise label. This decision is based on the Agency's view that its authority to require that notice be given of a product's noise level, or its effectiveness in reducing noise, is not limited to some technical parameter that expresses a product's acoustic

[4] *Ibid.*, p. 110 et seq.

performance and nothing more. EPA will address the issue of what comparative information, if any, is appropriate for a particular product at the time that EPA proposes and promulgates a labeling regulation for that product. Should the inclusion of comparative information be required on a label for a specific product, EPA will provide the comparative information to the manufacturers.

The proposed prohibition concerning the removal of the noise label prior to sale applied to products purchased and used by the consumer. The Agency now anticipates that situations may arise where a product may pose an adverse impact upon a user who does not make purchasing or use decisions, as in the case of an employee. Such products may be labeled to provide health and welfare (e.g., hearing loss) information. In such cases the Agency may require that the label be permanent. However, the requirement will be determined on a product-specific basis.

D. The Choice of Acoustic Descriptors

There was very little criticism of the use of a noise emission or reduction descriptor on the label or of its proposed location. Commenters felt that descriptors should be simple, understandable and uniform across product classes. Despite this agreement on characteristics, there were different opinions as to what kind of descriptor would best fulfill these requirements.

Commenters recommended a range of acoustic descriptors, the details of which are presented in the Regulatory Analysis,[6] the vast majority of commenters supported some type of numerical scale. There was little support for using symbols or word descriptions, nor was there much support for a linear 1–10 rating scale.

The most popular descriptor (to both manufacturers and private citizens) for noise emitting products was the decibel (dB), the basic unit of noise measurement with many persons suggesting the "A"-weighted scale (dB(A)). The commenters' major concern about using decibels as a descriptor was that the public would not understand the logarithmic nature of the unit. In contrast to the few criticisms of decibels, many commenters pointed out the unit's positive characteristics. First, they noted that much of the public already knows about decibels, and therefore any public education campaign would be building on a foundation of knowledge, although a somewhat limited one.

Second, a single-value noise emission descriptor, given in decibels, would provide the uniformity needed to permit consumers to learn from individual purchasing experiences across different product classes. A third advantage was noted by individuals responsible for enforcement at the local or state level. They asserted that the noise emission of a product, printed in decibels on the label, would help enforcement officials who need to know the actual noise level and not the range within which the product's noise is located (as would be provided by a 1–10 scale or by symbols). A similar advantage is that consumers would know the actual noise level of a particular product, albeit under certain fixed conditions. The use of decibels by consumers in their purchasing decisions would also help them in becoming more knowledgeable about noise, and more noise-conscious in general.

The Agency decided that as a matter of policy in implementing the noise labeling program, it will use the "A"-weighted decibel (dB(A)) as the acoustic descriptor for noise-emitting products. We believe that its current widely accepted use as a descriptor for sound, coupled with other positive aspects such as uniformity and the ease and accuracy of comparison, outweigh whatever unfamiliarity the public may currently have with this term.

An issue closely related to the acoustic descriptor is the acoustical parameter that the decibel represents; that is, sound pressure or sound power level. Current Federal noise emission standards are in terms of an energy averaged sound pressure level at a designated distance from the noise source. While the A-weighted sound pressure level is an accurate representation of the intensity of noise as it is experienced by the human ear, it is generally unique to the location at which it is measured. The sound power level of a product is the rate at which it releases acoustic energy to the environment and is therefore independent of location. Sound power is calculated from sound pressure measurements at multiple locations around the product.

In keeping with the Agency's intent to provide uniform acoustic descriptors across all product lines, we have adopted sound pressure level at one meter (approximately 3 feet) from the source as the acoustic parameter for noise emitting products. However, we recognize that there will be product-specific situations where a single value noise rating is best obtained under test conditions which favor the determination of sound power and the subsequent calculation of sound pressure. The Agency will determine, on a product-specific basis, the most appropriate technique for obtaining a single value product Noise Rating in terms of "A"-weighted sound pressure.

The acoustic parameter and descriptor that best characterizes the noise reducing qualities of a product is very much design and application dependent.

Noise reducing products will, in general, be characterized by different acoustic parameters and descriptors than those applicable to noise emitting products. Sound transmission loss and sound absorption are two of the more widely used acoustic parameters. Their respective acoustic descriptors are the decibel and the sabin. However, there are other possible acoustic parameters and descriptors that may be more suitable on a product-specific basis.

The choice of a noise emission or noise reduction descriptor is not specified as a regulatory requirement in the General Provisions for noise labeling. However, there will be a Noise Rating (NR) or Noise Reduction Rating (NRR) for every product designated for noise labeling. The choice of the acoustic parameter and descriptor will be included as a regulatory requirement on a product-specific basis in future subparts to this rule.

One important aspect of the EPA noise label is that the Noise Rating or Noise Reduction Rating is to be determined by a Federally specified and uniform test method. In many cases, the test methods will not be able to simulate the wide variety of actual environments in which the products will be operated, and therefore, the noise levels shown will not necessarily be those which users will actually experience.

The levels will, however, provide an accurate indication of the relative noisiness of similar products when they are tested in a uniform environment that best reflects those important aspects of their acoustic performance.

As noted in the preamble to the proposed rule, EPA will require test methodologies on a product-by-product basis. The emphasis in methodology selection will be to simplify the testing requirements and minimize the need for resources (facilities, people, and equipment), while maintaining a sufficient degree of reliability, repeatability of test results, and accuracy. The EPA wants to work closely with product manufacturers, industry associations, and voluntary consensus standard-setting organizations in developing test methods for any of the wide variety of

[6] Ibid., p.119 et seq.

products that may be candidates for possible Federal noise labeling action.

The program that the Agency intends to use in educating the public to the label, how it is used and what it means, will be, in general, a product-specific public awareness campaign.

E. Logo

Several commenters expressed opposition to the EPA logo appearing on the label because they felt it would prejudice sales of products, was wasteful of label space, or was unauthorized. Other commenters supported its inclusion in the label, but felt some persons might construe this as EPA endorsement or guarantee of the acoustic performance of the product, even though EPA did not itself develop the data to support the label values.

Since the product noise labeling program implements a nondiscretionary statutory requirement that is imposed upon the Administrator of the EPA by the Noise Control Act, the presence of the EPA logo on the label indicates that the program is Federally mandated and administered. Although the Agency does not itself test products and develop the data for labeling products, the Agency does have clear responsibility for enforcing the overall labeling program; consequently the logo *must* appear on the label so that the potential purchaser/user will know that EPA is ultimately responsible for the label. The logo lends authenticity to the data on the label since consumers generally recognize that EPA has the authority and procedures to compel manufacturers to ensure that their labels are accurate.

In addition, the logo on product noise labels is intended to inform consumers that the information provided on a label for a specific product class is in fact uniformly applied to all products of the same class.

The logo does not imply that EPA prefers certain products, for all labels will state that it is the Agency that requires that a certain product or class of products be labeled.

In response to the concerns about EPA endorsement of the actual levels indicated on the label, the label has been changed to read "Label required by U.S. EPA regulation 40 CFR Part 211, Subpart ———." The Subpart will be specified in the product-specific regulation.

F. Identification of Manufacturer

The Noise Control Act of 1972 defines "Manufacturer" as meaning "any person engaged in the manufacturing or assembling of new products, or the importing of new products for resale, or who acts for and is controlled by, any such person in connection with the distribution of such products."

For many products, there are diversities that occur in the packaging, or perhaps even final assembly of the product from its point of origin to the point of sale to the ultimate purchaser. For all products that are required to be labeled under the authority of Section 8 of the Act, the party labeling the product or its packaging will be accountable for the accuracy and completeness of information that is required on the label. To the extent that normal commercial practices apply, such as, another party tests the product and provides the test information to packagers of the product, the packagers may protect themselves through legally binding contracts or warranties.

G. Economic Effects

A number of oral and written comments focused on the economic impact of the noise labeling program. Many commenters were concerned about costs to the government in implementing the program. Several commenters questioned the Agency's decision to *not* consider economic effects which might result from market shifts arising from consumers purchasing products whose labels actually show that they are quieter than others, or that they are more effective at reducing noise. Other commenters were concerned about resulting higher prices for labeled products or the economic impact on product manufacturers.

EPA developed and will implement the noise labeling program in ways that will minimize the economic impact of the Federal requirements. Measurement methodologies will be as simple as possible and will require minimum resources; labeling requirements will be structured to allow as much flexibility as is possible to product manufacturers in their package design and product marketing.

The Agency maintains that costs to the government will be insignificant in light of the extremely small personnel and fiscal requirements necessary to produce the regulation, and the very limited resources that we anticipate will be necessary for enforcement.

There appears to have been confusion about the statement made in the preamble to the proposed rule that the Agency would not include in its economic impact analysis the consideration of potential market shifts due to consumer use of the labeled information.

The EPA maintains the position that the type of market shift which could develop as a result of consumers' preferences for quieter products should not be included in the economic impact analysis. The reason is that the Federal noise labeling program does not require that there be any product or market changes, but simply requires that manufacturers state their products' noise-producing or noise-reducing characteristics to facilitate more informed choices by product purchasers and users.

The EPA intends to address the economic impact on product manufacturers of any product-specific Section 8 noise labeling requirement with regard to costs resulting from required testing, labeling, and recordkeeping, as well as the economic impact on the public in the form of higher prices that result from these costs.

With regard to market shifts, EPA will study potential shifts resulting from the costs of the programs to product manufacturers and the consuming public. We will include this within the economic analyses performed during the development of labeling requirements for particular products.

H. Voluntary Noise Labeling

In the preamble to the proposed rule, the EPA stated that one of the objectives of the Federal noise labeling program was to promote adequate voluntary noise labeling efforts by product manufacturers. EPA received numerous comments from manufacturers and trade associations about the beneficial aspects of voluntary labeling as opposed to mandatory labeling. Product manufacturers also encouraged the EPA to promote and assist in the developing of such programs.

In response to these comments, the Agency has more fully developed its program for encouraging voluntary noise labeling. However, in view of the Congressional mandate to the EPA in Section 8 of the Act, the Agency must be concerned about the ability of voluntary programs to provide accurate and clearly understandable information to consumers at the time of purchase or use. It is important that voluntary programs be comparable to what the Agency would develop if they are to be used in place of mandatory labeling.

Listed below are the minimal elements that the Agency considers essential to any voluntary noise labeling program. The list is not intended to be a comprehensive outline for the structure of a voluntary program that EPA would definitely accept as a substitute for Federal labeling. Rather, it presents the basic requirements that the Agency believes should be in an effective voluntary noise labeling program if it is

to be considered as an alternative to Federal labeling.

The Agency will consider a voluntary labeling program in lieu of mandatory noise labeling requirements for a particular product on a case by case basis.

Major Elements of Adequate Voluntary Noise Labeling Programs

1. Participation—Uniform participation by all manufacturers or by a high percentage of the total market of a particular product.

2. Measurement Methodology—A uniform methodology which gives accurate and meaningful data.

3. Acoustic Descriptor:

A. Noise Emitting Products—Sound pressure in dBA at 1 meter in 1 dB increments (may be obtained by converting sound power levels or sound level data taken at other distances using a recognized standard method).

B. Noise Reducing Products—Meaningful numerical rating of product's noise attenuating or absorbing capability.

4. Minimum Label Content:

A. The term "Noise Rating" or "Noise Reduction Rating."

B. Acoustic Descriptor.

C. Comparative information—supplied by the industry, compiled from manufacturers' periodic data reports (depending on the product).

5. Label Format and Graphics:

A. Prominence of acoustic descriptor and the term "Noise Rating" or "Noise Reduction Rating."

B. A label shape dissimilar to the EPA noise label.

C. An industry-wide uniform label shape for a particular product or class of products.

6. Label Placement and Size—Readily visible to consumers at time of sale, taking into consideration various ways in which the product may be marketed.

7. Compliance Program—Incorporating product testing and the review of test reports, labels and associated marketing literature, and provisions for rectifying improper labeling.

8. Reports—Periodic reports (depending on the product) to the EPA which include the status and effectiveness of the program and a compilation of the labeled values for all labeled models.

9. Availability of Data—Availability to the EPA of all data, test reports, and other documentation related to the program.

The EPA encourages product manufacturers or trade associations to communicate with us to discuss any aspects of voluntary noise labeling, and will assist industry in developing such programs.

Inquiries should be addressed to: U.S. Environmental Protection Agency, Office of Noise Abatement and Control (ANR-490), Washington, D.C. 20460, (703) 557-2710.

I. Major Enforcement Comments to the General Labeling Provisions

Several of the commenters stated that EPA lacked the statutory authority for the proposed inspection and monitoring scheme.

The proposed regulations included inspection and monitoring provisions in the General Provisions of the Noise Labeling Standards on June 22, 1977 (40 CFR Part 211). Both the inspection and monitoring provisions were based in part on EPA's legal interpretation that the agency was not required to obtain judicial warrants in instances where regulated manufacturers did not willingly consent to EPA enforcement officers entering the facilities.

On May 23, 1978, the Supreme Court delivered a decision in *Marshall* v. *Barlow, Inc.*, 436 U.S. 307, (1978). In that decision, the Court held that administrative agencies must ordinarily obtain search warrants to enter private property for regulatory purposes, if the property owner has not consented.

Accordingly, EPA revised the proposed inspection and monitoring procedures. An EPA enforcement officer may enter a facility only with the consent of the manufacturer unless the enforcement officer first obtains a warrant authorizing such entry. Additionally, it is not a violation of the Act or of the regulation if a manufacturer refuses entry to an enforcement officer who does not have a proper warrant. Section 211.1.9 (§ 211.109) of the regulation has been revised.

The regulations retain the provisions which define the scope of the inspector's proper investigation. This will assure the manufacturers that both consensual and judicially warranted searches are reasonably limited.

Another amendment to paragraph (e) of § 211.1.9 (§ 211.109) clarifies the Administrator's right, as contemplated by *Barlow's* to proceed *ex parte* (without the other party's knowledge) to obtain a warrant, whether or not a manufacturer has refused to permit entry.

The provisions in paragraph (c)(3) of § 211.1.9 that applied to foreign manufacturing facilities have been eliminated, since EPA no longer requires domestic manufacturers to consent to entry. It is still necessary for foreign manufacturers to work with EPA to assure that their testing is performed according to the regulatory requirements.

The EPA cannot determine the validity of manufacturers' tests if it cannot monitor them in some manner.

The Agency has deleted paragraph (f) of § 211.1.9, which specified that the Administrator may issue "cease to distribute" orders when EPA Enforcement Officers are refused entry or denied reasonable assistance because it is unnecessary. If a manufacturer denies entry where the EPA enforcement officer has obtained a warrant, the Act and this regulation will be violated, and the Administrator will consider using the option of the enforcement authorities granted him in Section 11 of the Act.

One commenter suggested that EPA limit its access to only those areas of a manufacturer's facilities that are relevant to the investigation, and specifying those areas in writing before the inspection period.

The Director of the Noise Enforcement Division may request that a manufacturer who is subject to this Part admit an EPA Enforcement Officer: to examine records of tests conducted by the manufacturer on label verification products and on products tested under compliance audit testing (CAT); to inspect the locations where testing is conducted, and where regulated products are stored before testing; and to inspect those portions of the assembly line where the regulated products are being assembled. EPA has no interest in entering the manufacturer's development laboratory or areas that are not concerned with a manufacturer's activities under the Noise Control Act of 1972.

One commenter objected to EPA photographing unfinished products, while another commenter objected to the photographing of any product because of the possibility that a competitor might obtain the information through a freedom of information request:

The manufacturer who may be affected by EPA photographing either finished or unfinished products would be able to file a request under § 2.203 of the EPA procedures for Confidentiality of Business Information (40 CFR Part 2 Subparts A and B). The Agency may determine at the time of the request whether the information requires confidential treatment. At that time EPA will give the manufacturer the opportunity to comment on why the material should be treated as business confidential (i.e., proprietary), and the manufacturer has the opportunity to pursue the matter in the courts before any of that material is released.

One commenter suggested that the provision of proposed § 211.1.9(f)(1) which states that the Administrator has the authority to issue "cease to distribute" orders, conflicts with Section

11(d)(1) of the Noise Control Act, since it does not limit the Administrator's authority to issue orders that are necessary to protect public health and welfare.

As previously explained, paragraph (f) of § 211.1.9 has been dropped as unnecessary.

J. Granting Exemptions

Some commenters objected to the exemption that the Agency could grant for promotional, demonstrator or prototype products that are not intended for commerce, because those products could be used improperly in advertising or display settings.

The only products that would require exemptions under this Section are those that are introduced in commerce. These regulations do not require the manufacturer to apply for exemptions for products that are not introduced in commerce (i.e., do not leave the manufacturer's premises), and does not have to fullfill any of the requirements of Subparts A or other Subparts that are promulgated under 40 CFR Part 211.

To qualify for an exemption from this regulation the manufacturer must demonstrate that the requested exemption is consistent with the reasons specified in Section 10(b)(1) of the Act.

Manufacturers who request an exemption under these regulations for promotional, demonstrator, or prototype products which will be introduced in commerce will be required to demonstrate: sufficient necessity for, appropriateness of, and reasonableness of the request; and the existence of adequate control over the product to satisfy EPA's monitoring requirements. EPA may withdraw an exemption at any time if the products included in the exemption request are used improperly.

One commenter objected to the requirement that the industry apply for an exemption for prototype products, due to possible delays in the exemption process.

Industry only has to apply for exemptions for prototype products that will be introduced into commerce. If, in the ordinary course of business, a manufacturer introduces prototype products into commerce for a valid exemption such as product development, assessing a production method, or as a market promotion, the manufacturer should expect no delays in receiving the exemptions. Where the program does not involve leases or sales of the product, the manufacturer only has to state the nature of the product's use, the number of products involved, and demonstrate the use of adequate recordkeeping procedures for product control purposes.

One commenter suggested an automatic exemption for all qualified products that are not intended for general commercial use.

At this time, EPA will not grant automatic exemptions for products introduced in commerce. Products and their containers that are intended solely for export must be labeled to show they are for export and are excluded from the restrictions of Section 10 of the Act unless they are distributed in commerce within the United States. The Noise Control Act requires the Administrator to take into account the public health and welfare in setting the terms and conditions of the exemption. Therefore, it will be necessary for the Administrator to take into account the public health and welfare, based on information that the manufacturer supplies to him for the particular product under consideration. However, if during the enforcement of this program the Agency finds that it is advisable to grant an industry-wide exemption for one or more purposes, EPA will set out this exemption and its terms and conditions and supply them to all manufacturers. Only after gaining some experience in administering this program will the Agency consider whether to grant "automatic" exemptions.

K. Testing by the Administrator

Several of the commenters were concerned about the costs of the required testing, and about the Administrator's authority to require products to be shipped to a test facility specified by EPA.

The cost of the required testing under Subpart B (such as label verification or compliance audit testing), or any of the following Subparts, will be borne by the manufacturer. EPA will bear the cost of testing that it conducts under § 211.1.11 (§ 211.111), Testing by the Administrator. However, EPA will not bear costs in the following circumstances: (1) when the EPA requires the manufacturer to ship products to a particular test site for label verification testing, because the manufacturer has not label verified within a reasonable amount of time (the product-specific regulation will define the amount of time considered reasonable); (2) when EPA has reason to believe that products would not pass the Federal test at an EPA designated site even though they pass at a manufacturer's site; (3) when an EPA issued "notice of nonconformance" of the manufacturer's test site is effective up to the time the site has been re-qualified; and (4) whenever EPA requires that products be shipped to a designated test site because the manufacturer refused to allow EPA Enforcement Officers with a warrant to monitor a test.

EPA will generally not specify a test facility for any required compliance audit testing unless it has reason to believe that products which pass the test at the facility used by the manufacturer would not pass at an EPA designated facility. Under these circumstances, the Administrator will provide the manufacturer a statement of the reasons.

One commenter suggested that the regulations spell out what direct and indirect testing costs EPA would reimburse.

As previously explained, only under § 211.111, Testing by the Administrator, EPA will bear the cost of testing. The cost of testing when it is conducted by EPA under § 211.111, Testing by the Administrator, will be borne by the Agency except:

1. When the EPA requires the manufacturer to ship products to a particular test site for label verification testing, because the manufacturer had not label verified within a reasonable amount of time. The amount of time considered reasonable will be defined in the product specific regulation;

2. When EPA has reason to believe that products would not pass at an EPA designated site even though they pass at a manufacturer's site;

3. When a notice of nonconformance of the manufacturer's test site is effective until the site has been re-qualified; and

4. Whenever EPA requires shipment of products to a designated test site because the manufacturer refused to allow EPA Enforcement Officers with a warrant to monitor a test.

When EPA designates that testing under § 211.111 be conducted at the manufacturer's facility, EPA personnel will conduct that testing, using Agency equipment. The Agency does not expect that the manufacturers will incur any direct testing costs under these circumstances.

One commenter questioned the legal authority of EPA personnel to operate a manufacturer's private test facility under § 211.1.11(a)(2).

This Section has been changed to state that the Administrator, when testing at a manufacturer's test facility, will use Agency equipment.

One commenter suggested a revision to limit the Administrator's discretion to require products to be tested by EPA at the manufacturer's facility.

EPA will be amenable to limiting the Administrator's discretion regarding the number of products tested under this

Section of the regulation. However, the limits placed on the Administrator's discretion will be based on particular industry characteristics, such as the number of manufacturers, the total number of products the manufacturers distribute in commerce, and other characteristics which the Administrator may consider appropriate. Because of their nature, these limits will have to be specified under the individual product Subparts of Part 211. Consequently, we will not change § 211.111 (§ 211.111) of Subpart A at this time, but we may amend this Section in the Subparts specific to other products.

III. Supporting Documentation

A document has been prepared which contains the results of study efforts instituted by the EPA in the development of the noise labeling General Provisions, and the detailed comprehensive discussion of all comments received during the public comment period. Copies of the document, entitled "Regulatory Analysis Supporting The General Provisions For Product Noise Labeling, August 1979", are available at: U.S. Environmental Protection Agency, Public Information Center (PM-215), 401 M Street, S.W., Washington, D.C. 20460, Phone: (202) 755-0717.

IV. Evaluation Plan

EPA intends to review the effectiveness and need for continuation of the provisions contained in this action no more than five years after initial implementation of the final regulation. In particular, EPA will solicit comments from affected parties with regard to cost and other burdens associated with compliance, and will also review data on any labeled products built after promulgation of the regulation to determine how effective this measure has been.

V. Reporting and Recordkeeping Requirements

Under the EPA's new "sunset" policy for reporting requirements in regulations, the reporting requirements in this regulation will automatically expire five years from the date of promulgation, unless the Administrator extends them. To accomplish this, a provision automatically terminating the reporting requirements at that time is included in the text of each product-specific regulation issued as a Subpart to Part 211.

I have reviewed this regulation and determined that it is not a significant regulation that requires the preparation of regulatory analyses as called for in Executive Order 12044. The Agency has, nonetheless, developed the documentation mentioned above to support this regulation.

This regulation is promulgated under the authority of 42 U.S.C. 4907.

Dated: August 30, 1979.

Douglas M. Costle,

Administrator, Environmental Protection Agency.

PART 211—PRODUCT NOISE LABELING

Part 211 Subpart A is added to 40 CFR and is to read as follows:

Subpart A—General Provisions

Sec.

Authority: Sec. 6 of the Noise Control Act of 1972, (42 U.S.C. 4907), and other authority as specified.

Subpart A—General Provisions

§ 211.101 Applicability.

The provisions of Subpart A apply to all products for which regulations are published under Part 211 and manufactured after the effective date of this regulation, unless they are made inapplicable by product-specific regulations.

§ 211.102 Definitions.

(a) All terms that are not defined in this subpart will have the meaning given them in the Act.

(b) "Act" means the Noise Control Act of 1972 (Pub. L. 92-574, 86 Stat. 1234).

(c) "Administrator" means the Administrator of the Environmental Protection Agency or his authorized representative.

(d) "Agency" means the United States Environmental Protection Agency.

(e) "Acoustic descriptor" means the numeric, symbolic, or narrative information describing a product's acoustic properties as they are determined according to the test methodology that the Agency prescribes.

(f) "Export exemption" means an exemption from the prohibitions of Section 10(a)(3) and (4) of the Act; this type of exemption is granted by statute under Section 10(b)(2) of the Act for the purpose of exporting regulated products.

(g) "National security exemption" means an exemption from the prohibitions of Section 10(a)(3) and (5) of the Act, which may be granted under Section 10(b)(1) of the Act in cases involving national security.

(h) "Product" means any noise-producing or noise-reducing product for which regulations have been promulgated under Part 211; the term includes "test product".

(i) "Regulations published under this Part" means all Subparts to Part 211.

(j) "Testing exemption" means an exemption from the prohibitions of Section 10(a) (1), (2), (3), and (5) of the Act, which may be granted under Section 10(b)(1) of the Act for research, investigations, studies, demonstrations, or training, but not for national security.

(k) "Test product" means any product that must be tested according to regulations published under Part 211.

§ 211.103 Number and gender.

In this Part, words in the singular will be understood to include the plural, and words in the masculine gender will be understood to include the feminine, and vice versa, as the case may require.

§ 211.104 Label content.

The following data and information must be on the label of all products for which regulations have been published under this Part:

(a) The term "Noise Rating" if the product produces noise, or the term "Noise Reduction Rating" if the product reduces noise;

(b) The acoustic rating descriptor that is determined according to procedures specified in the regulations that will be published under this Part;

(c) Comparative acoustic rating information, which EPA will specify in the regulations published under this Part;

(d) A product manufacturer identification consisting of: (1) The Company name, and (2) The City and State of the principal office;

(e) A product model number or type identification;

(f) The phrase "Federal law prohibits removal of this label prior to purchase";

(g) The U.S. Environmental Protection Agency logo, as shown in Figure 1;

(h) The phrase "Label Required by U.S. EPA regulation 40 CFR Part 211, Subpart ———."

EPA

Figure - 1

§ 211.105 Label format.

(a) Unless specified otherwise in other regulations published under this Part, the format of the label must be as shown in Figure 2. The label must include all data and information required under § 211.104.

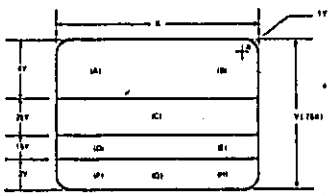

Figure - 2

(b) Unless EPA specifies otherwise in regulations published under this Part, the required data and information specified in § 211.104(a)–(h) must be located in the following areas of the prescribed label (see Figure 2 above):

(1) Section 211.104 (a)—Area A.
(2) Section 211.104 (b)—Area B.
(3) Section 211.104 (c)—Area C.
(4) Section 211.104 (d)—Area D.
(5) Section 211.104 (e)—Area E.
(6) Section 211.104 (f)—Area F.
(7) Section 211.104 (g)—Area G.
(8) Section 211.104 (h)—Area H.

§ 211.106 Graphical requirements.

(a) *Color.* Unless EPA requires otherwise, the product manufacturer or supplier must determine the colors used for the label background, borders, and all included letters, numerals, and figures. However, the colors on the label must contrast sufficiently with each other and with any information or material surrounding the label so that the label and the information within it are clearly visible and legible.

(b) *Label Size.* The prescribed label must be sized as specified in regulations published under this Part.

(c) *Character Style.* Except when specified otherwise in this Part, all letters and numerals that appear on the prescribed label must be Helvetica Medium.

(d) *Character Size.* All letters and numerals that appear on the prescribed label must be sized as specified in regulations published under this Part.

§ 211.107 Label type and location.

The prescribed label must be of the type and in the location specified in regulations published under this Part.

§ 211.108 Sample label.

Examples of labels conforming to the requirements of §§ 211.104, 211.105, and 211.106 are presented in Figure 3.

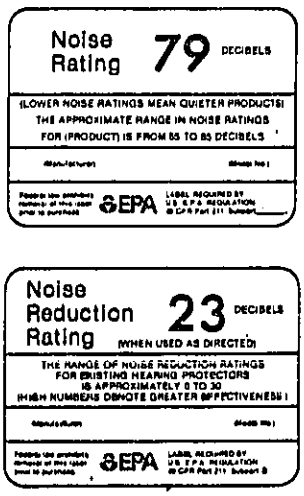

Figure - 3

§ 211.109 Inspection and monitoring.

(a) Any inspecting or monitoring activities that EPA conducts under this Part with respect to the requirements set out in regulations published under this Part, will be for the purpose of determining:

(1) Whether records required by the regulations are being properly maintained;

(2) Whether test products are being selected and prepared for testing in accordance with the provisions of the regulations;

(3) Whether test product testing is being conducted according to the provisions of those regulations; and

(4) Whether products that are being produced and distributed into commerce comply with the provisions of those regulations.

(b) The Director of the Noise Enforcement Division may request that a manufacturer who is subject to this Part admit an EPA Enforcement Officer during operating hours to any of the following:

(1) Any facility or site where any product to be distributed into commerce is manufactured, assembled, or stored;

(2) Any facility or site where the manufacturer performed or performs any tests conducted under this Part or any procedures or activities connected with those tests;

(3) Any facility or site where any test product is located; and

(4) Any facility or site where there are records, reports, other documents or information that the manufacturer must maintain or provide to the Administrator.

(c) (1) Once an EPA Enforcement Officer has been admitted to a facility or site, that officer will not be authorized to do more than the following:

(i) Inspect and monitor the manufacture and assembly, selection, storage, preconditioning, noise testing, and maintenance of test products, and to verify the correlation or calibration of test equipment;

(ii) Inspect products before they are distributed in commerce;

(iii) Inspect and make copies of any records, reports, documents, or information that the manufacturer must maintain or provide to the Administrator under the Act or under any provision of this Part;

(iv) Inspect and photograph any part or aspect of any product and any components used in manufacturing the product that is reasonably related to the purpose of this entry; and

(v) Obtain from those in charge of the facility or site any reasonable assistance that he may request to enable him to carry out any function listed in this Section.

(2) The provisions of this Section apply whether the facility or site is owned or controlled by the manufacturer, or by someone who acts for the manufacturer.

(d) For the purposes of this Section:

(1) An "EPA Enforcement Officer" is an employee of the EPA Office of Enforcement. When he arrives at a facility or site, he must display the credentials that identify him as an employee of the EPA and a letter signed by the Director of the Noise Enforcement Division designating him to make the inspection.

(2) Where test product storage areas or facilities are concerned, "operating hours" means all times during which personnel, other than custodial personnel, are at work in the vicinity of the area or facility and have access to it.

(3) Where other facilities or areas are concerned, "operating hours" means all times during which products are being manufactured or assembled; or all times during which products are being tested or maintained; or records are being compiled; or when any other procedure or activity related to labeling

verification testing, enforcement testing, or product manufacture or assembly is being carried out.

(4) "Reasonable assistance" means providing timely and unobstructed access to test products or to products and records that are required by this Part, and the means for copying those records or the opportunity to test the test products.

(e) The manufacturer must admit an EPA Enforcement Officer who presents a warrant authorizing entry to a facility or site. If the EPA officer does not have the warrant, he may enter a facility or site only if the manufacturer consents.

(1) It is not a violation of this regulation or the Act if anyone refuses to allow an officer without a warrant to enter the site.

(2) The Administrator or his designee may proceed *ex parte* (without the other party's knowledge) to obtain a warrant whether or not the manufacturer has refused entry to an EPA Enforcement Officer.

(Secs. 11 and 13, Pub. L. 92-574, 86 Stat. 1242, 1244 [42 U.S.C. 4910, 4912])

§ 211.110 Exemptions.

§ 211.110-1 Testing exemption.

(a) Except as provided in paragraph (f) of this section, any person who requests a testing exemption must demonstrate that the proposed test program:

(1) Has a purpose which is an appropriate basis for an exemption in accordance with paragraph (b) of this section;

(2) Shows a need for the granting of an exemption, as set forth in paragraph (c) of this section;

(3) Exhibits a reasonable scope as described in paragraph (d) of this section; and

(4) Exhibits a degree of control of the products that fulfills the purpose of the program and the EPA's monitoring requirements.

(b) An appropriate purpose for an exemption, as stated in Section 10(b)(1) of the Act, is one or more of the following: product research, investigations, studies, demonstrations, or training, but not national security (see § 211.110-2).

(c) Necessity for an exemption arises from an inability to achieve the stated purpose of a product noise labeling regulation in a practical manner without performing a prohibited act under Section 10(a) (3) or (5) of the Act. In appropriate circumstances, time constraints may be a sufficient basis for necessity.

(d) A test program must have a reasonable duration and affect a reasonable number of products. In this regard, the required items of information include:

(1) An estimate of the program's duration;

(2) The absolute number of products involved;

(3) The duration of the test;

(4) The ownership arrangement with regard to the products involved in the test;

(5) The intended final disposition of the products; and

(6) The means or procedure for recording test results.

(e) Paragraph (a) of this section applies no matter where the product is manufactured.

(f) Any manufacturer who requests an exemption for products that are used in the ordinary course of business for product development, production method assessment or market promotion, and that are not used in any way that involves lease or sale, must state only the general nature of the test or other program and the number of products involved. He must also demonstrate that he will employ adequate recordkeeping procedures for product control purposes. If the manufacturer does not receive a response from the Administrator within 15 working days from the day the Administrator receives the request, the exemption is granted for one year.

(Sec. 10(b)(1), Pub. L. 92-574, 86 Stat. 1242 [42 U.S.C. 4909(b)(1)])

§ 211.110-2 National security exemptions.

A manufacturer may request a national security exemption by submitting an application to the Administrator which states the purpose for which the exemption is required. The request must be endorsed by an agency of the Federal Government that is charged with responsibility for national defense.

(Sec. 10(b) (1), Pub. L. 92-574, 86 Stat. 1242 [42 U.S.C. 4909(b)(1)])

§ 211.110-3 Export exemptions.

(a) A new product intended solely for export, and which has satisfied the requirements of other applicable regulations of this Part, will be exempt from the prohibitions of Section 10(a) (3) and (4) of the Act.

(b) Requests for an export exemption are not required.

(c) For purposes of Section 11(d) of the Noise Control Act, the Administrator may consider any export exemption under Section 10(b)(2) void from the beginning if a new product, intended only for export, is distributed in commerce in the United States.

(d) In deciding whether to institute proceedings against a manufacturer, pursuant to Section 11(d)(1) of the Act, with respect to any product that was originally intended solely for export, but that was distributed in commerce in the United States, the Administrator will consider:

(1) Whether the manufacturer knew that the product would be distributed in commerce in the United States; and

(2) Whether the manufacturer made reasonable efforts to ensure that the product would not be distributed in commerce. Reasonable efforts would include: considering prior dealings between the manufacturer and anyone, which resulted in a product being introduced into commerce that was manufactured for export only; investigating prior instances that the manufacturer knew about, where a product that was manufactured for export only was introduced into commerce; and considering the provisions within a contract which minimize the probability that a product that was manufactured for export only will be introduced into commerce.

(Sec. 10(b)(2), Pub. L. 92-574, 86 Stat. 1242 [42 U.S.C. 4909(b)(2)])

§ 211.110-4 Granting of exemptions.

(a) After EPA completes the reviews of an exemption request, if EPA believes that it is appropriate to grant an exemption, it will prepare a memorandum of exemption and will submit it to the manufacturer who has requested the exemption. The memorandum will set forth the basis for the exemption, its scope, and the terms and conditions that are necessary to protect the public health and welfare. These terms and conditions will generally include the following agreements on the part of the applicant: to conduct the exempt activity in the manner described to EPA; to create and maintain adequate records that are accessible to EPA at reasonable times; to employ labels for the exempt products, setting forth the nature of the exemption; to take appropriate measures to assure that the applicant meets the terms of the exemption; and to inform EPA of the termination of the activity and the ultimate disposition of the products. EPA may limit the scope of any exemption by placing restrictions on time, location and duration.

(b) Any exemption that EPA grants under paragraph (a) of this section covers any product only to the extent that the manufacturer or his agents comply with the specified terms and conditions. A breach of any term or condition causes the exemption to be void from the beginning for purposes of

Section 11(d) of the Act, and may give rise to an order by the Administrator with respect to any product that is subject to the exemption, whether the product was distributed before or after the breach. The Administrator may also, upon notice to the manufacturer and with the opportunity for a hearing, withdraw the exemption at any time, if he determines that the public health or welfare is being endangered.

(Sec. 10(b)(1), Pub. L. 92-574, 86 Stat. 1242 (42 U.S.C. 4909(b)(1)))

§ 211.110-5 Submission of exemption request.

Address any requests for exemptions, or any requests for further information concerning exemption or the exemption request review procedure, to: Director, Noise Enforcement Division (EN-307), U.S. Environmental Protection Agency, Washington, D.C. 20460, (703) 557-7470.

(Sec. 10(b)(1), Pub. L. 92-574, 86 Stat. 1242 (42 U.S.C. 4909(b)(1)))

§ 211.111 Testing by the Administrator.

(a)(1) To determine whether products conform to applicable regulations under this Part, the Administrator may require that any product that is to be tested under applicable regulations in this Part, or any other products that are regulated under this Part, be submitted to him, at a place and time that he designates, to conduct tests on them in accordance with the test procedures described in the regulations.

(2) The Administrator may specify that he will conduct the testing at the facility where the manufacturer conducted required testing. The Administrator will conduct the tests with his own equipment.

(b)(1) If, from the tests conducted by the Administrator, or other relevant information, the Administrator determines that the test facility used by the manufacturer(s) does not meet the requirements of this Part for conducting the test required by this Part, he will notify the manufacturer(s) in writing of his determination and the reasons for it.

(2) After the Administrator has notified the manufacturer, EPA will not accept any data from the subject test facility for the purposes of this Part, and the Administrator may issue an order to the manufacturer(s) to cease to distribute in commerce products that come from the product categories in question. However, any such order shall be issued only after an opportunity for a hearing. Notification of this opportunity may be included in a notification under paragraph (b)(1) of this section. A manufacturer may request that the Administrator grant a hearing. He must make this request no later than fifteen (15) days (or any other period the Administrator allows) after the Administrator has notified the manufacturer that he intends to issue an order to cease to distribute.

(3) A manufacturer may request in writing that the Administrator reconsider his determination in paragraph (b)(1) of this section, if he can provide data or information which indicates that changes have been made to the test facility, and that those changes have remedied the reason for disqualification.

(4) The Administrator will notify a manufacturer of his decision concerning requalifying the test facility within 10 days of the time the manufacturer requested reconsideration under paragraph (b)(3) of this section.

(c)(1) The Administrator will assume all reasonable costs associated with shipment of products to the place designated pursuant to paragraph (a) of this section, except with respect to:

(i) Any label verification testing performed at a place other than the manufacturer's facility as provided for in the Section titled Label Verification of the product-specific Subpart or as a result of the manufacturer's not owning or having access to a test facility;

(ii) Testing of a reasonable number of products for purposes of compliance audit testing under the Section titled Compliance Audit Testing of the product-specific Subpart, or if the manufacturer has failed to establish that there is a correlation between his test facility and the EPA test facility or the Administrator has reason to believe, and provides the manufacturer with a statement or reasons, that the products to be tested would fail to meet their verification level if tested at the EPA test facility, but would meet the level if tested at the manufacturer's test facility;

(iii) Any testing performed during a period when a notice issued under paragraph (b) of this section, is in effect; and

(iv) Any testing performed at place other than the manufacturer's facility as a result of the manufacturer's failure to permit the Administrator to conduct or monitor testing as required by this Part.

(Secs. 11 and 13, Pub. L. 92-574, 86 Stat. 1243 (42 U.S.C. 4910, 4912))

[FR Doc. 79-30097 Filed 9-27-79; 8:45 am]

BILLING CODE 6560-01-M

40 CFR Part 211

[FRL 1270-3]

Approval and Promulgation of Noise Labeling Requirements for Hearing Protectors

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This notice establishes noise labeling requirements for hearing protectors under the authority of the Noise Control Act of 1972 (42 USC 4901 et seq.). These requirements were proposed in the Federal Register on June 22, 1977 (42 FR 31730) and have been modified to reflect the public comment.

These labeling standards require hearing protector manufacturers to state, on a clearly visible label and in a uniform manner, the noise reducing effectiveness of all hearing protectors which are sold in the United States.

The final rule provides a uniform test methodology for determining the noise reducing effectiveness of, and specifies a uniform rating scheme (Noise Reduction Rating in decibels) for stating the effectiveness of, all types of hearing protectors. It requires that information supporting the notice of effectiveness be supplied with the protector. It also provides the procedures for enforcing the labeling requirements.

The intent of this labeling requirement is to ensure that information on the noise reducing effectiveness of hearing protectors is available to prospective users of these devices, so that they will be capable (using this information) of selecting a device which can adequately protect their hearing in a given noise environment.

EFFECTIVE DATE: September 28, 1979.

ADDRESS: Written data, comments or views may be submitted to the: Director, Noise Enforcement Division (EN-307), U.S. Environmental Protection Agency, Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Timothy McBride, Standards and Regulations Division (ANR-490), or phone (703) 557-2710.

SUPPLEMENTARY INFORMATION:

I. Introduction

Effective September 27, 1980, this regulation, Subpart B of 40 CFR Part 211, requires manufacturers of hearing protectors sold in the United States to give notice to prospective users of their products, of the effectiveness of their products in reducing noise. This notice shall be given according to the labeling requirements of Subpart A of 40 CFR Part 211 (General Provisions—Product

Noise Labeling) and those additional requirements of Subpart B.

In order to provide this notice, this regulation requires manufacturers to test all categories of protectors in their product line according to the American National Standards Institute Standard (ANSI STD) S3.19–1974. This procedure measures the level of noise reduction developed by a protector or a category of protectors at specific frequencies.

The regulation specifies the method by which a manufacturer will uniformly convert, into a Noise Reduction Rating (NRR) in decibels, the measured levels of noise reduction for each category of protectors in his product line.

Manufacturers must state the NRR specific to a category of protectors on a label affixed or appended to every protector (or its packaging) that comes from that category. The manner in which the label is affixed to the protector or its packaging depends on how the protector is displayed for sale to the ultimate purchaser or for distribution to the prospective user.

The regulation requires that the manufacturer who packages the protector for ultimate distribution in commerce be identified on the label. That manufacturer is held responsible for the accuracy of the information on, and the visibility of, the label at the point of sale to the ultimate purchaser or distribution to the prospective user.

The label must also present information on the range of NRRs for existing protectors against which the ultimate purchaser or user can assess a specific protector's relative effectiveness in reducing noise. The "comparative range" data was determined by using data from the National Institute for Occupational Safety and Health publication (NIOSH 76–120) in the Noise Reduction Rating computation procedure in § 211.207 of the regulation. It is provided by EPA in this rule, and will be updated by EPA, as necessary, through a technical amendment to the regulation published in the Federal Register.

In order to assure that the NRR for a protector or a category of protectors is correct, the manufacturer is required to test each category of protectors in his product line to initially establish their NRRs. He is further required to maintain records to adequately substantiate these NRRs, and to submit reports of these test results to the Agency. The Agency may require that compliance audit testing be performed on specified protectors to assure that these products comply with their initially established label value. The Administrator may also require a manufacturer to relabel his hearing protectors entered into the distribution chain after the effective date of the regulation, or to take other reasonable steps necessary to remedy a violation of these requirements.

Supplementary to this rule, the Agency published a Regulatory Analysis [1] which includes a detailed study of hearing protectors, the industry, test procedures, analysis of public comments to the docket, and a list of all commenters.

II. Background

In the Noise Control Act of 1972 (The Act) (42 USC 4901 et seq.), "Congress declares that it is the policy of the United States to promote an environment for all Americans free from noise that jeopardizes their health or welfare." To further this policy, Section 8(a)(2) of the Act requires the Administrator of the Environmental Protection Agency (EPA) to designate by regulation any product "* * * sold wholly or in part on the basis of its effectiveness in reducing noise." It also requires that "for each such product (or class thereof) the Administrator shall by regulation require that notice be given to the prospective user * * * of [the product's] effectiveness in reducing noise, * * *" The regulation must specify "whether such notice shall be affixed to the product or to the outside of its container, or to both, at the time of its sale to the ultimate purchaser or whether such notice shall be given to the prospective user in some other manner." The regulation must also specify "* * * the form of the notice, and * * * the methods and units of measurement to be used."

Hearing protectors are principally sold on the basis of their ability to attenuate the level of sound entering a person's ear. The amount of sound attenuation provided by the broad range of insert and muff type protectors currently on the market varies widely. There are devices designed primarily to prevent water from entering a swimmer's ears that are frequently misused as hearing protectors. There are devices that can be purchased merely to reduce annoying sounds in a person's environment to levels that may permit sleep, study or relaxation. While these devices may afford a measure of sound reduction, their effectiveness in high noise environments may be marginal. Users of devices which give insufficient hearing protection for a particular noise environment can sustain permanent hearing loss because of exposure to levels of noise from which they believe they are protected.

In some cases, it is impractical to control noise at the source or along the propagation path sufficiently to protect the hearing of a person exposed to the noise. In these circumstances, the use of hearing protectors may be the only practical means of noise control on a short-term basis.

For a prospective user of hearing protective devices to make an informed choice of a protector for use in a particular noise environment, that person should be able to determine the level of hearing protection offered by a given hearing protector, and its effectiveness relative to other hearing protectors. This information is not now readily available to the prospective user.

The Agency announced its intention to consider the labeling of hearing protectors, under the authority of Section 8(a)(2) of the Act, through the publication of an Advanced Notice of Proposed Rulemaking (ANPRM) on December 5, 1974 (39 FR 42380).

The ANPRM established a public comment period for 60 days which closed on February 1, 1975, and solicited comments from all interested parties prior to the Agency undertaking the development of a regulation.

We received a total of 9 written comments to the ANPRM docket from the hearing protector industry and trade associations; laboratories involved in acoustic testing; and government agencies that use protectors or specify protector effectiveness, construction, composition or packaging requirements. These commenters recommended measurement standards and label placement and content, questioned the validity of single number rating schemes, and submitted examples of various protector characteristics and packaging. The Agency also sent letters to selected manufacturers and distributors of hearing protectors requesting information on manufacturing costs, manufacturing processes, marketing processes, extent of the market, numbers and types of protectors manufactured, and each manufacturer's share of the market. This was done because of the limited amount of this type of information obtained from comments to the ANRPM, and the Agency's desire to get this data so it could adequately assess the effect of various methods of hearing protector labeling.

EPA has worked closely with the National Institute for Occupational Safety and Health (NIOSH), the United States Air Force Aerospace Medical Research Laboratory (AMRL), the Federal Aviation Administration Civil Aeromedical Institute, and the Mine Safety and Health Administration to

[1] Regulatory Analysis Supporting the Labeling of Hearing Protectors; EPA 550/9-79-250, August, 1979.

develop test procedures and coordinate labeling requirements.

The EPA published a Notice of Proposed Rulemaking (NPRM) for Noise Labeling Requirements for Hearing Protectors on June 22, 1977 (42 FR 31730), and established a public comment period for 90 days which closed on September 20, 1977; public hearings were deferred pending public response. During this period we received 52 written comments. We also received 3 oral and 7 written comments pertaining to hearing protectors which had been directed to the concurrently established public comment period for the proposed General Provisions (Subpart A) for Product Noise Labeling (40 CFR Part 211). Because of a computerization program undertaken since the promulgation of the proposed rule, it was necessary in the final rule of both Subparts A and B to either replace the second decimal point in each section heading with a zero or delete it entirely.

As a result of written comments to the docket the Agency decided that, to fully understand the problems the hearing protector industry expressed in their comments, and to better clarify certain elements of the proposed rule, a public meeting was in the best public interest.

The Agency published a notice of the public meeting in the Federal Register on December 2, 1977 (42 FR 61289). The meeting was held on December 13, 1977 at the Agency's Office of Noise Abatement and Control in Arlington, Virginia. Attendees included manufacturers, the industry trade association, several members of the user industry; and Federal representatives. Oral comments were received from 10 speakers. The transcript of this meeting has been available for public review at the EPA Public Information Center, Washington, D.C.

Comments from industry during the NPRM comment period and from the public meeting were critical of various elements of the proposed regulation, but were not generally opposed to the concept of labeling hearing protectors with respect to their effectiveness. Comments from private citizens and user-industries were for the most part supportive of the proposed labeling rule. The range of issues covered in the comments is extensive, encompassing all aspects of the Federal noise labeling program.

The following discussion addresses only the major issues associated with the labeling of hearing protectors. Issues related to general labeling have been addressed in the General Provisions of this rule.

The Agency carefully reviewed and considered all information received from industry and the public on the potential impact a Federal labeling requirement might engender: on the cost of hearing protectors; on manufacturers' production processes; and on their packaging procedures. We reassessed the designated test methodology, availability of test facilities, enforcement procedures, and labeling responsibilities.

By making minor changes to the proposed requirements, the Agency has concluded that this regulation will result in the dissemination of adequate information to the prospective user of hearing protectors with minimum adverse impact on the industry.

The detailed comments and information presented to the Agency and the Agency's responses to the comments are contained in the Docket Analysis section of the Regulatory analysis.[2] A complete list of commenters is presented as an appendix within the document.

III. Discussion of Major Issues

General Issues

Several commenters questioned the Agency's statutory authority. They believed that EPA had exceeded its authority in proposing the labeling of hearing protectors, and that the Agency abused its discretionary authority and was "arbitrary and capricious".

The Act specifically states in Section 6(a)(2) that "the Administrator shall by regulation designate any product (or class thereof) which is sold wholly or in part on the basis of its effectiveness in reducing noise." This is a non-discretionary requirement for the Agency. As directed, the Administrator has designated all hearing protective devices as products which are sold wholly or in part on the basis of their effectiveness in reducing noise.

EPA is clearly authorized to require labeling of such designated products. Section 6(b) of the Act states that "for each product (or class thereof) designated under Subsection (a), the Administrator shall by regulation require that notice be given to the prospective user of the level of [the product's] effectiveness in reducing noise".

To effectively carry out the non-discretionary mandate in Section 6 which requires the Administrator to label noise-reducing products, the Agency conducted an investigation into hearing protective devices to identify both the effectiveness rating technique and the information most useful to the consumer. The Agency requested detailed data from the protector industry, consulted with other government organizations, analyzed and considered information received in response to the ANPRM on hearing protectors, and assessed the possible economic effects of Federal labeling and compliance requirements on the industry. The Agency has established the basis and background to support this regulatory action.

Several commenters stated that EPA has the authority to require only the effectiveness rating on the label, not such items as the comparative range, the EPA logo and a statement prohibiting removal of the label.

Section 8 of the Act requires that notice be given to a prospective user of the effectiveness of a product in reducing noise. As part of the notice given by the label, the Agency has developed, and will supply to the industry with periodic updating, the comparative range for hearing protectors as a complement to the effectiveness rating on the label. The effectiveness rating, by itself, would not indicate to the prospective user the available range of effectiveness ratings offered by hearing protectors, nor would it show the effectiveness of a specific protector relative to the noise reducing effectiveness available from other protectors. The comparative range information is intended to give support to the use of the NRR as a means of choosing an adequate hearing protector for a given noise environment. We believe that comparative range information on the label is a key element to the total notice of a protector's noise reducing effectiveness that is supplied by the label.

The Agency addressed in detail, within the General Provisions for Product Noise labeling, the requirement for the EPA logo on the label. In brief, the appearance of the logo on the label is intended to notify an ultimate purchaser or the prospective user that the label is Federally mandated across the industry, its contents are uniform and that the ratings are credible.

The inclusion of a statement prohibiting removal of the label before sale to the ultimate purchaser is based on the prohibition of Section 10(a)(4) of the Act. Removal of the label from a protector before it is sold to the ultimate purchaser is a violation of the Act. The person who removes the label is subject to District Court actions to restrain violations as provided by Section 11(C), as well as to a remedial order that the Administrator may issue under Section 11(d) of the Act. This restriction is important for the public to know.

[2] *Ibid.*, p. 62 et seq.

Another general issue raised by several commenters was the possibility of conflict between this labeling requirement and the labeling programs or product packaging requirements of other Federal agencies.

Particular concern was expressed over possible conflict between the Agency's labeling program and the certification program being developed by the National Institute for Occupational Safety and Health (NIOSH).

The Agency worked closely with NIOSH in the development of its requirements for the labeling of hearing protectors to ensure that the two programs would be complementary.

We will continue to coordinate activities with NIOSH to assure that the two programs work together, and produce no conflict or redundancy.

The Agency explored the possibility of conflict with Department of Defense Military Specifications (DOD MIL. SPEC.) on product and product package labeling. DOD MIL. SPEC. experts assured us that there were no apparent conflicts, and that if conflict should develop, the specifications would be changed to incorporate the Agency's regulatory requirements.

Label Content and Information

Several commenters questioned the limits EPA proposed for the comparative range of effectiveness ratings for hearing protectors. They felt that the values picked (i.e., "0" and "31") implied precision in the range that was not supportable by fact. According to information supplied by the industry and various testing laboratories, the upper end of the range of hearing protectors using the designated measurement standard could potentially be as high as 35 or as low as 25. Several commenters suggested that the range be stated as "approximate." They felt that an approximate range would allow for changes in the limits of the range resulting from deletion of protector models from, or addition of protector models to, the market, or from a breakthrough in hearing protector technology; yet the information that EPA wishes the prospective user to have would still be available. Manufacturers also wished to know how the comparative information would be developed. Would they have to perform their own research?

The Agency agrees that the range of Noise Reduction Ratings for hearing protectors may possibly change with time. Consequently, the rule has been changed so that the range information to be stated on the label will read "the range of Noise Reduction Ratings for existing hearing protectors is approximately 0 to 30." We determined this range by using data from the National Institute for Occupational Safety and Health publication (NIOSH #76-120) in the Agency's method for computing the NRR.

The Agency will examine the NRR values that manufacturers, as part of their compliance requirements, must report in the Labeling Verification Report as Labeled Values.

If analysis of the reported NRR values indicates that the initially specified comparative range information is not representative of available hearing protectors, the Agency will, within eighteen (18) months from the date of promulgation of this rule, publish in the Federal Register a technical amendment to this rule stating the revised range information. Manufacturers will have one year from the date the revised range information is published to change their labels.

The Agency will continue to monitor the reported NRR values annually, will publish further revisions to the comparative range as required, and will consider publishing, for public dissemination, a composite list of the NRRs for all hearing protective devices.

Commenters suggested that the Noise Reduction Rating (NRR)—as the acoustic descriptor for the label—could potentially cause purchasers or users of protectors to emphasize the NRR and neglect information concerning the effective use of a protector when making their selections.

The Agency acknowledges that certain information (for example, importance of protector fit, purchase price, durability of the protector's materials and the protector's noise reducing effectiveness at specific frequencies) would not be contained in a single number rating. It is for this reason that supporting information (for example, the presentation of the protector's noise attenuation values at specific test frequencies, and instructions on how to properly fit the protector to realize its maximum noise attenuation potential) is required to be supplied with the protector at the point of sale to the ultimate purchaser or distribution to the prospective user.

Commenters familiar with acoustics expressed concern over possible misinterpretation of NRR, the abbreviation of Noise Reduction Rating, with the abbreviated name of a popular noise related publication; or the possibility of making the value of the NRR proportional to the upper end of the comparative range in order to obtain the percent of cases in which a protector would be effective (e.g. range = 0 to 30, NRR = 20, the protector is effective in 20/30 or 66% of all cases).

That it is possible to misinterpret a descriptor abbreviation, or to misuse the numbers associated with a descriptor, is a problem that is common to every type of descriptor. However, the Agency believes that the NRR, the descriptor chosen to depict the noise reducing effectiveness of hearing protectors, has uniformity, objectivity, precision, understandability, and the relative familiarity of the user population with the decibel (dB) base of the descriptor.

There is a very close relationship between the NRR and the amount of "A"-weighted noise reduction to be expected from a protector if used in a noise environment that is not dominated by frequencies below about 500 Hz. For example, if a measured "A"-weighted [3] noise level is 92 dB (A), and if a protector with a NRR of 20 decibels is being worn properly in that environment, the level of noise entering the ear would be approximately 72 dB (A). This simple procedure offers a first order estimate of potential exposure when wearing a given protector.

In a noise environment dominated by frequencies below approximately 500 Hz, the NRR should be subtracted from the "C"-weighted [4] environmental noise level.

Considerable comment centered on the identification of the manufacturer of the protector on the label. In many cases, manufacturers stated, they simply produce the protector and do not package it for distribution into commerce.

Other commenters expressed opposition to the possibility that by being identified on the label, they could be held responsible for label verification of protectors that they make, but which are later incorporated into combination units or changed in other ways.

Considering both of these points, the Agency believes that the statutory definition of "manufacturer" adequately identifies the party responsible for: label verification of the protector; labeling the protector or its packaging; assuring the accuracy of the information on the label; and assuring the visibility of the label at the point of sale to the ultimate purchaser or distribution to the prospective user. We have, therefore, simply required that the "manufacturer", as defined in the Act, be identified on the label. The manufacturer packaging

[3] "A"-weighting is intended to match the response of the ear to sound of low-intensity, and discriminates against low frequency sound (used by Occupational Safety and Health Administration when regulating noise in the workplace).

[4] "C"-weighting is intended to match the response of the ear to sound of high intensity.

the protector for ultimate purchase or use is to be named on the label, is to assure that the information which must accompany the protector as supporting information (and from which the NRR is determined) is provided in the packaging and is to assure the accuracy of the information on the label. The "manufacturer" who packages and/or distributes the product may elect to either use the information provided by the product "manufacturer" who label-verified the protector, or to retest the protector.

Label Size, Placement and Packaging

Major concerns of several commenters were directed to EPA's proposed label size and placement, and to the associated possible need for significant changes to the manufacturing of and/or packaging of their product. Several commenters stated that there should be no minimum limits on the size of the label, for many protectors presently have different packaging requirements. They also commented that there should be a dual system of labeling because of the two very different markets served—industry and individual purchasers. Some of the protectors supplied to industrial customers are packaged in bulk with primary panels (defined in § 211.203 of the regulation) much smaller than the proposed minimum label size.

The Agency's original intent was to label every protector, regardless of market and packaging method, as to its effectiveness in reducing noise, and to have the label visible at the point of sale to purchasers or distribution to users.

We have changed the requirements for the labeling of protectors to allow the continuation of present industry marketing practices and packaging methods. Small protectors are often packaged in bulk quantities for reasons of economy when supplying industrial users. To require that bulk-packaged protectors be individually labeled with a visible minimum-sized label would cause an inappropriately large increase in costs to the industrial user. For sales of protectors to individuals, however, economy-of-scale packaging does not appear to be a factor based on statements from manufacturers and distributors.

While there might be extensive packaging changes resulting from the requirement that protectors be labeled with a minimum sized label, labels of a size smaller than 3.8 × 5.0 centimeters (cm) (approximately 1 ½ × 2 inches) with correspondingly smaller print are practically non-informative because of their illegibility. Therefore, the Agency maintains that the label must be no smaller than 3.8 × 5.0 cm.

However, in requiring that the minimum label size be 3.8 × 5.0 cm, the Agency has developed the following labeling criteria based on the means used to display them at the point of ultimate purchase or distribution to the prospective user. In the case of bulk packaging and dispensing, the supporting information must be affixed to the container in the same manner as the label and in a readily visible location.

(1) If the protector is individually packaged and so displayed at the point of ultimate purchase or distribution to users, the package must be labeled as follows:

(a) If the "primary panel," as defined in § 211.203 of the regulation, of the package has dimensions greater than 3.8 x 5.0 cm, the label must be presented on the primary panel.

(b) If the primary panel of the package is equal to or smaller than 3.8 x 5.0 cm, a label at least 3.8 x 5.0 cm must be affixed to the package in the form of a tag.

(2) If the protector is displayed at the point of ultimate sale or distribution to users in a permanent or disposable bulk container or dispenser, even if the protector is individually packaged within the dispenser and labeled as above, the container or dispenser itself must be appropriately labeled. The label must be readily visible to the ultimate purchaser or prospective user.

Labeling of the "Dispenser", as defined in § 211.203 of the regulation, requires that the accompanying protectors *not* be separated from the dispenser before ultimate purchase. Separation is tantamount to removal of the label which is prohibited by Section 10(a)(4) of the Act.

There were several comments concerning the placement of labels and clarification of "affixing" labels. Commenters also suggested that there should be some latitude in how labeling can be accomplished. Section 211.2.4–3 of the NPRM, which dealt with "Label Location and Type", was not meant to exclude "hang tags" as a labeling device, as was apparently feared by one manufacturer. The purpose of the label, as stated in the NPRM and in Section 8 of the Act, is to give notice to the prospective users of hearing protectors concerning the noise reducing effectiveness of the product. This is to be accomplished by making the information available before actual sale or use. It is the element of visibility of the label at the point of purchase or use that is of paramount importance. If the label is not visible to the ultimate purchaser or prospective user prior to purchase or use, then the information on the label will be of limited practical value.

Manufacturers may use any labeling means available as long as the labeling requirements are met.

Test Methodology

The test methodology, as proposed, was an issue that elicited considerable comment. One area of concern was the cost associated with the proposed use the American National Standards Institute Standard (ANSI Std) S3.19–19 as the Agency's test methodology. This standard is a subjective test using ten (10) human subjects tested three (3) separate times with different pairs of t same model hearing protector. The test was seen by several commenters as to costly, not repeatable, and not properly accounting for the effects of the fit of a protector on its noise reducing ability. Manufacturers would also have preferred an "objective test" [6] over the proposed test in the interest of test repeatability and reduced cost.

The Agency tries to use measuremen standards from voluntary standard setting organizations that have been developed, validated and in use. We determined, however, after consultatio with experts, that there are at present accepted standards for objective tests suitable for testing all types of hearing protectors. Data from various existing objective tests have not, to date, correlated well with results from other proven and accepted test standards. Th Agency determined, however, that objective testing could be used by manufacturers as a production process screening method, but not as a method for labeling verification. If a breakthrough should occur, such that a national or international standard is developed for an objective method that permits reliable testing of all hearing protectors to the accuracy of the presen subjective test method, the Agency will consider it as a candidate to replace th present method.

The Agency encourages the development of subjective and objectiv test methodologies. Procedures that have been demonstrated to correlate with the prescribed procedure should b submitted to the Agency for consideration as alternate methodologies or replacements to the procedure in this regulation.

[6] A procedure, using microphones inside and outside of an enclosure (e.g. dummy head) to simulate an ear, that measures the differences in a known level of sound (inside and outside of the enclosure) resulting from an obstruction (e.g. hearing protector) in the normal path of the sound the interior microphone.

The Department of Defense and several major industries that are affected by the Occupational Safety and Health Administration's (OSHA) rules, are already requesting effectiveness data on hearing protectors from manufacturers. Thus, with respect to the costliness of the method, the majority of manufacturers already include in their prices the costs of testing protectors to develop effectiveness ratings. This is addressed in greater detail under the section titled "ECONOMIC EFFECT".

The Agency gave careful consideration to a comment that the test method requires a report of the force that the headband produces, and its effect on the noise reducing effectiveness of protectors that use headbands as their principal means of attachment. The test method does not state how the data is to be derived for hardhat hearing protectors. EPA concluded, after conferring with technical experts, that the "band force", as derived in the standard, was designed to measure only "muff" type protectors that actually employ a band as the means of clamping the protectors to the user's head. Hearing protectors combined with hardhats do not normally depend on a headband for clamping force. However, until another measurement method is devised that adequately measures the clamping procedure used by hardhat hearing protectors and relates this to their Noise Reduction Rating, the mean attenuation levels at the test frequencies and the NRRs for this type of protective device must be derived according to the designated measurement method. When a validated procedure is available, an exception may be requested; and the Agency will review the request.

As labeling was proposed in the NPRM, the NRR reported for "muff" type protectors would have been that of the use position providing the lowest protection. This number alone would neither inform the ultimate purchaser or prospective user which position was labeled, nor would it indicate the NRR values of the other use positions. As a result of comments requesting notice of the NRRs of other use positions, and after conferring with technical experts, the Agency concluded that testing of all possible use positions of "muff" protectors is necessary. The NRR for the worst position will be labeled, and that position noted on the label. The NRRs for other positions will be included in the supporting data.

Commenters stated that there is neither a sufficient availability of laboratories capable of testing hearing protectors in the proposed manner, nor are the laboratories capable of handling the numbers of tests to be required. We consulted with experts on this subject and were assured that adequate facilities would exist given adequate lead time before the effective date. As a result of this consideration, the effective date has been extended from six months to one (1) year from the date of promulgation, which should assure sufficient availability of laboratory test facilities to accomplish the required testing.

Those laboratories now capable of testing protectors according to the required test method are: the Pennsylvania State University (Environmental Acoustics Laboratory, State College, PA), the Worcester Polytechnic Institute (Worcester, MA), the U.S. Naval Air Station (Pensacola, FL), the U.S. Aviation Center (Ft. Rucker, AL) and the National Institute for Occupational Safety and Health (Morgantown, WV).

Commenters suggested that protector performance variability from test-to-test and between testing laboratories is probable, considering the requirement in the NPRM for "subject fit" of the protector for the test.

The Agency concluded, after conferring with both private and government testing laboratory technical experts, that "experimenter fit", (i.e. the hearing protector is fitted to the test subject by the experimenter) rather than "subject fit" (where the test subjects fit themselves with the protectors), should be required.

While "subject fit" results in a more subjective rating of a protector, it also produces values of noise attenuation that spread much more widely about the "mean" (average) attenuation value for a test frequency. Consequently, enforcement procedures based on a test using "subject fit" would have to allow greater variability in the values derived from the test. This dispersion of values about the "mean" reduces the possibility of reproducing the attenuation values from test-to-test, and thus the test is less strictly enforceable.

"Experimenter fit", however, ensures greater consistency in the "fit" of the protector to all subjects, which tends to reduce the test-to-test variability.

We have examined the potential for variability in the test between facilities, and agree that there may be variations in measured attenuation from facility to facility as a result of slight differences in the physical facilities or in the way the facility implements the test. However, because of the modification of the test procedure to require "experimenter fit", we believe these variations to be small. Furthermore, the procedure of itself will reduce variations between test facilities because of the 30 tests required during labeling verification to obtain a single NRR for a category of protectors. The consensus of technical experts was that manufacturers will take possible variations between test facilities into account in designating NRRs for their protectors.

Commenters suggested that test result variability between laboratories might possibly cause protectors to be out of compliance merely as a result of Compliance Audit Testing at a laboratory different from that used for testing for labeling verification.

Compliance Audit Testing (CAT) may occur at any laboratory capable of testing according to the Agency's method, but in most cases it will take place at the laboratory used for Labeling Verification (LV). Any variabilities that would exist between two valid laboratories should be readily identifiable and included in the NRR value on the label. Also, the Agency has included a 3 dB(A) variability factor to be used in Compliance Audit Testing. The mean attenuation value at any one of the test frequencies (as measured during Compliance Audit Testing) plus the 3 dB(A) variability factor must be equal to or greater than the mean attenuation value, for the same test frequency, that is reported in the supplementary information which must accompany each protector. We believe that this resolves the potential test variability problem.

Noise Reduction Rating (NRR)

Commenters stated that the computation for the NRR should be understandable to those parties who are required to comply with this regulation; that logarithmic mathematics were not necessary to develop a NRR; and that the computations should be simpler. EPA conferred with technical experts and concluded that, for the sake of simplicity and greater understandability in the calculation of the NRR, we would implement a simplified method. The procedure for NRR calculation is demonstrated in Figure 2 of the regulation.

Special Claims and Exemptions

Several commenters stated that the proposed hearing protector labeling test methodology is not appropriate for non-linear hearing protectors, i.e. hearing protectors that do not begin to attenuate noise until a specific sound pressure level is reached. The low sound pressure levels of the test method are not sufficient to activate the non-linear protector and thus the Noise Reduction Rating determined from this test would

be essentially zero. The commenters claim that this low NRR would be injurious to sales since it would not reflect the claimed unique operating characteristics for these devices. One commenter requested an exception from the regulation for non-linear protectors.

EPA maintains that all hearing protectors must come under the same regulatory requirement, unless an exception is requested and technically supported as required in § 211.205. A request for exception to the prescribed test methodology and NRR must be accompanied by an alternate test procedure and a rating scheme suitable to the purpose of these regulatory requirements. The suggested test methodology, rating scheme, and scientific data conclusively supporting the requested exception must be submitted for consideration and approval to: Director, Noise Enforcement Division (EN-397), U.S. Environmental Protection Agency, Washington, D.C. 20460. If approved, the alternate method and rating scheme would apply to all hearing protectors of like design. Until a requested exception is approved, labeling of the product must adhere to the prescribed requirements.

The Agency will notify the manufacturer within 30 days if the request is approved, or if additional information or time is required for the Agency to properly consider the request.

The recordkeeping and reporting requirements proposed for special claims of acoustic effectiveness have been reduced. The Agency is not requiring manufacturers to obtain Agency approval of their suggested special claims before presenting them to the public; however, manufacturers wishing to make special claims about the noise reducing effectiveness of their devices, other than the Noise Reduction Rating (NRR), must be prepared to demonstrate the validity of those claims. Claims made in advertising are subject to Federal Trade Commission (FTC) regulations.

Several commenters stated that new products (prototypes, unmarketed new designs) should not be required to comply with the regulation for a period of twelve (12) months; otherwise product innovation would be hampered.

The rule applies to new products (the equitable or legal title of which has never been transferred to an ultimate purchaser) manufactured on or after the stated effective date. Exemptions from the requirements can be requested for prototype devices according to § 211.110 of Subpart A. Products that enter commerce before the effective date of this rule are not required to comply with the labeling requirements of this regulation. The manufacturer may label protectors produced up to 6 months before the effective date of the regulation, as stated in § 211.210-3(f) of the regulation, if the Agency is allowed to monitor the early label verification testing, and the testing is done with production-line protectors.

Label Verification

Several commenters questioned the necessity of yearly testing of every category of protector where no changes have been made which would affect the protector's attenuation characteristics. Based on these comments, the label verification requirement has been revised. It requires that a manufacturer test each category of protector once, and retest only if changes are made to the category which would affect its attenuation. New categories of protectors introduced into commerce must, of course, be tested and labeled according to the regulation.

The Agency decided to drop the annual labeling verification test requirement based, in part, on its plan to conduct tests on protectors selected off-the-shelf to determine whether they are labeled correctly. When the tests show they are not, we would follow up with an enforcement action to remedy the situation.

Some commenters suggested that because of variability inherent in the test procedure, the Agency should not consider a protector mislabeled, and in violation of the labeling requirements, where the results of the compliance audit test show a mean attenuation value at a one-third octave band to be slightly less than its labeled value. We agree with the commenters that small differences may occur.

Responding to these comments, the Agency has included a 3 dB(A) variability factor that it will use to compare the mean attenuation values stated in the supporting information supplied with each protector, with those determined for Compliance Audit Testing (CAT). We will take enforcement action only in those cases where the CAT mean attenuation values are lower than the labeled mean attenuation values by more than 3 dB(A). For example, if at one of the test frequencies the mean attenuation value specified for that frequency in the supporting information is 20 dB(A), we will take action only when the Compliance Audit Testing shows that the attenuation value at that test freqency is less than 17 dB(A), or 20 dB(A) minus the 3 dB(A) variability factor.

Several commenters asked whether the labeled Noise Reduction Rating and one-third octave band attenuation values should be actual test values, average attenuation levels for all protectors of a category, or minimum attenuation levels for that category of protectors.

It is important that the NRR of a category of protectors, derived from data taken under test conditions, equal or exceed the NRR on the label so that prospective users can in fact select a protector which meets their minimum requirements. We are therefore requiring that the one-third octave band mean attenuation levels, made available to the prospective user in the supporting information that accompanies a protector, be no greater than the levels obtained under Compliance Audit Testing plus the 3 dB(A) variability factor. The manufacturer who labels the device must take into account any test and product variability to assure that the NRR of each device determined under Compliance Audit Testing equals or exceeds its labeled NRR value. There is no variability factor for the NRR. The NRR determined from Compliance Audit Testing must equal or exceed the NRR on the label.

Some commenters assumed that any remedial order such as recall, relabel or repurchase, would require traceability to the purchaser or user, and thereby cause major recordkeeping costs. Some manufacturers commented that relabeling of products which have been packaged, or are a part of existing inventory, is unreasonable.

Traceability to the ultimate purchaser or user is not required in this rule. However, the Agency maintains the position that it may be reasonable to require relabeling of protectors in a manufacturer's possession or in the distribution chain, or to take other steps to remedy non-compliance. The reasonableness of a remedy, of course, will depend on the facts of the particular case. The manufacturer subject to a remedial action has the right to a hearing under Section 11(d)(2) of the Act. At the hearing, held according to 5 U.S.C. Section 554, the manufacturer can challenge both the existence of the violation and the appropriateness of the remedy.

Compliance Audit Testing

Several comments were received on the Compliance Audit Testing (CAT) requirements. One was that EPA should not specify the laboratory at which a manufacturer must conduct an audit test, but that EPA should permit a manufacturer to conduct the testing at the same laboratory at which he

conducted the Labeling Verification (LV) test. This suggestion is rooted in a concern for test variability and differences in test results expected between laboratories.

Responding to this comment, we have reduced test variability with the change in the test procedure requiring "experimenter fit" rather than "subject fit" as was proposed. We have also included the 3 dB(A) variability factor to be used when determining the compliance of a protector to its labeled values. These were discussed earlier in the preamble. The Agency is not relinquishing its authority to require testing at any laboratory that meets regulatory requirements.

Several manufacturers stated that EPA should certify laboratories for LV and CAT. The Agency does not intend to become involved in the certification of laboratories across the country and possibly overseas for purposes of testing hearing protectors or other products for noise. It is the responsibility of each manufacturer to conduct testing according to the regulatory requirements.

Several manufacturers felt that EPA should limit orders for a compliance audit to only those cases where the Agency can show probable cause that products are in violation.

The Act does not require that the Agency have probable cause before issuing a test order. This authority will not be limited by regulation. In most cases, the Agency would issue compliance audit test requests where there is reason to believe there is non-compliance, but it reserves the right to issue test requests on a random basis.

Manufacturers took exception to providing EPA with future production schedules for EPA use in selecting categories for testing. There was concern that this information would become public knowledge and put a manufacturer at a competitive disadvantage.

Whenever the EPA requests product information which a manufacturer considers proprietary, the manufacturer may protect that information from a Freedom of Information Act request by following the procedures contained in 40 CFR 2.201 et seq. Those provisions govern the Agency's treatment of confidential business information. In particular, § 2.303 contains special provisions for certain information obtained under the Noise Control Act.

We proposed that the manufacturer date each product to facilitate the identification of mislabeled products in the distribution chain. Several manufacturers objected to placing the date of manufacture on the label. One manufacturer suggested that a code established by the manufacturer, which identified a lot or batch of protectors, should be sufficient to identify a group of mislabeled products.

We agree with the suggestion that manufacturers be allowed to place their own code in the supporting information which would identify a group of protectors and the time period during which they were produced. We have revised the regulation accordingly.

Manufacturers identified two proposed requirements which in some cases may be conflicting. In selecting protectors for Compliance Audit Testing, manufacturers are required to select the test protectors from the next 30 produced. This could in some cases mean that all those selected would be of the same size. This could conflict with another requirement that the manufacturer test all sizes of protectors in a test audit.

This potential conflict will be taken into account when individual CAT orders are prepared. If it is infeasible for a manufacturer to satisfy both requirements, the EPA will modify the order so that proper selection of test protectors is possible. The test request provision is flexible enough to handle this problem if it ever arises.

One manufacturer asked who warrants or guarantees the hearing protector's performance. The Act does not provide that any manufacturer warrant to a consumer the noise attenuation performance of a protector.

One commenter felt that there was a conflict between the General Provisions for Product Noise Labeling and the Hearing Protector regulation with respect to who will bear the costs of Compliance Audit Testing. The commenter felt that CAT costs should be borne by the Agency.

There is no conflict between the General Provisions and the Hearing Protector regulation with respect to costs for CAT; however, confusion is possible between § 211.111 of the General Provisions (Testing by the Administrator) and § 211.212 of this regulation (Compliance Audit Testing).

Section 211.111, Testing by the Administrator, in Subpart A reserves to the Agency the right to test products as a part of its enforcement strategy, and to order manufacturers to conduct tests and report the results to EPA. When EPA conducts the tests, the manufacturer can be required to submit the test products to EPA. The Administrator may test at any facility or order the manufacturer to test at any facility. When the Agency conducts the test, it will use its own equipment. This will assure the Agency that testing is being conducted properly. The cost of testing under this section is borne by the Agency. Subject to the exceptions discussed in the preamble to the General Provisions, and in § 211.111(c), EPA will absorb the cost of shipments when EPA conducts tests under § 211.111, Testing by the Administrator. The manufacturer only pays for LV, CAT or other tests that the manufacturer may be ordered to conduct.

Section 211.212, Compliance Audit Testing, details a specific procedure which the Agency will use to assure itself that manufacturers are continuing to produce products complying with their label value that was determined from the label verification test. The manufacturer bears the cost of compliance audit testing. The audit is designed to minimize the number of tests that a manufacturer will have to perform while still providing assurance to EPA that only complying products are being distributed in commerce. The EPA may elect to monitor, with the manufacturer's consent or with a warrant, the actual conducting of the audit tests.

Several manufacturers were concerned about advance approval of labels. There is no requirement for advance approval of compliance labels under this regulation.

Economic Effect

There was considerable comment concerning the costs that the hearing protector industry would incur if the regulation was promulgated as it was proposed. Several commenters stated that the burdens would be impossible for smaller companies to carry, or would make insert devices less competitive with "muff"-type devices because of the disproportionate increase in costs. The bases for these concerns were the anticipated changes in the packaging of some devices to accommodate a label, the costs of labeling individual protectors, and the costs of testing.

The final rule incorporates changes through which the required labeling is compatible with current packaging processes. Therefore, any costs that would have been attributable directly to changes in packaging to accommodate a label have been essentially eliminated.

The hearing protector industry has been less than cooperative in providing the Agency with cost, market size, and market share information. Therefore, the Agency developed the best estimate of the costs of this regulation based, in part, on data received from three manufacturers. These costs are the "worst case" estimates that we believe the industry will experience.

The Agency's estimate for total first year costs to the industry is $920,000 compared to $500,000 as stated in the proposed rule. This increase is due primarily to developing cost estimates based on a revised industry size of 70 manufacturers and distributors rather than the previously determined figure of 40, and secondarily because of including label preparation, label verification reporting, and personnel overhead costs in this estimate.

The first year cost estimate includes: testing all models of protectors in each of their use positions (as many as three positions for muff-type protectors)—these costs are not expected to exceed $350,000 based on 175 tests at $2,000 per test; and the Agency's best estimate of costs for label development, preparation and label verification reporting for each class of protector—these costs are not expected to exceed a total of $570,000.

The Agency's "worst case" estimate of annual costs of this regulation to the industry is $302,000, compared to the estimate of $300,000 stated in the proposed rule.

The annual cost estimate of this regulation is based on including: costs for Compliance Audit Testing by not more than 15% of the industry in one year; label-verifying new classes of protectors or classes of protectors that in one year have undergone changes which result in decreased noise reducing effectiveness (this is not expected to exceed 10% of the models of protectors in one year); and administrative costs for reporting and recordkeeping.

To develop these estimates the Agency assumed that every manufacturer and wholesale or retail distributor (considered "manufacturers" under the Noise Control Act) identified in the National Institute for Occupational Safety and Health publication #78-120, and through a search of the Thomas Register, would be impacted by the requirements of this regulation equally. However, distributors in this industry are not likely to incur the costs of complying with these requirements to the same extent that manufacturers will. Distributors generally repackage protectors supplied by manufacturers, and put their brand names on the packaging. Therefore, a single device may be marketed under several different private labels.

This regulation states however, that distributors may use a manufacturer's previously developed Noise Reduction Rating and Mean Attenuation data when packaging and labeling protectors. Therefore, in these situations, the only costs incurred for complying with these requirements would be the labeling costs as a result of repackaging, not the testing, recordkeeping and reporting costs.

It is the practice of this industry to pass 100% of production costs through to the ultimate purchaser. We believe this practice will continue.

While the potential percent price increase per pair of protectors is impossible to determine in the absence of market size information, the Agency estimates, based on limited data, that prices may increase between $0.03 and $0.05 per pair of insert devices (if previously bulk-packaged protectors are required to be individually packaged and labeled), and $0.10 for "muff" devices.

The current prices for typical ear insert devices (plugs) range from approximately ten cents per pair of disposable inserts in bulk industrial quantities to as much as seven dollars per pair for individually packaged plugs typically offered to the consumer. Customized plugs can cost as much as thirty dollars per pair but they are the exception in terms of insert devices. Ear-muff-type protectors range in price from several dollars when purchased in commercial bulk quantities to approximately fifteen dollars per pair when individually packaged for consumers.

The Department of Defense and several major industries that are affected by the Occupational Safety and Health Administration's (OSHA) rules are already requesting effectiveness data on hearing protectors. Therefore, a majority of the manufacturers already include in their prices the costs of testing protectors to develop effectiveness ratings.

While manufacturers have measured the effectiveness of their products, they in general do not convey this information to prospective users. Those few that do, do not relay effectiveness information in a uniform manner for similar categories of protectors; nor is comparative range information available upon which protector selections adequate for a user's needs can be made.

These final hearing protector labeling requirements reflect the Agency's overall sensitivity to the costs that accompany regulation, and our policy, with respect to product labeling, of minimizing the economic impact of a regulation. To this end, the Agency extended the effective date of the regulation by six months, so that it becomes effective one year from date of promulgation. This change is intended to allow manufacturers to minimize the obsolescence of packaging and literature supplies that they may have on-hand due to the lead-time procurements necessary in this industry. The extension will provide a longer phase-in period for the testing requirements, and also allow extra time for greater availability of testing laboratories thereby reducing a potential supply/demand imbalance that might cause an increase in test cost. We are establishing a method of labeling compatible with current marketing practices, which reduces the probability of packaging changes and associated cost increases.

The Agency has had no indication that this rulemaking would impose appreciable burdens on any manufacturer within the hearing protector industry, nor that the regulation in itself will result in business closure. Also, our economic analysis did not attempt to predict potential market shifts or potential adverse economic effects that might occur as a result of labeling requirements which would identify some protective devices as being low in effectiveness. The Agency believes that any market shifts or other economic effects beyond the direct costs of labeling are solely related to the competitive nature of this industry. We believe that the industry will adjust itself to reflect purchasers' and users' selections made as the result of newly available information from these noise labeling requirements; not as a result of the restrictions of command and control regulations.

This rule will make effectiveness rating and comparative range information available to prospective users in an easily readable, understandable, and uniformly applicable manner.

IV. Revisions to the Proposed Regulation

This final rulemaking incorporates several changes to the regulation as proposed in the Notice of Proposed Rulemaking of June 22, 1977. The significant changes are:

(A) The requirement that a hearing protector manufacturer affix the label to the package has been modified to require that the label be affixed by the manufacturer who packages the protector for ultimate sale or use.

(B) Responsibility for accurate and visible labeling of the protector is also assigned to that manufacturer. To support this change, § 211.2.4–3 (§ 211.204–3) "Label location and type" has been revised to require that labeling be based on the means used to display the protector at the point of sale to the ultimate purchaser or at the point of distribution to the prospective user. This Section also includes a prohibition on separation of the protector from the dispenser (if one is used) prior to sale to

the ultimate purchaser. Separation would be tantamount to removal of the label which is prohibited by Section 10(a)(4) of the Act.

(C) Section 211.2.3 (§ 211.203)- "Definitions" now includes entries for "Label", "Manufacturer", "Dispenser," and "Spectral uncertainty."

(D) Section 211.2.4-1(c) (§ 211.204-1(c))—the comparative information on the label now reads "The range of Noise Reduction Ratings for existing hearing protectors is approximately 0 to 30." This eliminates the implied precision of the range as proposed, and also gives the comparative range the flexibility required to accommodate changing protector capabilities and changing protector availability.

(E) Section 211.2.4-1(b) (§ 211.204-1(b))—now states that "* * * in different positions, the worst case NRR must be specified. The top of Area B must state the position(s) associated with that NRR. The other positions and respective NRRs must be included with the supporting information specified in § 211.204-4." This revision takes into account the possible large differences in protection due to the wearing position, and avoids the possible loss of useful information at the point of ultimate sale or use.

(F) Section 211.2.4-4(a) (§ 211.204-4(a))—was changed to include the statement "For "muff" type protectors with various use positions, the positions providing higher values shall be identified, and their associated NRR values listed in bold type.

(G) Section 211.2.6-1(b)(2) (§ 211.206-1(b)(2))—is replaced with "Section 3.2.1, 3.2.2, 3.3.2 and 3.3.3 shall be accomplished in this order during the same testing session to insure that distortions introduced by a Temporary Threshold Shift (TTS) do not occur. Also, any breaks in testing should not allow the subject to engage in any activities that may cause a TTS."

(H) Section 211.2.6-1(b)(3) (§ 211.206-1(b)(3))—is changed from "subject fit" to "experimenter fit" of the protector to the subject in order to achieve test consistency and repeatability.

(I) Section 211.2.7 (§ 211.207)—computation procedure for the NRR is changed to reflect the new procedure.

(J) Section 211.2.10-7 (§ 211.210-7)—modified to include changes to an existing product.

(K) Section 211.2.10-8—deleted.

(L) The effective date of this regulation is set at one (1) year from promulgation rather than the proposed six months, in order to lessen the cost impact on the industry and to allow for greater availability of testing facilities.

(M) Section 211.2.12 (§ 211.212)—provides a 3 dB(A) variability factor to be used when determining compliance of a protector by comparing the mean attenuation values at one-third octave bands determined from CAT testing with those contained in the supporting information supplied with the protector.

V. Supporting Documentation

Background Document

The Agency has prepared a background document containing a detailed study of hearing protectors, the protector industry, test methodologies, written and oral comments from the Notice of Proposed Rulemaking comment period and the public meeting, the Agency's answers and policy statements on these comments, and a listing of commenters.

The document is sufficiently lengthy that publishing it in the **Federal Register** is not practical. If a copy of the document, titled "Regulatory Analysis Supporting The Labeling of Hearing Protectors"; EPA 550/9-79-256, is desired, it may be obtained by writing to the following address: Public Information Center, PM-215, U.S. Environmental Protection Agency, Washington, D.C. 20460.

VI. Future Public Comment

It is the intent of EPA to monitor and carefully assess, on a continuing basis, improvements in hearing protectors, the economic and other impacts of the regulation, the effects of testing, and any further public response associated with this rulemaking. If regulatory revision is warranted or required we will act accordingly.

Written data, comments or views may be submitted to the: Director, Noise Enforcement Division (EN-307), U.S. Environmental Protection Agency, Washington, D.C. 20460.

VII. Evaluation Plan

EPA intends to review the effectiveness and the need for continuing the provisions contained in this action no more than five years after initial implementation of the regulation. In particular, EPA will solicit comments from affected parties with regard to cost and other burdens associated with compliance, and will also review data on hearing protectors built after promulgation of the regulation to determine how effective this measure has been.

VIII. Reporting and Recordkeeping Requirements

Under the EPA's new "sunset" policy for reporting requirements in regulations, the reporting requirements in this regulation will automatically expire five years from the date of promulgation, unless the Administrator takes appropriate steps to extend them. To accomplish this, a provision automatically terminating the reporting requirements is included in the text of the regulation.

IX. Impact Statements

An Environmental Impact Statement and an Economic Impact Statement are not required for this rulemaking according to Agency criteria.

Note.—I have reviewed this regulation and determined that it is not a significant regulation that requires the preparation of regulatory analyses called for in Executive Order 12044. The Agency has, nonetheless, developed documentation, mentioned above, to support this regulation.

This regulation is promulgated under the authority of 42 U.S.C. 4907.

Dated: August 30, 1979.

Douglas M. Costle,

Administrator, Environmental Protection Agency.

PART 211—PRODUCT NOISE LABELING

40 CFR Part 211 is amended by adding a new Subpart B to read as follows:

Subpart B—Hearing Protective Devices

Sec.

Authority: Sec. 8, Pub. L. 92-574, 86 Stat. 1241 (42 U.S.C. 4907), and additional authority as specified.

Subpart B—Hearing Protective Devices

§ 211.201 Applicability.

Unless this regulation states otherwise, the provisions of this subpart apply to all hearing protective devices manufactured after the effective date of this regulation. (See § 211.203(m) for definition of "hearing protective device.")

§ 211.202 Effective date.

Manufacturers of hearing protectors must comply with the requirements set forth in this part for all hearing protective devices manufactured on or after September 27, 1980.

§ 211.203 Definitions.

(a) As used in subpart B, all terms not defined here have the meaning given them in the Act or in Subpart A of Part 211.

(b) *ANSI Z24.22-1957*—A measurement procedure published by the American National Standards Institute (ANSI) for obtaining hearing protector attenuation values at nine of the one-third octave band center frequencies by using pure tone stimuli presented to ten different test subjects under anechoic conditions.

(c) *ANSI S3.19-1974*—A revision of the ANSI Z24.22-1957 measurement procedure using one-third octave band stimuli presented under diffuse (reverberant) acoustic field conditions.

(d) *Carrying Case*—The container used to store reusable hearing protectors.

(e) *Category*—A group of hearing protectors which are identical in all aspects to the parameters listed in § 211.210-2(c).

(f) *Claim*—An assertion made by a manufacturer regarding the effectiveness of his product.

(g) *Custom-molded device*—A hearing protective device that is made to conform to a specific ear canal. This is usually accomplished by using a moldable compound to obtain an impression of the ear and ear canal. The compound is subsequently permanently hardened to retain this shape.

(h) *Dispenser*—The permanent (intended to be refilled) or disposable (discarded when empty) container designed to hold more than one complete set of hearing protector(s) for the express purpose of display to promote sale or display to promote use or both.

(i) *Disposable Device*—A hearing protective device that is intended to be discarded after one period of use.

(j) *Ear Insert Device*—A hearing protective device that is designed to be inserted into the ear canal, and to be held in place principally by virtue of its fit inside the ear canal.

(k) *Ear Muff Device*—A hearing protective device that consists of two acoustic enclosures which fit over the ears and which are held in place by a spring-like headband to which the enclosures are attached.

(l) *Headband*—The component of hearing protective device which applies force to, and holds in place on the head, the component which is intended to acoustically seal the ear canal.

(m) *Hearing Protective Device*—Any device or material, capable of being worn on the head or in the ear canal, that is sold wholly or in part on the basis of its ability to reduce the level of sound entering the ear. This includes devices of which hearing protection may not be the primary function, but which are nonetheless sold partially as providing hearing protection to the user. This term is used interchangeably with the terms, "hearing protector" and "device."

(n) *Impulsive Noise*—An acoustic event characterized by very short rise time and duration.

(o) *Label*—That item, as described in this regulation, which is inscribed on, affixed to or appended to a product, its packaging, or both for the purpose of giving noise reduction effectiveness information appropriate to the product.

(p) *Manufacturer*—As stated in the Act "means any person engaged in the manufacturing or assembling of new products, or the importing of new products for resale, or who acts for, and is controlled by, any such person in connection with the distribution of such products."

(q) *Noise Reduction Rating (NRR)*—A single number noise reduction factor in decibels, determined by an empirically derived technique which takes into account performance variation of protectors in noise reducing effectiveness due to differing noise spectra, fit variability and the mean attenuation of test stimuli at the one-third octave band test frequencies.

(r) *Octave Band Attenuation*—The amount of sound reduction determined according to the measurement procedure of § 211.206 for one-third octave bands of noise.

(s) *Over-the-Head Position*—The mode of use of a device with a headband, in which the headband is worn such that it passes over the user's head. This is contrast to the behind-the-head and under-the-chin positions.

(t) *Package*—The container in which a hearing protective device is presented for purchase or use. The package in some cases may be the same as the carrying case.

(u) *Primary Panel*—The surface that is considered to be the front surface or that surface which is intended for initial viewing at the point of ultimate sale or the point of distribution for use.

(v) *Spectral uncertainty*—Possible variation in exposure to the noise spectra in the workplace. (To avoid the underprotection that would result from these variations relative to the assumed "Pink Noise" used to determine the NRR, an extra three decibel reduction is included when computing the NRR.)

(w) *Tag*—Stiff paper, metal or other hard material that is tied or otherwise affixed to the packaging of a protector.

(x) *Test Facility*—For this subpart, a laboratory that has been set up and calibrated to conduct ANSI Std S3.19-1974 tests on hearing protective devices. It must meet the applicable requirements of these regulations.

(y) *Test Hearing Protector*—A hearing protector that has been selected for testing to verify the value to be put on the label, or which has been designated for testing to determine compliance of the protector with the labeled value.

(z) *Test Request*—A request submitted to the manufacturer by the Administrator that will specify the hearing protector category, and test sample size to be tested according to § 211.212-1, and other information regarding the audit.

(aa) *Random Incident Field*—A sound field in which the angle of arrival of sound at a given point in space is random in time.

(bb) *Real-Ear Protection at Threshold*—The mean value in decibels of the occluded threshold of audibility (hearing protector in place) minus the open threshold of audibility (ears open and uncovered) for all listeners on all trials under otherwise identical test conditions.

(cc) *Reverberation Time*—The time that would be required for the mean-square sound pressure level, originally

in a steady state, to fall 60 dB after the source is stopped.

§ 211.204 Hearing protector labeling requirements.

All provisions of Subpart A apply to this subpart except as otherwise noted.

§ 211.204-1 Information content of primary label.

The information to appear on the primary label must be according to § 211.104 of Subpart A except as stated here and shown in Figure 1 of § 211.204-2:

(a) Area A must state "Noise Reduction Rating."

(b) (1) Area B must state the value of the Noise Reduction Rating (NRR) in decibels for that model hearing protector. The value stated on the label must be no greater than the NRR value determined by using the computation method of § 211.207 of this Subpart.

(2) For devices with headbands that are intended for use with the headband in different positions, the worst case NRR must be specified. The top of Area B must state the position(s) associated with that NRR. The other positions and the respective NRRs must be included with the supporting information specified in § 211.204-4.

(c) Area C must contain the statement "The range of Noise Reduction Ratings for existing hearing protectors is approximately 0 to 30 (higher numbers denote greater effectiveness)."

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

§§ 211.204-2 Primary label size, print and color.

The primary label characteristics are the same as those specified in § 211.105 and 211.106 of Subpart A except as stated here.

(a) The label must be no smaller than 3.6 centimeters by 5.0 centimeters (cm) (approximately 1.5 inches by 2.0 inches).

(b) The minimum type face size for each area shall be as follows, based upon a scale of 72 points=1 inch:

(1) Area A—2.6 millimeters (mm) or 8 point.

(2) Area B—7.0 mm or 22 point for the Rating; —1.7 mm or 5 point for "Decibels".

(3) Area A-B—1.5 mm or 4 point.

(4) Area C—1.5 mm or 4 point.

(5) Area D—0.7 mm or 2 point.

(6) Area E—0.7 mm or 2 point.

(7) Area F—0.7 mm or 2 point.

(8) Area H—0.7 mm or 2 point.

These type face sizes apply to the 3.6 cm x 5.0 cm label; type face sizes for larger labels must be in the same approximate proportion to the label as those specified for the 3.6 cm x 5.0 cm label.

(c) The use of upper and lower case letters and the general appearance of the label must be similar to the example in Figure (1).

(d) The color of the label must be as specified in Subpart A.

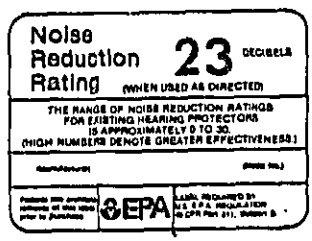

Figure - 1

§ 211.204-3 Label location and type.

(a) The manufacturer labeling the product for ultimate sale or use selects the type of label and must locate it as follows:

(1) Affixed to the device or its carrying case; and

(2) Affixed to primary panel of the product packaging if the label complying with § 211.204-3(a)(1) is not visible at the point of ultimate purchase or the point of distribution to users.

(b) Labeling with a minimum sized label will occur as follows:

(1) If the protector is individually packaged and so displayed at the point of ultimate purchase or distribution to the prospective user, the package must be labeled as follows:

(i) If the primary panel of the package has dimensions greater than 3.6 x 5.0 cm (approximately 1½ x 2 in) the label must be presented on the primary panel.

(ii) If the primary panel of the package is equal to or smaller than 3.6 x 5.0 centimeters, a label at least 3.6 x 5.0 centimeters must be affixed to the package by means of a tag.

(2) If the protector is displayed at the point of ultimate purchase or distribution to prospective users in a permanent or disposable bulk container or dispenser, even if the protector is individually packaged within the dispenser and labeled as above, the container or dispenser itself must be labeled. The label must be readily visible to the ultimate purchaser or prospective user.

§ 211.204-4 Supporting information.

The following minimum supporting information must accompany the device in a manner that insures its availability to the prospective user. In the case of bulk packaging and dispensing, such supporting information must be affixed to the container in the same manner as the label, and in a readily visible location.

(a) The mean attenuation and standard deviation values obtained for each test frequency according to § 211.206, and the NRR calculated from those values. For "muff" type protectors with various use positions, the positions providing higher NRR values shall be identified, and their associated NRR values listed in bold type.

(b) The following statement, example and cautionary note: "The level of noise entering a person's ear, when hearing protector is worn as directed, is closely approximated by the difference between the A-weighted environmental noise level and the NRR.

Example

1. The environmental noise level as measured at the ear is 92 dBA.
2. The NRR is 17 decibels (dB).
3. The level of noise entering the ear is approximately equal to 75 dBA.

Caution: For noise environments dominated by frequencies below 500 Hz the C-weighted environmental noise level should be used."

(c) The month and year of production, which may be in the form of a serial number or a code in those instances where the records specified in § 211.209(a)(1)(iv) are maintained;

(d) The following statement: "Improper fit of this device will reduce its effectiveness in attenuating noise. Consult the enclosed instructions for proper fit";

(e) Instructions as to the proper insertion or placement of the device; and

(f) The following statement: "Although hearing protectors can be recommended for protection against the harmful effects of impulsive noise, the Noise Reduction Rating (NRR) is based on the attenuation of *continuous* noise and may not be an accurate indicator of the protection attainable against *impulsive* noise such as gunfire."

§ 211.205 Special claims and exceptions.

(a) Any manufacturer wishing to make claims regarding the acoustic effectiveness of a device, other than the Noise Reduction Rating, must be prepared to demonstrate the validity of such claims.

(b) If a manufacturer believes that the Noise Reduction Rating is inapplicable to a given device, the manufacturer may submit a request that the Agency consider granting an exception to certain provisions of this subpart for that device. The request must support the manufacturer's contention that an

exception is necessary and offer a suitable alternative effectiveness rating for the device.

(c) Any request concerning an exception must be supported by scientific test data that establishes the exception without doubt, and must be submitted for consideration and approval to: Director, Noise Enforcement Division (EN-397), U.S. Environmental Protection Agency, Washington, D.C. 20460. The Agency will notify the manufacturer within thirty (30) days of receipt of the request if: the special claim or exception is approved, additional information is needed, or the Agency needs additional time to consider the request.

§ 211.206 Methods for measurement of sound attenuation.

§ 211.206-1 Real ear method.

(a) The value of sound attenuation to be used in the calculation of the Noise Reduction Rating must be determined according to the "Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs." This standard is approved as the American National Standards Institute Standard (ANSI STD) S3.19-1974. The provisions of this standard, with the modifications indicated below, are included by reference in this section. Copies of this standard may be obtained from: American National Standards Institute, Sales Department, 1430 Broadway, New York, New York 10018.

(b) For the purpose of this subpart only, Sections 1, 2, 3 and Appendix A of the standard, as modified below, shall be applicable. These Sections describe the "Real Ear Method." Other portions of the standard are not applicable in this section.

(1) The sound field characteristics described in paragraph 3.1.1.3 are "required."

(2) Sections 3.2.1, 3.2.2, 3.3.2 and 3.3.3 shall be accomplished in this order during the same testing session to insure that distortions introduced by a Temporary Threshold Shift (TTS) do not occur. Any breaks in testing should not allow the subject to engage in any activity that may cause a TTS.

(3) Section 3.3.3.1(1) shall not apply. Only "Experimenter fit" described in Section 3.3.3.1(2) is permitted.

(4) Section 3.3.3.3 applies to all devices except custom-molded devices. When testing custom-molded devices, each test subject must receive his own device molded to fit his ear canal.

§ 211.206-2 through § 211.206-10 Alternative test methods [Reserved].

§ 211.207 Computation of the noise reduction rating (NRR).

Calculate the NRR for hearing protective devices by substituting the average attenuation values and standard deviations for the pertinent protector category for the sample data used in steps #6 and #7 in Figure 2. The values of −.2, 0, 0, 0, −.2, −.8, −3.0 in Step 2 and −16.1, −8.6, −3.2, 0, +1.2, +1.0, −1.1 in Step 4 of Figure 2 represent the standard "C"- and "A"-weighting relative response corrections applied to any sound levels at the indicated octave band center frequencies. (NOTE: The manufacturer may label the protector at values lower than indicated by the test results and this computation procedure, e.g. lower NRR from lower attenuation values. (Ref. Section 211.211(b).)

FIGURE 2

COMPUTATION OF THE NOISE REDUCTION RATING

Octave Band Center Frequency (Hz)	125	250	500	1000	2000	3000	4000	6000	8000
1 assumed Pink noise (dB)	100	100	100	100	100		100		100
2 "C" weighting corrections (dB)	-.2	0	0	0	-.2		-.8		-3.0
3 unprotected ear "C"-weighted level (dB)	99.8	100	100	100	99.8		99.2		97.0
(The seven logarithmically added "C"-weighted sound pressure levels of Step #3 = 107.9 dB)									
4 "A"-weighting corrections (dB)	-16.1	-8.6	-3.2	0	+1.2		+1.0		-1.1
5 unprotected ear "A"-weighted level (step #1-step #4) (dB)	83.9	91.4	96.8	100	101.2		101		98.9
6 average attenuation in dB at frequency	21	22	23	29	41		(43 + 47)/2 = 45		(41 + 36)/2 = 38.5
7 standard deviation in dB at frequency	3.7 x2 7.4	3.3 x2 6.6	3.6 x2 7.6	4.7 x2 9.4	4.3 x2 8.6		(3.3 + 3.4) = 6.7		(6.1 + 6.5) = 12.6
8 Step #5-(step #6-step #7) develops the protected ear "A"-weighted levels (dB)	70.3	76.0	81.4	80.4	66.8		67.7		73.0
(The seven logarithmically added "A"-weighted sound pressure levels of Step #8 using this sample data = 85.1 dB)									

9 NRR = Step #3 - Step #8 - 3 dB*
= 107.9 dB - 85.1 dB - 3 dB*
= 19.8 dB (or 20) (Round values ending in .5 to next lower whole number)
*Spectral uncertainty (as defined in [redacted] 211.203)

The value for #3 is constant. Use Logarithmic mathematics to determine the combined value of protected ear levels (Step #8) which is used in Step #9 to exactly derive the NRR; or use the following table as a substitute for logarithmic mathematics to determine the value of Step #8 and thus very closely approximate the NRR.

Difference between any two sound pressure levels being combined (dB)	Add this level to the higher of the two levels (dB)
0 to less than 1.5	3
1.5 to less than 4.5	2
4.5 to 9	1
Greater than 9	0

§ 211.208 Export provisions.

(a) The outside of each package or container containing a hearing protective device intended solely for export must be so labeled or marked. This will include all packages or containers that are used for shipping, transporting, or dispersing the hearing protective device along with any individual packaging.

(b) In addition, the manufacturer of a hearing protective device intended solely for export is subject to the export exemption requirements of § 211.110-3 of Subpart A.

(Sec. 10(b)(2), Pub. L. 92-574, 86 Stat. 1242 (42 U.S.C. 4909(b)(2)))

§ 211.209 Maintenance of records: Submittal of information.

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

(1) *General records.* (i) Identification and description by category parameters of all protectors comprising the manufacturer's product line;

(ii) A description of any procedures, other than those contained in this regulation, used to perform noise tests on any test protector, and the results of those tests;

(iii) A record, signed by an authorized representative of the laboratory, of any calibration that was performed during testing by the test laboratory; and

(iv) A record of the date of manufacture of each protector subject to this regulation, keyed to the serial number or other coded identification contained in the supporting information required by § 211.204–4(c).

(2) *Individual records for test protectors.* A complete record, or exact copies of the complete record, of all noise attenuation tests performed (except tests performed by EPA directly), which includes all individual worksheets, and other documentation relating to each test required by the Federal test procedure.

(3) The manufacturer may fulfill this record retention requirement by keeping a copy of the labeling verification report that he has submitted to EPA in the format recommended by the Administrator, and by establishing a record of the information required by § 211.209(a)(1)(iv).

(4) The manufacturer must retain all required records for a period of three (3) years from the labeling verification date. Records may be retained as hard copy or reduced to microfilm, punch cards, or other forms of data storage, depending on the record retention procedures of the manufacturer.

(b) On request by the Administrator, the manufacturer must submit to the Administrator information regarding the number of protectors, by category, produced or scheduled for production during the time period designated in the request.

(Sec. 13, Pub. L. 92–574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.210 Labeling verification.

§ 211.210–1 General requirements.

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

(1) Must have its noise reducing effectiveness verified according to the Labeling Verification requirements described in § 211.210–2 of this subpart;

(2) Must be represented in a Labeling Verification Report as required by § 211.210–3 of this subpart;

(3) Must be labeled at the point of ultimate purchase or distribution to the prospective user according to the requirements of § 211.204 of this Subpart; and

(4) Must meet or exceed the mean attenuation values determined by the procedure in § 211.206 and explained in § 211.211(b).

(Sec. 13, Pub. L. 92–574, 86 Stat. 1244 (42 U.S.C. 4912))

(b) Manufacturers who distribute protectors in commerce to another manufacturer for packaging for ultimate purchase or use must provide to that manufacturer the mean attenuation values and standard deviations at each of the one-third octave band center frequencies as determined by the test procedure in § 211.206. He must also provide the Noise Reduction Rating calculated according to § 211.207.

§ 211.210–2 Labeling verification requirements.

(a) (1) A manufacturer responsible for label verification must satisfy the label verification requirements of this subpart for a category of hearing protectors before distributing that category of hearing protectors in commerce, *except* as provided in paragraph (a)(2) of this section.

(2) A manufacturer may apply to the Administrator for an extension of time to comply with the labeling verification requirements for a category of protectors before he distributes any protectors in commerce. The Administrator may grant the manufacturer an extension of up to 20 days from the date of distribution. The manufacturer must provide reasonable assurance that the protectors equal or exceed their mean attenuation values, and that labeling verification requirements will be satisfied before the extension expires. Requests for extension should go to the: Director, Noise Enforcement Division (EN–397), U.S. Environmental Protection Agency, Washington, D.C. 20460. The Administrator must respond to a request within 2 business days. Responses may be either written or oral.

(3) A manufacturer, receiving hearing protectors through the chain of distribution that were label verified by a previous manufacturer, may use that previous manufacturer's data when labeling the protectors for ultimate sale or use, but is responsible for the accuracy of the information on the label. The manufacturer may elect to retest the protectors.

(b) Labeling verification requirements regarding each hearing protector category in a manufacturer's product line consist of:

(1) Testing hearing protectors according to § 211.206 that were selected according to § 211.210–4.

(2) Submitting a labeling verification report to the Administrator according to § 211.210–3.

(c) Each category of hearing protectors is determined by the combination of at least the following parameters. Manufacturers may use additional parameters as needed to create and identify additional categories of protectors.

(1) *Ear muffs.* *(i) Head band tension (spring constant);*

(ii) Ear cup volume or shape;

(iii) Mounting of ear cup on head band;

(iv) Ear cushion;

(v) Material composition.

(2) *Ear inserts.* (i) Shape;

(ii) Material composition.

(3) *Ear caps.* (i) Head band tension (spring constant);

(ii) Mounting of plug on head band;

(iii) Shape of plug;

(iv) Material composition.

If an ear insert or ear cap is manufactured in more than one size (small, medium, large, etc.) each size does not constitute a separate category and is not required to be separately label verified. However, each size must be used when conducting the required test to determine the labeled values for the specified category.

(d) When the Director of the Noise Enforcement Division requests, either orally or in writing, what labeling verification testing is scheduled by a manufacturer under this section, the manufacturer must notify the Director so that EPA Enforcement Officers may be present to observe the testing, or to conduct the testing in lieu of the manufacturer.

§ 211.210–3 Labeling verification report: Required data.

(a) All manufacturers must submit the labeling verification report to: Director, Noise Enforcement Division (EN–397), U.S. Environmental Protection Agency, Washington, D.C. 20460. A manufacturer may choose to submit separate labeling verification reports for different categories of protectors. A suggested label verification report form is included as Appendix A.

(b) The report must be signed by an authorized representative of the manufacturer and include the following:

(1) The name and location of the test facility that was used to conduct testing under this Subpart;

(2) A description of all hearing protector categories, determined according to § 211.210–2(c), that the manufacturer intends to distribute in commerce. The manufacturer may satisfy the hearing protector category description by submitting, as part of the labeling verification report, a copy of the sales data literature that describes the product line;

(3) For each test conducted:

(i) A data sheet, as specified, showing the mean attenuation values with standard deviation at each of the one-third octave band center frequencies, along with the Noise Reduction Rating, for all official tests conducted under this Subpart, including each invalid test and the reason it was invalid;

(ii) A copy of the label including the NRR that will be used for the labeling of that specified category; and

(iii) The test results (if any) for any hearing protector replaced, and the reason why it was replaced.

(4) The following statement and endorsement:

This report is submitted under Section 6 and Section 13 of the Noise Control Act of 1972. All testing, for which data are reported here, was conducted in strict conformance with applicable regulations under 40 CFR Part 211 et seq. All the data reported here are true and accurate representations of this testing. All other information reported here is, to the best of (*company name*) and (*test laboratory name*) knowledge, true and accurate. I am aware of the penalties associated with violation of the Noise Control Act of 1972 and the regulations published under it.

(authorized representative).

If the testing is conducted by an outside laboratory the manufacturer must require an authorized representative of the laboratory to cosign the statement and endorsement.

(c) Where a manufacturer elects to submit separate labeling verification reports for portions of his product line, as provided for in paragraph (a) of this Section, information provided in previous reports need not be resubmitted unless it is information that is necessary to update previously submitted information.

(d) Any change concerning any information reported under this section must be reported as soon as it becomes available.

(e) The reporting requirements of this regulation will no longer be effective after five (5) years from the date of publication; however, the requirements will remain in effect if the Administrator is taking appropriate steps to repromulgate or modify the reporting requirements at that time.

(f) A manufacturer may conduct label verification testing on protectors which were produced up to 6 months before the effective date of this regulation. The manufacturers must test models of protectors scheduled for production during the first year after the effective date of this regulation. For these early label verification reports to be acceptable to the Agency, the manufacturer must:

(1) Use production protectors as the test protectors; and

(2) Permit the Agency to inspect and monitor the early label verification tests.

(Sec. 13, Pub. L. 92–574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.210–4 Test hearing protector selection.

A test hearing protector must be a hearing protector selected from the category for which labeling verification testing is required; it must have been assembled by the manufacturer's normal production process; and it must have been intended for distribution in commerce.

(Sec. 13, Pub. L. 92–574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.210–5 Test hearing protector preparation.

(a) A test hearing protector selected according to § 211.210–4 must not be tested, modified, or adjusted in any manner before the official test unless the adjustments, modifications and/or tests are part of the manufacturer's prescribed manufacturing and inspection procedures.

(b) Quality control, testing, assembly or selection procedures must not be used on the completed protector or any portion of the protector, including parts, that will not normally be used during the production and assembly of all other protectors of that category to be distributed in commerce.

(Sec. 13, Pub. L. 92–574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.210–6 Testing.

(a) The manufacturer must conduct one valid test on the hearing protectors selected from each category for verification testing according to the test procedures as specified.

(b) The test hearing protectors must not be repaired or adjusted once testing has begun. In the event a unit is unable to complete the test, the manufacturer or test laboratory may replace the protector; testing may be continued or reinitiated. Any replacement hearing protector will be a protector of the same category and will be subject to all the provisions of these regulations. Any replacement must be reported in the labeling verification report, including the reason for the replacement.

(Sec. 13, Pub. L. 92–574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.210–7 Addition of new categories: Modifications.

(a) Any modifications to a hearing protector, so that one or more of the category parameters listed in § 211.210–2(c) are modified, constitutes the addition of a new and separate category to the manufacturer's product line.

(b) A new category of products is also introduced whenever a manufacturer makes a design change which decreases the noise attenuation characteristics of the product.

(c) When a manufacturer introduces a new category to his model line he must proceed according to the label verification requirements of § 211.210–2.

(Sec. 13, Pub. L. 92–574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.211 Compliance with labeling requirement.

(a) All hearing protective devices manufactured after the effective date of this regulation, and meeting the applicability requirements of § 211.201, must be labeled according to this subpart, and must comply with the Labeled Values of mean attenuation as reported in the Labeling Verification Report.

(b) A manufacturer must take into account both product variability and test-to-test variability when labeling his devices in order to meet the requirements of paragraph (a) of this section. A specific category is considered in compliance with the requirements of § 211.210–1, when the attenuation value at the tested one-third octave band is not greater than the mean attenuation value, reported as Labeled Values in the Labeling Verification Report. The attenuation value must be determined according to the test procedures of § 211.206. The Noise Reduction Rating for the label must be calculated using the Labeled Values of mean attenuation in the Labeling Verification Report that will be included in the supporting information required by § 211.204–4. Actual mean attenuation values at the one-third octave bands may exceed the Labeled Values.

§ 211.212 Compliance audit testing.

§ 211.212-1 Test request.

(a) The Administrator will request all testing under this section by means of a test request addressed to the manufacturer.

(b) The test request will be signed by the Assistant Administrator for Enforcement or his designee. The test request will be delivered by an EPA Enforcement Officer or sent by certified mail to the plant manager or other responsible official as designated by the manufacturer.

(c) In the test request, the Administrator must specify the following:

(1) The hearing protector category selected for testing;

(2) The manufacturer's plant or storage facility from which the protectors must be selected;

(3) The selection procedure the manufacturer will use to select test protectors;

(4) The test facility where the manufacturer is required to have the protectors tested (which could be the facility where they went through labeling verification testing);

(5) The number of test hearing protectors to be tested;

(6) The time period allowed for the manufacturer to initiate testing; and

(7) Any other information that will be necessary to conduct testing under this section.

(d) The test request may provide for situations in which the selected category is unavailable for testing. It may include an alternative category to be selected for testing in the event that protectors of the first specified category are not available because the protectors are not being manufactured at the specified plant, at the specified time, and are not being stored at the specified plant or storage facility.

(e) (1) Any testing conducted by the manufacturer under a test request must commence within the period specified within the test request. The Administrator may extend the time period on request by the manufacturer, if a test facility is not available to conduct the testing.

(2) The manufacturer must complete the required testing within one week following commencement of the testing.

(3) The manufacturer will be allowed 24 hours 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.

(f) Failure to comply with any of the requirements of this section will not be considered a violation of these regulations if conditions and circumstances outside the control of the manufacturer render it impossible for him to comply. These conditions and circumstances include, but are not limited to, the temporary unavailability of equipment and personnel needed to conduct the required tests. The manufacturer bears the burden of establishing the presence of the conditions and circumstances.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.212-2 Test hearing protector selection.

(a) The test request will specify that thirty (30) protectors be selected, from which up to twenty (20) test protectors will be drawn for testing. The remainder may be used as replacement protectors if replacement is needed. The request will also specify that the 30 protectors be the next 30 produced after receipt of the request, or that the 30 be randomly drawn from the group of up to 100 that are next scheduled for production.

(b) If random selection is specified, it must be achieved by sequentially numbering all the protectors in the group and then using a table of random numbers to select the test hearing protectors. The manufacturer may use an alternative random selection plan when it is approved by the Administrator.

(c) Each test protector of the category selected for testing must have been assembled, by the manufacturer, for distribution in commerce using the manufacturer's normal production process.

(d) At their discretion, EPA Enforcement Officers, rather than the manufacturer, may select the protectors designated in the test request.

(e) The manufacturer must keep on hand the thirty (30) protectors designated for testing under this test request until such time as the category is determined to be in compliance. Hearing protectors actually tested and found to be in conformance with these regulations may be distributed in commerce.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.212-3 Test hearing protector preparation.

The manufacturer must select the test hearing protector according to § 211.212-2 before the offical test, and must comply with the test protector preparation requirements of § 211.210-5.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.212-4 Testing procedures.

(a) The manufacturer must conduct one valid test according to the test procedures specified in § 211.206 for each hearing protector selected for testing under § 211.212-2.

(b) The manufacturer must not repair or adjust the test hearing protectors once compliance testing has been initiated. In the event a hearing protector is unable to complete the test, the manufacturer may replace the protector. Any replacement protector will be of the same category as the protector being replaced. It will be selected from the remaining designated test protectors and will be subject to all the provisions of these regulations. Any replacement and the reason for replacement must be reported in the compliance audit test report.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.212-5 Reporting of test results.

(a)(1) The manufacturer must submit to the Administrator a copy of the Compliance Audit Test report for all testing conducted under § 211.212. It must be submitted within 5 days after completion of testing. A suggested compliance audit test report form is included as Appendix B.

(2) The manufacturer must provide the following test information:

(i) Category identification;

(ii) Production date, and model of hearing protector;

(iii) The name and location of the test facility used;

(iv) The completed data sheet in the form specified for all tests including, for each invalid test, the reason for invalidation; and

(v) The reason for the replacement where a replacement protector was necessary.

(3) The manufacturer must provide the following statement and endorsement:

This report is submitted under Section 8 and Section 13 of the Noise Control Act of 1972. All testing, for which data are reported here, was conducted in strict conformance with applicable regulations under 40 CFR 211 et seq. All the data reported are true and accurate representations of this testing. All other information reported here is, to the best of (company name) and (test laboratory name) knowledge, true and accurate. I am aware of the penalties associated with violation of the Noise Control Act of 1972 and the regulations published under it.
(authorized representative)

If the testing is conducted by an outside laboratory the manufacturer must require an authorized representative of

the laboratory to cosign both the statement and the endorsement.

(b) In the case where an EPA Enforcement Officer is present during testing required by this Subpart, the written reports required in paragraph (a) of this section may be given directly to the Enforcement Officer.

(c) The reporting requirements of this regulation will no longer be effective after five (5) years from the date of publication; however, the requirements will remain in effect if the Administrator is taking appropriate steps to repromulgate or modify the reporting requirements at that time.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.212-6 Determination of compliance.

(a) A category will be in compliance with these requirements if the results of the test conducted under the test request, show that:

(1) The mean attenuation value, at each one-third octave band center frequency as determined from the Compliance Audit Test values plus 3 dB(A), is equal to or greater than the mean attenuation value at the same one-third octave band reported in the "Labeled Values" section of the labeling Verification Report; and

(2) The Noise Reduction Rating, when calculated from the mean attenuation values determined by Compliance Audit Testing, equals or exceeds the Noise Reduction Rating as reported in the "Labeled Values" section of the Labeling Verification Report.

(b) If a category is not in compliance, as determined in paragraph (a) of this section, the manufacturer must satisfy the continued testing requirements of § 211.212-7, and the relabeling requirements of § 211.212-8 before further distributing hearing protectors of that category in commerce.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.212-7 Continued compliance testing.

If a category is not in compliance as determined under § 211.212-6, the manufacturer must satisfy the requirements of paragraph (a) or (b) of this section.

(a) The manufacturer must continue to test additional sets of (20) protectors 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.

(b) Upon approval by the Administrator, the manufacturer may relabel at a lower level in compliance with § 211.212-6 in lieu of testing under paragraph (a) of this section. The manufacturer must obtain approval by showing that the relabeled values adequately take into account results achieved from the Compliance Audit Testing and product variability. The Administrator is to exercise his discretion in light of factors including the prior compliance record of the manufacturer, the adequacy of the proposed new labeling value, the amount of deviation of test results from the labeled values, and any other relevant information.

(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 only two additional tests and relabel at least as low as the mean attenuation values received from the two tests.

(d) The manufacturer may request a hearing on the issue of whether the compliance audit testing was conducted properly and whether the criteria for non-compliance in § 211.212-6 have been met; and the appropriateness or scope of a continued testing order. In the event that a hearing is requested, the hearing shall begin no later than 15 days after the date on which the Administrator received the hearing request. Neither the request for a hearing, nor the fact that a hearing is in progress, shall affect the responsibility of the manufacturer to commence and continue testing required by the Administrator pursuant to paragraph (a) of this section.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

§ 211.212-8 Relabeling requirements.

(a) Any manufacturer who is found to not conform with § 211.212-6, and who has met the requirement of § 211.212-7, must relabel all protectors of the specified category already in his possession according to § 211.211 before distributing them in commerce. The manufacturer shall relabel at values no greater than any mean attenuation values received from Compliance Audit Testing. Any manufacturer who proceeds with § 211.212-7(a) or (b) must relabel his product line with the lowest mean attenuation value at each octave band received from testing; or he may take into account product variability under § 211.211(b) and label with a lower mean attenuation value than the worst case values obtained from Compliance Audit Testing.

(Sec. 10(a)(3), Pub. L. 92-574, 86 Stat. 1242 (42 U.S.C. 4909(a)(3)))

§ 211.213 Remedial orders for violations of these regulations.

(a) The Administrator may issue an order under section 11(d)(1) of the Act when any person is in violation of these regulations.

(b) A remedial order will be issued only after the violator has been notified of the violation and given an opportunity for a hearing according to § 554 of Title 5 of the United States Code.

(c) All costs associated with a remedial order shall be borne by the violator.

(Sec. 11(d) Pub. L. 92-574, 86 Stat. 1243 (42 U.S.C. 4910(d)))

§ 211.214 Removal of label.

Section 10(a)(4) of the Act prohibits any person from removing, prior to sale, any label required by this Subpart, by either physical removal or defacing or any other physical act making the label and its contents not accessible to the ultimate purchaser prior to sale.

(Sec. 10(a)(4), Pub. L. 92-574, 86 Stat. 1242 (42 U.S.C. 4909(a)(4))

Appendix A.—Labeling Verification Report

Data Sheet

Company name: _____
Address: _____
Test laboratory: _____
Address: _____
Model number of hearing protector: _____
Category designation: _____

Test Results—Frequency, Mean Attenuation, and Standard Deviation

125 _____
250 _____
500 _____
1000 _____
2000 _____
3150 _____
4000 _____
6300 _____
8000 _____
Noise Reduction Rating: _____

Labeled Values—Frequency, Mean Attenuation, and Standard Deviation

125 _____
250 _____
500 _____
1000 _____
2000 _____
3150 _____
4000 _____
6300 _____
8000 _____
Noise Reduction Rating: _____

If replacement hearing protector was necessary to conduct test, reason for replacement:

This report is submitted under Section 6 and Section 13 of the Noise Control Act of 1972. All testing, for which data are reported here, was conducted in strict conformance with applicable regulations under 40 CFR 211, et seq. All data reported here are true and accurate representations of this testing. All other information reported here is, to the best of (company name) and (test laboratory

name) knowledge, true and accurate. I am aware of the penalties associated with violation of the Noise Control Act of 1972 and the regulations published under it.

(Authorized representative of company)

(Authorized representative of test laboratory)

Appendix B.—Compliance Audit Testing Report

Data Sheet

Company name: _____
Address: _____
Test laboratory: _____
Address: _____
Model number of hearing protector: _____
Category designation: _____
Production date: _____

Test Results—Frequency, Mean Attenuation, and Standard Deviation

125 _____
250 _____
500 _____
1000 _____
2000 _____
3150 _____
4000 _____
6300 _____
8000 _____
Noise Reduction Rating: _____

If replacement hearing protector was necessary to conduct test, reason for replacement:

This report is submitted under Section 8 and Section 13 of the Noise Control Act of 1972. All testing, for which data are reported here, was conducted in strict conformance with applicable regulations under 40 CFR 211, et seq. All the data reported here are true and accurate representations of this testing. All other information reported here is, to the best of (company name) and (test laboratory name) knowledge, true and accurate. I am aware of the penalties associated with violation of the Noise Control Act of 1972 and the regulations published under it.

(Authorized representative of company)

(Authorized representative of test laboratory)

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