Regulatory Flexibility Act

The Regulatory Flexibility Act requires EPA to explicitly consider the effect of regulations on small entities. If there is a significant effect on a substantial number of small entities, EPA must seek to minimize the effect.

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities. The rule provides laboratories with two additional alternatives for THM testing. Because these methods are optional, and because EPA is not promulgating any new requirement, the Agency believes that this notice will not have any significant effect on a substantial number of small entities.

Paperwork Reduction Act

Today's rule places no additional information collection or record-keeping burden on respondents. Therefore, an information collection request has not been prepared and submitted to the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 40 CFR Part 141

Administrative practice and procedure, Chemicals, Intergovernmental relations, Reporting and Recordkeeping requirements, Water supply.

Dated: July 22, 1993.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, part 141 of title 40 of the Code of Federal Regulations is amended as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, and 300j–9.

2. In § 141.30, paragraphs (e)(3) and (e)(4) are added, and two new sentences are added at the beginning of the concluding text of paragraph(e) to read as follows:

§ 141.30 Total trihalomethanes sampling, analytical and other requirements.

* * * * *

(e) * * *

(3) "Volatile Organic Compounds in Water by Purge and Trap Capillary Gas Chromatography with Photoionization and Electrolytic Conductivity Detector in Series," Method 502.2, EMSL, EPA, Cincinnati, Ohio. EPA Method 502.2 is contained in Methods for the Determination of Organic Compounds in Drinking Water, EPA/600/4–88/039 (revised July 1991).

(4) "Volatile Organic Chemicals in Water by Purge and Trap Capillary Gas Chromatography/Mass Spectrometry," Method 524.2, EMSL, EPA, Cincinnati, Ohio. EPA Method 524.2 is contained in Methods for the Determination of Organic Compounds in Drinking Water, EPA/600/4–88/039 (revised July 1991).

For the methods cited in paragraphs (e)(1) and (e)(2) of this section, see appendix C to this subpart C. The methods cited in paragraphs (e)(3) and (e)(4) of this section are available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (order number PB91–231480.) * * *

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[FR Doc. 93–18226 Filed 8–2–93; 8:45 am]

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federal register

Tuesday
August 3, 1993

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 210 and 211

Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Labeling Controls; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210 and 211

[Docket No. 88N–0320]

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the current good manufacturing practice (CGMP) regulations for human and veterinary drug products to revise certain labeling control provisions. Specifically, the final rule defines the term "gang-printed labeling," specifies conditions for the use of gang-printed or cut labeling, exempts manufacturers that employ automated 100-percent labeling inspection systems from CGMP labeling reconciliation requirements, and requires manufacturers to identify filled drug product containers that are set aside and held in an unlabeled condition for future labeling operations. These changes are intended to reduce the frequency of drug product mislabeling and associated drug product recalls.

EFFECTIVE DATE: August 3, 1994.

FOR FURTHER INFORMATION CONTACT: Tom Kuchenberg, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8046. or Paul J. Motise, Center for Drug Evaluation and Research (HFD–323), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8089.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 23, 1989 (54 FR 26394), FDA published a proposed rule to amend the packaging and labeling control provisions of the CGMP regulations. The proposal: (1) Specified conditions for the use of gang-printed or cut labeling, (2) exempted manufacturers that employ 100 percent labeling inspection systems from CGMP labeling reconciliation requirements, and (3) required manufacturers to identify filled drug product containers that are not immediately labeled.

The proposed amendments were based on an agency study of drug product recalls that identified label mixups as the leading cause of recalls involving mislabeled products. An agency analysis of the recalls attributed to label mixups showed that the use of cut labels, labels of similar size, shape, or color, and deviations from existing CGMP labeling requirements were the leading causes of such mixups. In contrast, three label control practices were not involved in any of the recalls attributed to label mixups: (1) the use of labels differentiated by size, shape, or color; (2) the use of dedicated packaging lines; and (3) the use of electronic 100-percent label inspection systems that validate the labeling of each drug product during finishing operations.

The proposed rule was intended to encourage desirable labeling operations and to contribute significantly to preventing drug product mislabeling and associated drug product recalls. The proposal gave interested persons an opportunity to submit written comments by August 22, 1989.

In response to a request for an extension of the comment period, in the **Federal Register** of September 8, 1989 (54 FR 37342), FDA published a notice extending the comment period for submissions to October 20, 1989.

FDA is now issuing a final rule based upon the proposal with changes made in response to public comments. These changes are discussed in the preamble to this final rule.

FDA is continuing to monitor recalls related to mislabeling, and FDA notes that the total number of these recalls for each of 3 fiscal years, 1988 to 1990, exceeded the number of these recalls in any of the 5 fiscal years, 1983 to 1987, that were covered by the agency's recall study. FDA notes also that recalls related to mislabeling are the primary cause of recalls classified by FDA as presenting a significant risk of serious health consequences or death (Class I). In many cases, mislabeled drug products subject to a Class I recall are detected by health care professionals before they are dispensed or by consumers before use. Unfortunately, mislabeled drug products continue to cause consumer injuries.

For example, a 41-year-old woman was hospitalized after becoming comatose from a medication used to lower blood sugar in diabetics that had been mislabeled as a medication to treat a bacterial infection. In another instance, a 6-year-old child was hospitalized after being given a potent liquid tranquilizer that had been mislabeled as a medication used for the treatment of cough and cold symptoms. For 3 fiscal years, 1988 to 1990, recalls related to mislabeling have accounted for almost 50 percent of Class I recalls. Further, for fiscal year 1990, mislabeling-related recalls have accounted for almost 60 percent of Class I recalls. FDA remains convinced that the CGMP regulations must address effectively this disturbing and persistent trend.

II. Comments

FDA received 44 comments on the proposed rule. These comments represented many interests—29 human drug manufacturers, 6 biological drug manufacturers, 2 veterinary drug manufacturers, 2 drug equipment suppliers, and 5 trade organizations representing manufacturers, repackers, and distributors. In general, the comments supported the agency's initiative to modify the CGMP labeling control requirements to reduce the frequency of drug product mislabeling. However, many comments suggested modifications. FDA has carefully considered all comments and suggested alternatives and has adopted those comments that would reduce the burden on manufacturers while at the same time achieving the goal of significantly reducing mislabeling-related recalls. A section-by-section summary of the comments and the agency's responses to them are set out below.

A. General Comments

1. Several comments objected to specifying a "how to" approach instead of an "objective" approach with respect to labeling control requirements. The comments argued that requiring specific labeling systems or procedures would unduly restrict innovative approaches and technological advances. The comments recommended that the regulations state the objective that is sought and leave the method of attaining that objective to the reasonable discretion and ingenuity of the manufacturer. In contrast, two comments urged that FDA adopt a "how to" approach, stating that the revised requirements should specify acceptable types of "electronic or electromechanical equipment."

The agency agrees with the view that, with few exceptions, it should generally describe "what" is to be accomplished and provide great latitude in "how" a requirement is to be achieved by manufacturers. Indeed, in many instances the CGMP regulations expressly provide manufacturers with considerable latitude to determine the manner in which requirements are to be accomplished. In this instance, because of the continuingand serious problems experienced by the industry in maintaining adequate control over cut labeling, the agency has concluded that somewhat greater labeling control is

needed. While the regulation reflects the agency's view that somewhat greater control over cut labeling is needed to reduce the incidence of drug product mislabeling, the final rule permits manufacturers considerable latitude under § 211.122(g)(1), (g)(2), and (g)(3) of these final regulations in achieving the greater degree of control.

The agency is aware that these regulations apply to a wide variety of drug products, but believes that the regulations are sufficiently flexible to permit technological innovation. Indeed, the rate of technological improvements of automated labeling inspection systems will likely accelerate with the increased use of such systems to comply with these regulations. Therefore, the agency concludes that the proposed regulations are specific enough to address a serious problem effectively while offering regulated industry sufficient flexibility to accommodate a great variety of present and future technologies.

2. Several comments addressed the scope of the proposed regulations. One comment stated that the regulations should not apply to preparation of bulk pharmaceutical chemicals. Another comment claimed that, because clinical supplies (i.e., investigational new drug products) are produced in small lots, there is less chance of labeling errors. The comment urged that such products be exempt from the regulations. Another comment suggested that medicinal oxygen repackers who handle no other compressed medical gases are not likely to experience labeling errors and, therefore, should be exempt from these regulations.

While the good manufacturing practice provisions under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) apply to both bulk and finished drugs, the CGMP regulations set forth in 21 CFR part 211, including the provisions governing labeling controls, apply solely to finished dosage forms, whether or not in packaged form. (See 21 CFR 211.1.) Although the revised labeling control provisions in the CGMP regulations do not apply to the preparation of bulk pharmaceutical chemicals, FDA may use these provisions as a guide in its inspections of the labeling practices of manufacturers of bulk pharmaceutical chemicals.

The revised labeling control provisions apply to the preparation of dosage forms that are under clinical investigation, whatever the size of the product lot. The small size of a product lot does not reduce the need for labeling controls. In fact, in some cases, the manufacture of many small lots may increase the opportunities for mixups and the need for label controls. Furthermore, in cases where firms label both investigational and noninvestigational products, the suggested exemption for investigational lots could create additional difficulties in labeling control for all products on the line. Therefore, the agency does not accept the suggested exemption for clinical supplies.

Finally, the agency rejects the suggested exemption for oxygen repackers who handle no other compressed medical gas. The agency notes that mixups can occur in a facility dedicated to repacking a single product among different lots or different private label distributors for the same product. Such mixups may have considerable public health significance.

3. Two comments addressed the effective date of the final rule. One comment suggested that at least 1 year would be needed, after the date of publication in the **Federal Register**, to acquire and start up new equipment. Another comment requested an 18- to 24-month time period to adopt new electronic systems or to convert from cut to roll labels.

This rule becomes effective August 3, 1994. The agency believes that the 12 months provided gives firms sufficient time to exhaust noncomplying labeling stocks and to make necessary changes to labeling control systems. The period given for compliance in this rule is the same as the period given firms to comply with the final rule requiring tamper-resistant packaging for over-the-counter drug products, a rule which, like these revisions to labeling controls, may have required some firms to install new equipment.

4. Several comments addressed the economic impact of complying with the proposed regulations. The comments argued that costs for new equipment and specially coded labeling could be especially significant for small firms that perform short labeling runs. The comments claimed that compliance would be costly if required for all labeling instead of being restricted to immediate-container labels.

As discussed in comment 13, the agency is adopting as part of the final rule a cut labeling control procedure for hand labeling operations that involves the use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations. Because this alternative can be implemented without new equipment or specially coded labeling, small firms should be able to comply with the new requirements without incurring significant incremental costs.

The agency believes that it is crucial to apply these regulations to package inserts and other pieces of labeling in addition to immediate-container labels. Recalls involving incorrect package inserts and outer/shipping cartons continue to be a problem. The agency does not believe that it is in the public interest to disregard this part of the overall problem of drug product mislabeling. Indeed, some manufacturers already recognize the need to improve controls on all labeling and have instituted bar code control systems for all labeling.

The agency believes that this final rule will bring the regulated drug industry up to the minimum level of current good manufacturing practice necessary for the prevention of drug product mislabeling. The agency agrees that some firms may incur costs in order to adopt suitable labeling control systems, but has determined that the overall cost impact of this final rule is minimal. For those manufacturers that choose to acquire an automated labeling verification system to inspect labeling, estimated cost based on bar-coded or keyhole-coded labeling is between $10,000 and $20,000, an expense that is comparable to the cost of general purpose manufacturing equipment. A more elaborate automated machine vision system for labeling verification may cost approximately $40,000. These equipment expenses will be offset for many manufacturers by the annual cost savings realized by the exemption from the requirement to perform label reconciliation. Further, these costs are considerably less than the costs to manufacturers and the public of label mixups, including the costs of product recalls that may follow a label mixup. Such costs include potential consumer injury and death, the expense of conducting product recalls, loss of goodwill, lost sales, and product liability claims.

B. Materials Examination and Usage Criteria

5. Nearly all comments supported the proposed revision under § 211.122(f) to the provisions governing the use of gang-printed labeling. One comment favored retaining the existing regulations, contending that the existing regulations already prohibit gang printing. The comment claimed that the proposal would relax existing requirements and fail to reduce the rate of mislabeling.

FDA does not agree. Existing regulations do not prohibit use of gang printing labeling for dissimilar items.

Rather, the existing regulations require that gang printing of labeling to be used for dissimilar items "be minimized," and that gang printing in such cases take place under special control procedures for labeling and packaging operations. As revised, the regulations prohibit use of gang-printed labeling for dissimilar items unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color. As stated in the preamble to the proposed rule, the agency views the change as a positive measure that will contribute significantly to preventing drug product mislabeling.

6. Three comments recommended that the regulations define the term "gang-printed labeling." One comment described a system for label printing that prints labels two to four across on a continuous roll on a sequential basis for dozens of different lots. Identical lots of labels are then separated from the roll for final container labeling. This comment sought to distinguish this printing method from conventional gang printing methods and, thus, exclude it from the proposed restrictions on gang printing. One comment suggested a definition for gang-printed labeling that would exclude sequentially generated computer printed labels. One comment requested the agency to distinguish between sheet-printed and gang-printed labeling.

After considering these and related comments, the agency concludes that a definition of the term "gang-printed labeling" is warranted. Accordingly, the agency is revising 21 CFR 210.3 to define gang-printed labeling as labeling derived from a sheet of material on which more than one item of labeling is printed.

As discussed in the preamble to the proposed rule, the agency has found that labeling mixups related to gang printing frequently arise when the multiple items of gang-printed labeling are insufficiently differentiated by size, shape, or color. Under these conditions, the proximity of the different labeling items to each other is problematic because the items, when cut and separated from gang-printed sheets into individual stacks, are easily mixed up. These proximity-derived mixups may go undetected at the printer, or at the drug manufacturer. Thus, the agency regards even a single sheet of gang-printed labeling (when printed by a manufacturer's computer, for example) to be prone to proximity-derived mixups because separation of similar labeling items may mistakenly include adjacent different labeling items. Likewise, similar labels for different items may be gang printed across roll stock sheets that are subsequently cut into individual rolls. These rolls may be inadvertently spliced onto adjacent rolls of labeling for different items where lack of adequate differentiation can mask the splicing error. The agency considers the continuous roll labeling printing method as gang-printed labeling, and the provisions of § 211.122(f) are intended to apply to roll stock sheets as well as individual stock sheets.

7. Two comments recommended that sequentially generated computer-printed labels, i.e., similar labels for different items that are printed by computer on rolls or flat sheets and separated before application to containers, not be considered gang printing within the meaning of proposed § 211.122(f). One comment asked about the acceptability of printing incomplete identical labels on a single sheet, subsequently separating these labels, and then filling in the blanks with information unique to each different item, as appropriate.

The agency considers the printing system described by the comment to be a type of gang printing within the meaning of § 211.122(f) (see comment 6). The fact that the printing process is controlled by computers is not relevant to the problems attendant to removing individual labels from a roll or sheet, nor does the use of computerized processes reduce the need for special control and handling of individual labels to prevent mixups. At the same time, the agency notes that the use of computer-controlled labeling procedures may make differentiation of labeling by size, shape, or color easier.

Preprinting incomplete identical stock labels on a single sheet or roll is not prohibited under these regulations. The agency advises, however, that labels that have been separated from a roll or sheet are considered cut labels and are subject to the special control procedures for labeling and packaging operations under § 211.122(g) of these regulations.

8. Two comments requested that the regulations allow gang printing of labeling for different items that are not differentiated by size, shape, or color, provided special control procedures are used to separate and control each unique set of labels. One comment argued that, where a firm handles many different products, the printing of distinctive labels for each product is not practical.

The previous regulation under § 211.122(f) permitted gang printing of labeling of the same size and identical or similar format and/or color schemes with the use of special control procedures in packaging and labeling operations, taking into account sheet layout, stacking, cutting, and handling during and after printing. The agency has concluded, through its analysis of product labeling recalls and inspectional findings, that the use of special controls during and after printing cannot be relied on to prevent mixups of cut labeling derived from such gang printing. Therefore, use of undifferentiated labeling derived from such gang printing is prohibited by these final regulations. However, it should be emphasized that the regulation does not require a firm to use labeling that is differentiated by size, shape, or color for each product in a firm's entire line. Differentiation is only required when a single sheet is used for the gang printing of labeling for different drug products, or different strengths or net contents of the same drug product.

9. One comment recommended that the regulations governing the labeling of insulin products be revised to permit product differentiation by the use of color coded labels. The comment claimed that color coding would not only help manufacturers control labeling, but also help consumers distinguish between insulin products.

Color coding of labeling for insulin products is already prescribed by regulation (21 CFR 429.12). The use of color coding to differentiate insulin products is beyond the scope of this final rule. Any person who believes that the color coding of insulin products should be changed may, of course, petition the agency under the provisions of 21 CFR 10.30 to amend 21 CFR 429.12.

10. One comment recommended that the agency not apply § 211.122(f) to the use of gang-printed labeling for small labeling lots, e.g., lots fewer than 100 in number.

The agency disagrees. Mixups involving gang-printed labeling can occur in small lots. As noted above, the small size of a lot does not reduce the need for labeling controls. Therefore, the agency declines to accept this recommendation.

11. Two comments requested the agency to define cut labels. One comment asked that cut labels be restricted to "traditional print shop operations." The second comment asked whether labels removed from a roll are considered to be cut labels.

"Cut labels" and "cut labeling" are items of labeling that have been detached from printed stock material prior to being brought to a labeling line. The agency advises that labels printed on a roll but not directly applied to packaging from the roll (i.e., where the labels are removed from the roll for

subsequent storage and handling prior to actual labeling) are cut labels.

12. Two comments recommended that the proposed special control procedures for cut labeling in § 211.122(g) also apply to roll labeling. One comment noted the potential for mixups involving roll labeling when a single roll has items of labeling of similar size, shape, or color.

Although use of roll labels, in itself, does not prevent mixups, the agency has determined that the use of cut labels is much more likely to cause labeling mixups and recalls and that special labeling control procedures for cut labels are justified. Specifically, FDA has found that 76 percent of recalls due to label mixups involved the use of cut labels; only 24 percent of recalls involved the use of roll labels. The agency has determined that individual cut labeling is more liable to result in mixups than labeling that is securely affixed to a roll from the time of printing until immediate application to containers. Therefore, the agency declines to extend special labeling controls to roll labeling at this time.

13. Several comments expressed concerns about the applicability of the proposed requirement regarding cut labels under § 211.122(g) to low volume labeling operations for such products as clinical supplies, bulk pharmaceutical substances, allergenic extracts, veterinary products, and compressed medical gases, and products produced in small lots such as radiopharmaceuticals or orphan drug products. The comments stated that, in low volume labeling operations, labeling is typically applied by hand and claimed that adequate labeling control can be attained by documented 100-percent visual examination by two persons in conjunction with labeling reconciliation. The comments contended that the use of electronic or electromechanical equipment for low volume operations is unwarranted.

The agency has concluded that, for labeling runs of a low enough volume to make hand application of cut labeling practical, visual examination performed by one person with independent verification by a second person of all labeling, in conjunction with labeling reconciliation, provides reasonable assurance of labeling control. Although visual examination is somewhat less effective than electronic or electromechanical examination, differences in effectiveness are insignificant in low volume situations where operators have sufficient time to check the labeling. The agency believes that, by limiting the provision to labeling applied by hand, the labeling control procedure will be confined to reasonably low volume labeling operations where visual checks of all labeling can be both practical and effective. Accordingly, the final regulation is amended to permit as an alternative control for cut labeling the use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling. Documentation that all products were visually examined for correct labeling must be made a part of the batch production record (see 21 CFR 211.188(b)).

14. Several comments asked whether proposed §§ 211.122(g) and 211.125(c) would apply to labeling other than the immediate container label.

As previously noted, the regulations are intended to apply to all labeling, not just immediate-container labels, and the agency has revised the final regulations accordingly. The agency's experience with product mislabeling recalls continues to show that use of incorrect cartons or inserts constitutes a significant portion of labeling control problems.

15. Several comments requested clarification of the term "dedication" as used in § 211.122(g)(1). Specifically, the comments asked whether "dedication" meant "permanent" or "per job" dedication of labeling and packaging lines. Some comments suggested that a packaging line should be considered to be dedicated if it is physically separated from other lines and if labeling runs for different products on a given line are not conducted concurrently.

For purposes of § 211.122(g)(1), the agency considers "dedication" of a labeling or packaging line to be the exclusive use of a line for a given strength of a given product for as long as that product and its labeling are in a firm's physical inventory or catalog of marketed products. A line may only be rededicated after exhaustion of the product and its labeling from the firm's physical inventory and removal of the product from the firm's catalog of marketed products. Physical or spatial separation of different packaging and labeling lines is already required under § 211.130(a) of the CGMP regulations and is not relevant to whether those lines are considered to be dedicated. Further, the agency has decided that exclusive use for a prescribed period of time as a measure of line dedication would not assure that incorrect labeling is not brought to a labeling or packaging line.

16. One comment recommended that FDA not adopt line dedication as an alternative control for cut labeling because line dedication will not prevent mixups where cut labels are mixed up before delivery to the line.

The agency acknowledges that line dedication alone will not prevent mistakes involving the delivery of labeling to a labeling or packaging line. Compliance with the other pertinent labeling control provisions on the receiving, sampling, inspection, and acceptance of labeling, as well as subsequent storage, issuance, and use of labeling, is still necessary to reduce the risk of mixups before delivery to the line. Line dedication is intended to provide additional assurance that correct labeling is used in labeling and repackaging operations. The agency, therefore, rejects this recommendation.

17. Several comments complained that line dedication is not feasible for firms making many different products, especially where lot sizes are small. Several comments requested that the agency accept as dedicated use of a given labeling and packaging line for different products when sequential packaging/labeling runs are distinguished by a variety of conditions, such as: (1) changes in mechanical equipment on the line; (2) shut down intervals of at least 4 working hours; (3) runs of distinctively different products or identical products having distinctively different net contents; and (4) use of labeling differentiated by size, shape, and color.

The agency considers that the effectiveness of using dedicated lines to prevent cut labeling mixups can be achieved only when a given line is used solely for one strength of one drug product, thus minimizing the chance that incorrect labeling would ever be brought to that line. The schemes suggested by the comments would not be, in the agency's view, effective labeling control methods. The agency notes that, under this final rule, use of dedicated lines is not the only option open to manufacturers. Firms may use nondedicated lines if: (1) an automated examination of 100 percent of the labeling is conducted, (2) roll labeling is used; or (3) labeling is applied by hand, if a visual examination of 100 percent of the labeling is conducted. The agency notes that the latter labeling control procedure should be a viable option for small lot sizes. Thus, the agency does not believe it appropriate to delete or qualify § 211.122(g)(1).

18. One comment asked whether a line may be considered dedicated under § 211.122(g)(1) if it is used for the labeling or packaging of several strengths of a single product.

The agency has revised this provision in the final rule to make clear that a

labeling or packaging line may be dedicated only to a single strength of a drug product.

19. Several comments recommended that the differentiation of cut labels by size, shape, or color be included as a special control procedure under proposed § 211.122(g).

Although there is value as a labeling control in differentiation of cut labeling by size, shape, or color, the agency believes that the use of differentiation of cut labeling, in itself, does not adequately assure that a product has been appropriately labeled. Therefore, the agency declines to accept this recommendation.

20. Three comments objected to proposed § 211.122(g)(2) because it requires the use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling. These comments asserted that such equipment is insufficiently reliable and does not guarantee that the correct label will be applied to the correct container.

The agency acknowledges that electronic and electromechanical inspection systems do not completely assure that the correct labeling will be applied to the correct product container. Automated labeling inspection systems are only one part of a total labeling control system. Additional labeling control procedures, including preacceptance inspection, and appropriate storage and handling, are also needed to reduce the risk of labeling mixups. However, the agency thinks that automated labeling inspection systems can serve as a significant safeguard to reduce the chance that cut labeling will be mixed up. The agency is confident that the performance characteristics of automated systems will improve greatly as demand for such systems increases.

The agency is keenly aware of the need to accommodate a wide variety of new technologies in various areas, including technologies applied to labeling controls. The agency is committed to facilitating appropriate use of technologies, consistent with the agency's mandate to protect consumers. Accordingly, any party claiming knowledge of a technology or method of assuring that correct cut labeling is used and which provides at least the same degree of protection against label mixup as the methods specifically stated in the final rule, may submit a citizen petition under 21 CFR 10.30. In addition to the requirements under 21 CFR 10.30, such a petition should be clearly identified as a "Request for Exemption from § 211.122(g) Cut Labeling Control Provisions." The petition shall provide FDA with evidence that the technology or method of labeling control advanced by the petitioner provides protection against labeling mixup either equal or superior to the methods provided for in § 211.122(g)(1), (2), or (3). If FDA agrees with the petitioner, FDA will approve the petition and may propose to amend § 211.122 to add the new control methods.

21. One comment recommended that the term "finishing operations" as used in proposed § 211.122(g)(2) be defined.

Finishing operations include all steps taken by a drug manufacturer to complete packaging and labeling of a drug product. Finishing operations for a solid oral dosage form might include, for example, placing the dosage form in an immediate container; placing a cotton fill and labeling insert in such container; applying a label, cap liner, and cap; placing the immediate container in a carton; applying a labeling outsert; and placing unit cartons in labeled shipping containers. The agency thinks that the term is well understood in the pharmaceutical industry and sees no need for the suggested revision in the definition section.

22. One comment asked whether the process of preparing labeling in an area specifically designed for control of labeling, but separate from the actual packaging operations, is a process that takes place "during or after completion of finishing operations" within the meaning of proposed § 211.122(g)(2).

Although some firms label and package products on contiguous lines, the agency notes that packaging operations may be conducted in areas separate from labeling operations. Section 211.122(g)(2) is intended to cover examination of labeling applied during or after completion of finishing operations. The provision does not pertain to the process of preparing labeling. Thus, labeling preparation is not a finishing operation within the meaning of § 211.122(g)(2).

C. Labeling Issuance

23. Many comments argued that the labeling reconciliation requirement under proposed § 211.125(c) be deleted because labeling reconciliation is not an effective means of label control, either alone or as an adjunct to other procedures. Several comments recommended that the proposed waiver for label reconciliation be expanded to the use of any labeling control procedures, such as dedicated labeling and packaging lines, 100-percent visual examination of hand applied labeling, 100-percent examination of roll labeling by automated systems, or differentiation of cut labels by size, shape, or color. Several comments supported labeling reconciliation as a cost-effective and practical alternative to automated 100-percent labeling examination, especially in low volume situations where labeling is applied by hand and visually examined.

The agency agrees that the proposed waiver of labeling reconciliation should extend to roll labeling which undergoes 100-percent automated inspection, and has revised § 211.125(c) accordingly. The agency does not believe that the other alternative labeling controls suggested by the comments are sufficiently effective labeling control measures to warrant waiver of labeling reconciliation. The agency is convinced that labeling reconciliation has prevented a number of mislabeling incidents. The agency wishes to stress, however, that reconciliation alone will not prevent labeling mixups. Compliance with other pertinent provisions of the CGMP regulations (e.g., on receiving, sampling, inspecting, accepting, storing, issuing, and using labeling) is also required.

D. Packaging and Labeling Operations

24. Several comments recommended that the word "immediately" be deleted from the phrase "not immediately labeled" under proposed § 211.130(b) because it does not take into consideration reasonable holding times between filling and labeling operations. Additionally, these comments stated that this requirement should not apply to situations where there are normal processing delays, such as employee rest breaks and product flow holding times between filling and labeling operations.

The intent of the proposed requirement was to require manufacturers to identify unlabeled filled containers that are set aside and held for future labeling operations. The proposed identification provision was not intended to apply to situations where there are reasonable delays between filling and labeling and where containers are otherwise identified during the production process by their phase of processing, as currently required under § 211.105 of the CGMP regulations. The final regulation has been revised accordingly.

25. Several comments argued that identification of unlabeled drug product containers under proposed § 211.130(b) need not include the expiration date because the inclusion of this information will not help the manufacturer identify the product. Several comments also stated that, for certain biological drug products, the

expiration date is based upon potency assays, which are not always available when containers are filled.

The agency agrees and has revised the final regulation accordingly.

26. Many comments stated that proposed § 211.130(b) would be unreasonable if the intention of this provision is to require that each unlabeled filled drug product container be uniquely identified with its name, strength, quantity of contents, lot or control number, and expiration date. These comments recommended that only groupings of such unlabeled containers need to be identified and that instead of including these specific identifiers, a system of identification, such as use of lot numbers or color coding traceable to each drug product's name, strength, quantity of contents, lot or control number, and expiration date, would suffice to prevent mixups.

The agency did not intend to require that the identifying information be affixed to each unlabeled filled drug product container. The agency's intention was to require manufacturers to incorporate into their written procedures provisions for the proper handling and identification of unlabeled containers so as to preclude mislabeling. Any identification system that permits the manufacturer to determine all of the required information is acceptable. This identification system may apply to secure groupings of containers provided that there is no question as to the correct identity of each container in the group. The final regulation has been revised to clarify the agency's intention.

Therefore, the agency is amending the CGMP regulations for human and veterinary drug products to revise certain labeling control provisions by amending § 210.3 by adding new paragraph (b)(22), by amending § 211.122 by revising paragraph (f), by redesignating paragraph (g) as paragraph (h), and by adding new paragraph (g), and by amending § 211.125 by revising paragraph (c).

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Economic Impact

The agency has analyzed the potential economic impact of the final rule and has determined that it requires neither a regulatory impact analysis as specified in Executive Order 12291, nor a regulatory flexibility analysis as defined in the Regulatory Flexibility Act (Pub. L. 96–354). Specifically, the final rule establishes additional conditions for the use of certain types of labeling and for the control of packaged drug products that will be labeled at a later date. In addition, the final rule provides an exemption from an existing label control requirement when certain conditions are met. The agency believes that the overall cost effect of this final rule is minimal.

As stated in both the 1989 proposal and the agency's economic assessment of this final rule, a significant number of firms already take advantage of electronic or electromechanical equipment to inspect all labeling. This final rule would result in cost reductions to those firms by exempting them from the current label reconciliation requirement. Also, most firms that choose to install automated, 100-percent labeling verification systems would achieve annual cost reductions that exceed the annualized acquisition costs of new equipment. Finally, the final rule provides for a cut-labeling control procedure for hand labeling operations that many small firms already use. Therefore, the agency believes that most firms, both large and small, will experience either unchanged or reduced regulatory costs because of these requirements. The 1989 proposal and the agency's economic assessment of this final rule are on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

In summary, the agency concludes that the final rule is not a major rule because the labeling control revisions do not result in a significant overall cost to manufacturers. Moreover, the final rule is intended to reduce the likelihood of mislabeling-related recalls and in many cases will reduce the industry's regulatory burden by relieving industry from certain CGMP labeling reconciliation requirements. For these reasons, therefore, the agency has determined that this final rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that this final rule does not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act.

V. Effective Date

To allow for sufficient time for necessary changes to labeling control operations and the consumption of existing labeling stocks made obsolete by labeling conversions, manufacturers are given until August 3, 1994 to comply with the new requirements.

List of Subjects

21 CFR Part 210

Drugs, Packaging and containers.

21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 210 and 211 are amended as follows:

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS;GENERAL

1. The authority citation for 21 CFR part 210 continues to read as follows:

Authority: Secs. 201, 501, 502, 505, 506, 507, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374).

2. Section 210.3 is amended by adding new paragraph (b)(22) to read as follows:

§ 210.3 Definitions.

* * * * *

(b) * * *

(22) Gang-printed labeling means labeling derived from a sheet of material on which more than one item of labeling is printed.

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

3. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: Secs. 201, 501, 502, 505, 506, 507, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374).

4. Section 211.122 is amended by revising paragraph (f), by redesignating paragraph (g) as paragraph (h), and by adding new paragraph (g) to read as follows:

§ 211.122 Materials examination and usage criteria.

* * * * *

(f) Use of gang-printed labeling for different drug products, or different strengths or net contents of the same drug product, is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color.

(g) If cut labeling is used, packaging and labeling operations shall include

one of the following special control procedures:

(1) Dedication of labeling and packaging lines to each different strength of each different drug product;

(2) Use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or

(3) Use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling. Such examination shall be performed by one person and independently verified by a second person.

* * * * *

5. Section 211.125 is amended by revising paragraph (c) to read as follows:

§ 211.125 Labeling issuance.

* * * * *

(c) Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 211.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with § 211.122(g)(2).

* * * * *

6. Section 211.130 is amended by redesignating paragraphs (b), (c), and (d) as paragraphs (c), (d), and (e), respectively, and by adding new paragraph (b) to read as follows:

§ 211.130 Packaging and labeling operations.

* * * * *

(b) Identification and handling of filled drug product containers that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. Identification need not be applied to each individual container but shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container.

* * * * *

Dated: March 30, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–18377 Filed 8–2–93; 8:45 am]

BILLING CODE 4160–01–F

federal register

Tuesday
August 3, 1993

Part VI

Federal Trade Commission

16 CFR Part 306
Automotive Fuel Ratings, Certification and Posting; Rule

FEDERAL TRADE COMMISSION

16 CFR Part 306

Automotive Fuel Ratings, Certification and Posting

AGENCY: Federal Trade Commission.
ACTION: Final rule.

SUMMARY: The Federal Trade Commission ("Commission") amends its Octane Certification and Posting Rule ("Octane Rule") to include alternative liquid automotive fuels, including methanol, denatured ethanol, and other alcohols; blends of methanol, denatured ethanol and other alcohols with gasoline or other fuels; liquefied natural gas; and, liquefied petroleum gas. The amendments require that marketers of these fuels certify and post an automotive fuel rating that describes the fuel being marketed in terms of a minimum percentage, by volume, of its principal component. This action is being taken to comply with the Petroleum Marketing Practices Act ("PMPA"), as amended. The Commission has decided to defer a decision on whether to prescribe disclosure requirements for diesel fuel oil. The title of the rule is amended to be Automotive Fuel Ratings, Certification and Posting ("Fuel Rating Rule").

EFFECTIVE DATE: The amendments are effective October 25, 1993. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 25, 1993.

FOR FURTHER INFORMATION CONTACT: Neil Blickman, Attorney, 202–326–3038, or James Mills, Attorney, 202–326–3035, Division of Enforcement, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Statement of Basis and Purpose

I. Introduction

Section 1501 of the Energy Policy Act of 1992 ("EPA 92")[1] requires the Commission, within 270 days of enactment, to amend[2] the Commission's Octane Rule.[3] Specifically, the Commission must issue automotive fuel[4] certification and posting requirements, like those that exist now for gasoline, for all liquid alternative fuels[5] for vehicular use. These alternative liquid automotive fuels include such existing automotive fuels as methanol, denatured ethanol, liquefied petroleum gas, and liquefied natural gas. The Commission has the authority to require certification and posting of octane or other ratings for alternative liquid automotive fuels after consultation with the American Society for Testing and Materials ("ASTM").[6] For diesel fuel oil, the Commission has the discretionary authority to require certification and posting of cetane (a rating similar to octane), if the Commission finds this would be appropriate after a rulemaking proceeding.[7]

The purpose of PMPA's requirements for the certification and posting of octane ratings for gasoline sold at retail was to ensure that purchasers have the information they need to purchase gasolines with sufficient octane to prevent engine knocking while avoiding wasteful octane overbuying.[8] The purpose of the EPA 92 amendments to PMPA is to extend the Octane Rule's certification and posting requirements to alternative liquid automotive fuels to allow purchasers to compare posted octane or other fuel ratings with their engines' requirements. Thus, the amendments attempt to increase consumer confidence in and information about motor fuels. The amendments recognize "that motorists have a right to know what they pay for, and that dealers have a right to know that their competitors are not cheating."[9] Simply stated, the purpose is to give purchasers information they need to choose the correct type or grade of fuel for their vehicles.

In accordance with section 203(d)(1) of PMPA,[10] this proceeding was conducted pursuant to section 553 of the Administrative Procedure Act ("APA"),[11] except that interested persons were afforded the opportunity to present oral, as well as written, data, views and arguments. On March 26, 1993, the Commission published a Notice of Proposed Rulemaking ("NPR") in the **Federal Register** that sought comment on four proposed certification and posting options for certain alternative liquid automotive fuels and certification and posting requirements for diesel fuel oil for vehicular use.[12] (A hearing was not requested, so one was not held.) The options and the comments received are discussed in Part III, below. The final amendments appear in Part VIII.B., below. Additional technical amendments, e.g., new § 306.0—Definitions, are discussed in Part VIII.A., below.

The Commission tentatively concluded in the NPR that the proposed amendments would not have a significant economic impact on a substantial number of small entities in the alternative liquid automotive fuel industry and the diesel fuel oil industry, as defined in the Regulatory Flexibility Act.[13] The Commission, however, sought comments about these industries and the impact of the proposed amendments on small entities in them. Under the requirements of the Paperwork Reduction Act,[14] the Commission also tentatively concluded that the recordkeeping burden associated with the proposed amendments would be minimal. To ensure the accuracy of its burden estimates, however, the Commission solicited comments on the paperwork burden that the proposed amendments would impose. Lastly, in accordance with the Commission's modified ten-year regulatory schedule, the Commission sought comments about the

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[1] Pub. L. 102–486, 106 Stat. 2776. Title XV of EPA 92, Pub. L. 102–486, 106 Stat. 2776, 2996–99, amends title II of PMPA, 15 U.S.C. 2821–25.

[2] Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821).

[3] Final Rule Governing Certification and Posting of Octane Numbers Under Title II of PMPA, 44 FR 19160 (Mar. 30, 1979), codified at 16 CFR part 306.

[4] Section 1501(a)(6) of EPA 92 defines the term "automotive fuel" to mean liquid fuel of a type distributed for use as a fuel in any motor vehicle. Section 1501(a)(6) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821(6)).

[5] Section 301(2) of EPA 92 defines the term "alternative fuel" as: Methanol, denatured ethanol, and other alcohols; mixtures containing 85 percent or more (or such other percentage, but not less than 70 percent, as determined by the Secretary [of the Department of Energy], by rule, to provide for requirements relating to cold start, safety, or vehicle functions) by volume of methanol, denatured ethanol, and other alcohols with gasoline or other fuels; natural gas; liquefied petroleum gas; hydrogen; coal-derived liquid fuels; fuels (other than alcohol) derived from biological materials; electricity (including electricity from solar energy); and any other fuel the Secretary determines, by rule, is substantially not petroleum and would yield substantial energy security benefits and substantial environmental benefits. Pub. L. 102–486, 106 Stat. 2776, 2866 (codified at 42 U.S.C. 13211).

[6] Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821(17)(C)).

[7] Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821(1)(B)).

[8] S. Rept. No. 731, 95th Cong., 1st Sess. 15–16, 19–21, reprinted 1978 U.S. Code Cong. and Adm. News 873–75, 877–79.

[9] H. Rept. No. 474 (I), 102nd Cong., 1st Sess. 151, reprinted in 1992 U.S. Code Cong. and Adm. News 1953, 1974.

[10] 15 U.S.C. 2823(d)(1).

[11] 5 U.S.C. 553.

[12] 58 FR 16464. The alternative liquid automotive fuels that the Commission identified in the NPR as currently being distributed in the marketplace are methanol; denatured ethanol; M–85 (a mixture of 85% methanol and 15% gasoline); E–85 (a mixture of 85% denatured ethanol and 15% gasoline); liquefied propane gas (LPG); and liquefied natural gas (LNG). See Part III.A., *infra*.

[13] 5 U.S.C. 605.

[14] 44 U.S.C. 3501–3520.

costs and benefits of the Octane Rule and its regulatory and economic impact.

The Commission has additional rulemaking responsibilities regarding alternative fuels under section 406 of EPA 92.[15] Although the Commission will address the requirements of section 406 in a subsequent proceeding, in the NPR the Commission invited suggestions on how to meet the requirements of both sections 406 and 1501 of EPA 92.[16] The Commission received limited comments concerning the section 406 proceeding. Those comments have been considered and will be taken into account when the Commission publishes its NPR in that proceeding.

II. Background

A. Overview of the Octane Rule

In this notice, the Commission amends the Octane Rule to include for alternative liquid automotive fuels certification and posting requirements like those now required by the Octane Rule for gasoline. On March 30, 1979, the Commission issued the Octane Rule, under section 203(c)(1) of title II of PMPA.[17] The Octane Rule, which took effect on June 1, 1979, establishes standard procedures for determining, certifying, and posting (by means of a label on the fuel dispenser) the octane rating of automotive gasoline intended for sale to consumers. The Octane Rule covers refiners, producers, importers, distributors, and retailers.[18]

Refiners, producers, and importers must determine the octane rating of the gasoline they distribute in accordance with the PMPA-prescribed formula.[19] For purposes of certification and posting, if distributors and retailers do not blend gasoline, they have the option of using the octane rating certified to them or of determining the octane rating by testing in accordance with the (R+M)/2 method.[20] If distributors or retailers blend different gasolines, they must either: (1) Test in accordance with the (R+M)/2 method; (2) use the weighted-average formula prescribed by section 202(f)(1) of PMPA; or (3) use the lowest octane rating certified to them for any of the gasolines in a mixture.[21]

The Octane Rule requires that refiners, producers, importers, and distributors certify the octane rating of gasoline that they distribute in commerce for resale. Refiners, producers and importers must certify consistent with their determination of the gasoline's octane rating. Distributors must certify consistent with the certification they received or, optionally, the octane rating determined by them. Certification can be accomplished in either of two ways: On a delivery ticket with each transfer of gasoline or by a letter of certification or other written statement. A letter or other written statement constituting certification is valid until gasoline with a lesser octane rating is shipped.[22]

Retailers must post the octane rating of all gasoline they sell to consumers. They must post a whole or half number, which must be equal to or less than the octane rating certified to them or determined by them. They must post at least one label on each face of each gasoline dispenser and, if more than one kind of gasoline is sold from a single dispenser, separate disclosures for each kind of gasoline must be put on each face of the dispenser. The label must show the octane rating preceded by the words "MINIMUM OCTANE RATING" and (R+M)/2 METHOD."[23]

Refiners, producers, importers, distributors, and retailers must keep for one year records of any delivery tickets, letters of certification, or tests upon which they based the octane ratings that they certified or posted. These records must be open for inspection by Commission and Environmental Protection Agency ("EPA") staff members or by persons authorized by the Commission or EPA.[24]

B. Amendments to the Octane Rule Required by EPA 92

Section 1501 of EPA 92 amends Title II of PMPA to extend automotive fuel certification and posting requirements to all liquid automotive fuels.[25] Specifically, under this section, the term "gasoline" is deleted from PMPA and replaced with the term "automotive fuel."[26] The term "automotive fuel" means liquid fuel of a type distributed for use in any motor vehicle.[27] For vehicular use, such fuels include the following fuels: Gasoline (including gasohol, and oxygenated and reformulated gasolines),[28] diesel fuel oil, and alternative fuels. "Alternative fuel" is defined in section 301(2) of EPA 92 as including: methanol, denatured ethanol and other alcohols (including mixtures containing 70 percent to 85 percent or more by volume of methanol, denatured ethanol and other alcohols with gasoline or other fuels), liquefied petroleum gas and liquefied natural gas.[29]

This means that all liquid automotive fuels (with the exception of diesel fuel oil), including alternative liquid automotive fuels, must post either an octane rating or another rating specified by the Commission on fuel dispensers. As delineated in EPA 92, the alternative liquid automotive fuels identified during this proceeding as being currently distributed are methanol, denatured ethanol, blends of methanol or denatured ethanol with gasoline,

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[15] Specifically, section 406 of EPA 92 requires the Commission to propose labeling requirements for alternative fuels and alternative fuel vehicles, including requirements for information about their costs and benefits to enable consumers to make choices and comparisons. The Commission has authority to consolidate this required labeling with other labels. Sec. 406, Pub. L. 102–486, 106 Stat. 2776, 2880–81 (codified at 42 U.S.C. 13232).

[16] Under section 406 of EPA 92, the Commission must issue a Notice of Proposed Rulemaking by April 24, 1994. *Id.* Section 406 requires the Commission to establish labeling requirements for alternative fuels such as compressed natural gas (CNG), hydrogen and electricity, as well as the liquid alternative fuels.

[17] 15 U.S.C. 2823.

[18] 16 CFR 306.1. This coverage parallels the coverage in PMPA's definitions of "refiner," "gasoline retailer" and "distributor."

[19] 16 CFR 306.4, .7(a), .9(c). The formula is the sum, divided by two, of the Research Method and the Motor Method, two accepted laboratory test methods for evaluating the antiknock performance of automotive gasoline. Tests using the (R+M)/2 formula must be conducted in accordance with ASTM procedures. 16 CFR 306.4(b).

[20] 16 CFR 306.7(a)(1), .9(c).

[21] *Id.*

[22] 16 CFR 306.5, .7.

[23] 16 CFR 306.9. The octane label must be put on the face of the dispenser as near as possible to the price per gallon of the gasoline and placed so it is in full view of consumers. Octane labels for gasoline must be printed in black ink on a yellow background and conform to the Octane Rule's size, type style, and dimensional requirements. No marks or information other than that called for by the Rule may appear on the label. The Commission has granted several conditional exemptions to the Octane Rule's specific posting requirements to allow use of other labels under certain conditions.

[24] 16 CFR 306.6, .8, .10.

[25] Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821(17)–(18)).

[26] Section 1501(c) of Pub. L. 102–486, 106 Stat. 2776, 2996–7 (codified at 15 U.S.C. 2821).

[27] Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821(6)).

[28] "Gasohol" is generally recognized as being a blend of approximately 90% unleaded gasoline and 10% denatured ethanol. The Commission considers gasohol to be gasoline in the traditional sense, and already covered by the Octane Rule. See Commission advisory opinion concerning gasohol dated January 8, 1993, issued to the Nebraska Gasohol Committee. Further, because gasohol is substantially gasoline, it does not fall within the definition of "alternative fuel" in EPA 92. Sec. 301(2), Pub. L. 102–486, 106 Stat. 2776, 2866 (codified at 42 U.S.C. 13211). See note 5, *supra*. Similarly, for "reformulated gasoline," which will be required to be available by the Clean Air Act in 1995, 42 U.S.C. 7545(k), and for current "oxygenated gasoline," the reformulations (to reduce emissions) will not otherwise change the inherent properties of the fuels. Because reformulated and oxygenated gasolines are not specified as alternative fuels and they are substantially gasoline, they are not alternative liquid fuels. Thus, as with other gasolines, octane ratings can and should be derived and posted for reformulated and oxygenated gasolines.

[29] Pub. L. 102–486, 106 Stat. 2776, 2866 (codified at 42 U.S.C. 13211). See note 5, *supra*.

liquefied petroleum gas ("LPG"), and liquefied natural gas ("LNG").[30] These fuels are described briefly below. The Fuel Rating Rule, however, applies to all present and future alternative liquid automotive fuels. If new types of alternative liquid automotive fuels are developed in the future, sellers can petition the Commission for further rulemaking if they believe that different or additional disclosures are necessary, or they can seek an exemption from specific certification and posting requirements if they believe those requirements are unnecessary for such new fuels.

Methanol, or wood alcohol, is commonly used in the U.S. as a raw material source (feedstock) for producing methyl tertiary butyl ether ("MTBE"), an octane-enhancing gasoline additive, and as a chemical feedstock, extractant, or solvent. It can be used in neat (100%) form as a gasoline substitute or in a blend with gasoline, most commonly as M–85 (85% methanol, 15% gasoline). The majority of methanol produced in the U.S. is from natural gas resources, but it also can be produced from coal, residual oil, and biomass.[31]

Ethanol, or grain alcohol, is also produced from biomass sources.[32] Once denatured, it can be used as a pure fuel or as a blend with gasoline, such as E–85 (85% denatured ethanol, 15% gasoline).[33]

LPG is composed primarily of propane and butanes, with smaller amounts of propylene and butylenes. About two-thirds of the LPG available today is a by-product of natural gas processing. It is supplied in four grades of different composition, with HD–5 being the grade usually recommended for automotive use. HD–5 is approximately 95% propane. The terms "LPG" and "propane" are often used interchangeably.[34]

Natural gas is a fossil fuel composed primarily of methane, along with other hydrocarbons such as ethane, propane, butane, and inert gases such as carbon dioxide, nitrogen, and helium. It is produced both in compressed ("CNG") and liquefied ("LNG") forms.[35] LNG is natural gas that has been liquefied at temperatures as low as −259°F. The amendment adopted by the Commission today covers only LNG.

C. Identification of Comments Received

Below is an alphabetical list of the comments submitted in response to the NPR. The list includes the document number assigned to the comment on the public record and a general description of the commenter and its interests relating to this proceeding (for those comments that included a description).[36] The Commission received a total of 29 comments.[37] In the remainder of this notice, each comment is referred to by its acronym or the abbreviation given in parentheses.

1. American Automobile Manufacturers Association ("AAMA")—D–7. AAMA represents producers of approximately 81% of all U.S.-built motor vehicles.

2. Advanced Business Development, Inc. ("ABDI")—E–6. ABDI is a private consulting firm.

3. Atmos Energy Corp. ("AEC")—D–20. AEC is a natural gas distribution company with operations in Kentucky, Louisiana and Texas.

4. American Gas Association ("AGA") and Natural Gas Vehicle Coalition ("NGVC")—D–11. AGA represents 250 natural gas distribution and transmission companies, which account for approximately 85% of the nation's total annual natural gas utility sales. NGVC has over 200 members, including vehicle manufacturers, natural gas vehicle component manufacturers, natural gas distribution, transmission, and production companies, natural gas development organizations, environmental and non-profit advocacy organizations, state and local government agencies, and fleet operators. NGVC is dedicated to developing long-term markets for natural gas vehicles (NGVs) and building an NGV infrastructure.

5. Association of International Automobile Manufacturers ("AIAM")—D–17. AIAM is a non-profit trade association that represents U.S. importers, distributors and manufacturers of passenger cars and light trucks produced both here and abroad.

6. American Methanol Institute ("AMI")—D–23. AMI represents the majority of the methanol industry.

7. American Petroleum Institute ("API")—D–10. API represents approximately 300 companies involved in all aspects of the oil and gas industry.

8. American Trucking Associations, Inc. ("ATAI")—D–2. ATAI is a federation with associations in every state and the District of Columbia that represents every type and class of motor carrier in the country, for-hire and private. ATAI's members collectively consume 24 billion gallons of diesel fuel oil annually.

9. Alternative Transportation Fuels Inc. ("ATFI")—D–15. ATFI is a wholly-owned subsidiary of Skelgas Propane, Inc., a propane marketer.

10. CENEX ("CENEX")—D–21. CENEX is a regional agricultural cooperative, serving 320,000 farmers and ranchers through more than 1,800 local cooperatives in 15 states from the Great Lakes across the Midwest to the Pacific Northwest. Through a joint venture, CENEX sells refined petroleum products, including gasoline and diesel fuel oil, and propane, with annual sales of up to 36 million gallons of petroleum products.

11. Clean Fuels Development Coalition ("CFDC")—D–14. CFDC promotes the use of fuels such as ethanol as a means of achieving clean air. It is a non-profit coalition comprised of ethanol producers, ethanol marketers, ETBE [ethyl tertiary butyl ether]

[30] Sec. 301(2), Pub. L. 102–486, 106 Stat. 2776, 2866 (codified at 42 U.S.C. 13211).

[31] Fact sheet on methanol, developed by Development and Communications Office, Technical Information Program, for the U.S. Department of Energy, NREL SP–220–4315, DE91002157, Rev. Feb. 1992. "Biomass" is a renewable, virtually inexhaustible domestic resource that can be used to produce methanol and ethanol. Corn is a major biomass feedstock being used today. Other biomass sources currently being used, or subject to research as potential feedstocks, include crop residues, forage (grass) crops, wood resources (forest residues and short-rotation wood energy crops), and the cellulosic components of municipal solid waste.

[32] "Denatured ethanol," also known as "fuel ethanol," is ethanol made non-potable by being blended with unleaded gasoline or other unleaded hydrocarbons according to specific regulations of the Bureau of Alcohol, Tobacco and Firearms, U.S. Department of the Treasury. 27 CFR 19.966, .1005. Because of denaturing, an E–100 fuel would contain less than 100% ethanol.

[33] Fact sheet on ethanol, developed by the Development and Communications Office, Technical Information Program, for the U.S. Department of Energy, NREL SP–220–3587, DE91002129, Rev. Feb. 1992.

[34] Fact sheet on liquefied petroleum gas and propane, developed by the Development and Communications Office, Technical Information Program, for the U.S. Department of Energy, NREL SP–220–4066, DE 91002114, Rev. Feb. 1992.

[35] Fact sheet on compressed and liquefied natural gas, developed by the Development and Communications Office, Technical Information Program, for the U.S. Department of Energy, NREL SP–220–4005, DE 90000388, Rev. Feb. 1992. The Commission cannot include CNG in this rulemaking, because PMPA, as amended, limits the Commission's jurisdiction in the proceeding to liquid fuels. Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821). However, CNG will be included in the rulemaking proceeding the Commission conducts under sec. 406 of EPA 92. See note 16, *supra*.

[36] All public documents are filed in the Commission's Rulemaking Record No. R811005. Industry comments are filed in category "D. Industry comments." Other comments are filed in category "E. Comments from other sources." Documents are numbered sequentially in the order received, such as Document No. D–1, Document No. D–2. In this notice, comments are cited by an identification of the commenter, the comment number and the relevant page number(s), e.g., "RFA, D–1, 1–3."

[37] The Commission originally set April 26, 1993, as the deadline for submitting written comments in response to the NPR. In response to a petition, the Commission extended the comment period to May 10, 1993. 58 FR 25582 (April 27, 1993).

manufacturers, agriculture organizations, automobile manufacturers, design and engineering firms, and other related industries and interest groups.

12. Chevron U.S.A. Products Company ("Chevron")—D–5. Chevron is a multinational oil company participating in exploration, production, and refining of crude oil and marketing of petroleum products. Within the United States, Chevron's activities in these functional areas are conducted by divisions of Chevron U.S.A. Inc., a wholly owned subsidiary of Chevron.

13. U.S. Department of Energy ("DOE")—E–5. DOE coordinates and administers the energy functions of the Federal Government.

14. Engine Manufacturers Association ("EMA")—D–6. EMA represents worldwide manufacturers of internal combustion engines for all applications except passenger cars and airplanes. EMA's 31 members produce diesel engines for on-highway truck and bus applications, as well as off-highway construction and agricultural equipment.

15. Marathon Oil Company ("Marathon")—D–9. Marathon, an integrated petroleum company, represents that it is the seventh largest U.S. refiner. The company supplies over 3,800 Marathon and subsidiary-brand retail motor fuel outlets located throughout the Midwest and Southeast, and is one of the refining industry's largest suppliers of petroleum products to independent, private-brand jobbers and wholesalers.

16. Mobil Oil Corporation ("Mobil")—D–4. Mobil is a major, integrated, international petroleum company, with five domestic refiners, more than 50 marketing terminals that distribute gasoline and diesel fuel oil, and over 8,500 branded retail outlets in 29 states. Mobil currently is testing several alternative fuels at selected stations.

17. North Carolina Department of Agriculture ("NCDA")—E–1. NCDA regulates the quality specifications for motor vehicle fuels offered for sale in North Carolina.

18. National Propane Gas Association ("NPGA")—D–19. NPGA represents the LP-gas (principally propane) industry with 3,400 to 3,500 members, including affiliated state and regional associations in 46 states, which represent members in all 50 states. The largest group of members are retail marketers of propane gas. The membership also includes propane producers, transporters, and wholesalers, and manufacturers and distributors of associated equipment, containers and appliances.

19. National Soydiesel Development Board ("NSDB")—D–16. NSDB is a non-profit organization established to develop a market for biodiesel fuels in the U.S. Its members are primarily soybean growers in the U.S. and their various organizations. NSDB seeks greater use of fuels derived from biological materials as an addition to conventional diesel fuels or as replacements for them in certain applications.

20. New York Department of Agriculture and Markets ("NYDAM")—E–4. NYDAM enforces state requirements for certification and labeling of gasoline octane ratings and diesel fuel oil cetane ratings. Pending state legislation would expand NYDAM's authority to other fuels, particularly those affected by the Clean Air Act.

21. Propane Consumers Coalition ("PCC")—E–3. PCC represents residential, agricultural, and industrial propane users.

22. Phillips 66 Company ("Phillips 66")—D–3. Phillips 66 produces and markets gasoline, diesel fuel oil and alternative fuels. It has an active interest in alternative fuels and programs, including a propane evaluation and emissions test fleet of 12 vehicles operating since 1990; emission test data for a variety of vehicles and fuel combinations on LPG; full service bulk propane plants in three states; approximately 200 company vehicles operating on LPG; more than 600 customer vehicles operating on LPG; over 100 LPG vehicle refueling dispensers; and 2 CNG dispenser stations.

23. Petroleum Marketers Association of America ("PMAA")—D–18. PMAA is a federation of 44 state and regional trade associations representing more than 11,000 independent petroleum marketers throughout the U.S. These marketers sell in excess of 40% of the gasoline, 75% of the home heating oil, and 60% of the diesel fuel oil consumed in this country.

24. Railroad Commission of Texas ("RCT")—E–2. RCT regulates energy and transportation industries in Texas. It operates under statutory mandates to support technical and market research and to educate the public about propane and other alternative fuels.

25. Renewable Fuels Association ("RFA")—D–1. RFA represents the domestic fuel industry in the U.S. Its membership includes ethanol producers that represent approximately 90% of operable U.S. ethanol capacity, as well as fuel blenders, providers of equipment, supplies, and services to the industry, and other interested parties.

26. Society of Independent Gasoline Marketers of America ("SIGMA")—D–13. SIGMA represents approximately 285 private brand marketers and chain retailers who market motor fuels in all 50 states, the District of Columbia, and Puerto Rico. In 1991, SIGMA members marketed approximately 22.75 billion gallons of motor fuel, or about 17% of all motor fuels sold in the U.S. that year. Diesel fuel oil sales accounted for 4.6 billion gallons.

27. Sun Company, Inc. ("Sun")—D–8. Sun produces diesel fuel oil at five U.S. refineries and sells automotive diesel fuel oil at some service stations. Sun is evaluating alternative fuels through in-house research, through participation in alternative fuel industry programs, and through installation of alternative fuel refueling facilities in selected Sun service stations for LPG, M–85, and E–85. It is planning a CNG facility.

28. Texaco Inc. ("Texaco")—D–22. Texaco Inc. is a vertically integrated enterprise, which is directly, or through ownership in affiliated operating companies, engaged in the worldwide exploration, production, transportation, and refining and marketing of crude oil and its products, including petrochemicals.

29. Wagner & Brown, Ltd. ("W&B")—D–12. W&B produces oil and gas.

D. Comment Suggestions Beyond Commission's Authority Under PMPA

Several comments suggested that the Commission amend the Octane Rule in ways that are beyond the Commission's authority under PMPA, as amended by EPA 92. Specifically: (1) NCDA suggested the Commission address pump nozzle size and require a nozzle on all diesel fuel oil dispensers with a sufficient diameter to prevent fueling a gasoline powered vehicle with diesel fuel oil;[38] (2) AGA/NGVC[39] and PCC[40] urged the Commission to require posting based on a unit pricing concept to compare the cost of alternative fuels to that of gasoline; (3) RCT suggested that the Commission require labeling that educates consumers about alternative and conventional fuels' emissions of toxins and other pollutants;[41] (4) RCT also recommended that the Commission conduct consumer education (at least as to the advantages of HD–5 propane over other mixtures of propane) instead of requiring the posting of information;[42]

[38] NCDA, E–1, 1, 3.
[39] AGA/NGVC, D–11, 3–4, 6–8.
[40] PCC, E–3, 1–3.
[41] RCT, E–2, 3.
[42] *Id.* at 4.

and (5) AAMA,[43] AGA/NGVC,[44] Chevron,[45] Phillips 66,[46] and Sun[47] urged the Commission to include CNG in any posting requirements at this time.[48]

PMPA, as amended by EPA 92, requires the Commission to amend the Octane Rule to require posting for liquid alternative fuels of each fuel's octane rating, or of another form of rating that the Commission, after consultation with ASTM, determines to be more appropriate to carry out the purposes of PMPA's testing, certification and posting requirements.[49] Because this is a statutorily mandated rulemaking proceeding, the Commission's authority is limited to that granted by the mandating legislation.

First, PMPA does not authorize the Commission to specify nozzle sizes for pumps dispensing different types of automotive fuels. Second, although comparative unit pricing would give information to purchasers about different types of fuels, it does not constitute an alternative rating more appropriate than an octane rating. Third, labeling that educates consumers about alternative and conventional fuels' emissions of toxins and other pollutants goes beyond assisting purchasers in identifying the specific type(s) of fuel required for their vehicles and therefore is not an alternative rating more appropriate to carry out PMPA's requirements.[50] Fourth, PMPA, as amended, also does not allow the Commission discretion to require consumer education in lieu of testing, certification, and posting of ratings. Lastly, the Commission is not free to include compressed natural gas (CNG) in this rulemaking, because PMPA, as amended, limits the Commission's jurisdiction in this proceeding to liquid fuels.[51] Accordingly, the Commission does not adopt any of these suggestions.

III. Ratings Proposed in the NPR

A. Alternative Liquid Automotive Fuels

In the NPR, the Commission proposed that the Octane Rule be amended to require the certification and posting of the octane rating of alternative liquid automotive fuels. Because of information that became available to the Commission during the course of its investigation into the alternative liquid automotive fuels area, however, the Commission tentatively concluded that it may not be practical or workable to require the disclosure of octane ratings for these fuels. Consequently, after consultation with ASTM and others, the Commission also proposed three other "rating" options for alternative liquid automotive fuels in the NPR. The four options are summarized below.

Option One, as already mentioned, proposed requiring the octane rating to be certified and posted for the alternative liquid automotive fuels. Option Two proposed requiring fuel composition ratings, such as, the range of hydrocarbon content of the alcohol fuels (which relates to the cold start capability of alcohol fuels) or a minimum percentage of the principal component of the fuel. Option Three proposed requiring the posting of labels that would compare the alternative fuel to gasoline in terms of the approximate mileage one would obtain by using an equivalent volume of each fuel. The proposed labels for Option Three were based on the heating values, or energy contents, of the alternative fuels and gasoline. Option Four proposed establishing fuel descriptors based on certain material specifications such as those developed by the California Air Resources Board. This option would require certification and posting of the identity of the fuels using these descriptors and minimum specifications for each fuel. In the NPR, the Commission sought comment on whether any of the four proposed ratings or combination of ratings, or ratings not yet proposed, would be appropriate. This section contains a review and analysis of the comments on each option and a detailed discussion of the automotive fuel rating that the Commission is prescribing today.

1. Octane Rating Option

In the NPR, the Commission proposed requiring octane ratings for alternative liquid automotive fuels, but noted that other options may better implement the purposes of section 1501 of EPA 92.[52] The Commission explained that the octane rating currently required for gasoline is a measure of how well the gasoline resists engine knocking. The octane rating needed to prevent knocking varies with the engine's compression ratio, and different engines may require grades of gasoline with different octane ratings. The Octane Rule is designed to enable consumers to buy gasoline with an octane rating high enough to prevent engine knock, and to help consumers avoid "octane overbuying" or buying gasoline with an octane higher than needed to prevent engine knock.[53]

In requesting comments on its proposal to require octane ratings for alternative liquid automotive fuels, the Commission noted that, unlike gasoline, the physical and chemical properties of each such fuel may not vary much.[54] The Commission also observed that it expected that engines designed for alternative fueled vehicles would be designed to use fixed-octane alternative fuels without engine knock. The Commission further stated that there might be practical problems in implementing a reliable octane certification and posting program for alternative liquid automotive fuels, because of the lack of a standardized, such as an ASTM-approved, test method for determining octane ratings of such fuels.[55] Finally, the Commission expressed concern that the posting of high octane ratings associated with alternative liquid automotive fuels may contribute to the misperception that high-octane gasoline always is best for vehicles, and thereby aggravate existing gasoline octane overbuying.[56]

To account for the lack of significant variations in octane levels within classes of alternative liquid automotive fuels, and the lack of a standardized test method, the Commission proposed an option of assigning specified octane ratings to alternative liquid automotive fuels and requiring that these assigned octane ratings be posted at the pump and certified by suppliers through the chain of distribution.[57] The Commission proposed the following octane ratings for alternative liquid automotive fuels,

[43] AAMA, D–7, cover letter, 1, Att. A, 1.

[44] AGA/NGVC, D–11, 4–5. AGA/NGVC stated more broadly that the current rulemaking proceeding should apply to all fuels, not just to liquid fuels.

[45] Chevron, D–5, 1.

[46] Phillips 66, D–3, 1.

[47] Sun, D–8, 1.

[48] W&B stated that it understands that PMPA limits the current proceeding to liquid fuels, but urged the Commission to include in the current amendment a statement that the Commission did not overlook the significance of CNG as an alternative fuel and that CNG will be addressed in a later proceeding. W&B, D–12, 1–2.

[49] Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821).

[50] Although disclosures concerning fuel costs and emissions are not viewed as appropriate ratings for purposes of this proceeding, the Commission will consider labeling requirements about costs and benefits of alternative fuels, including gaseous, liquid and other alternative fuels, and alternative fueled vehicles in the proceeding it conducts under section 406 of EPA 92. See notes 15–16, *supra*.

[51] Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821). However, CNG and other alternative non-liquid automotive fuels will be included in the rulemaking proceeding the Commission conducts under sec. 406 of EPA 92. See note 50, *supra*.

[52] 58 FR 16464, 16465.

[53] *Id.*

[54] *Id.* at 16469.

[55] *Id.*

[56] *Id.* at 16470.

[57] *Id.* at 16469.

which are based on tests conducted by DOE's National Renewable Energy Laboratory in Golden, Colorado.

Methanol	98
Ethanol	99
M-85	95
E-85	96
LPG	104
LNG	120

Eighteen of the 24 comments that addressed the octane rating option for alternative liquid automotive fuels opposed it.[58] Opponents included major industry trade associations representing refiners, distributors, and retailers of automotive fuels, and U.S. manufacturers of motor vehicles.[59] The most common criticisms were that octane ratings for alternative liquid automotive fuels (1) do not provide useful information to consumers,[60] and (2) may mislead consumers either by implying that fuels are interchangeable or that higher octane is always better.[61]

In particular, several commenters stated that the octane ratings of a given type of alternative liquid automotive fuel tend not to vary.[62] Others said that posted ratings also have little value, because dedicated alternative fueled vehicles, as well as alternative fueled vehicles capable of using both gasoline and a alternative liquid automotive fuel,[63] use only one type of liquid alternative fuel.[64] Moreover, four commenters stated all alternative liquid automotive fuels have high enough octane ratings to prevent engine knock in vehicles designed to use alternative fuels.[65] Four commenters said that engines are not designed to take advantage of the high octane content of alternative liquid automotive fuels [66] One stated that there also is no correlation between octane ratings for alternative liquid automotive fuels and vehicle performance criteria such as mileage, cleanliness, and vehicle life.[67]

Additionally, four commenters opposed adopting the proposed octane ratings assigned to each alternative liquid automotive fuel without ASTM review of the test procedure and proof that the test results could be duplicated.[68] Four noted that there currently is no reliable, standard test method for determining the octane ratings of alternative liquid automotive fuels.[69]

Six comments supported requiring octane ratings for alternative liquid automotive fuels.[70] DOE recommended that the Commission require certification and posting of specific octane ratings for alternative liquid automotive fuels as a way of meeting the Commission's statutory obligations under EPA 92 pending consideration of additional labeling requirements in the rulemaking to be concluded by April 23, 1995, under section 406 of the EPA 92.[71] Two trade associations representing producers and sellers of natural gas and manufacturers of natural gas fueled vehicles also supported the use of octane ratings until a more satisfactory method of labeling could be developed.[72]

After considering all comments received in this proceeding, the Commission has determined not to require the posting of octane ratings for alternative liquid automotive fuels. Unlike disclosing octane ratings for gasoline, there appears to be little or no benefit to disclosing octane ratings for alternative liquid automotive fuels. Octane ratings for all alternative liquid automotive fuels are high enough to avoid engine knock problems, and such ratings do not provide information relevant to vehicle performance of alternative fueled vehicles. In addition, octane ratings for alternative liquid automotive fuels of a given composition would not vary significantly.

In contrast, there are significant disadvantages to requiring octane posting and certification for alternative liquid automotive fuels. In particular, the Commission is reluctant to require a disclosure that may mislead consumers about the significance of the high octane ratings of alternative liquid automotive fuels, all of which far exceed the minimum octane requirements of vehicles that can use such fuels. Such a disclosure may cause consumers to believe that gasoline and alternative liquid automotive fuels are interchangeable, or that different alternative liquid automotive fuels are interchangeable with one another. It also may foster consumer misperceptions that higher octane necessarily signifies higher quality and better performance. Accordingly, as authorized by EPA 92, the Commission determines that another form of rating is more appropriate, as discussed in detail below in Part III.A.5.

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[58] ATFI, D–15, 2; AAMA, D–7, 1–2; API, D–10, 3–4; CENEX, D–21, 2–3; Chevron, D–5, 1–2; CFDC, D–14, 2–3; Marathon, D–9, 2; Mobil, D–4, 1; NPGA, D–19, 2; NSDB, D–16, 5; NYDAM, E–4, 1; PMAA, D–18, 1–2; Phillips 66, D–3, 2–3; RCT, E–2, 2; RFA, D–1, 3; SIGMA, D–13, 1–2; Sun, D–8, 2, 4; Texaco, D–22, 1.

[59] See comments of API, D–10, 3–4; SIGMA, D–13, 1–2; AAMA, D–7, 1–2. But see discussion of other comments supporting interim or limited posting of the octane ratings of alternative liquid fuels, notes 70–72, *infra*.

[60] See specific reasons cited, notes 62–67, *infra*.

[61] API, D–10, 3–4 (octane ratings for liquid alternative fuels falsely will imply fuel interchangeability); Mobil, D–4, 1 (posting octane ratings for alternative fuels may lead consumers to believe higher octane alternative fuels obtain higher miles per gallon); RFA, D–1, 3 (availability of higher octane ratings on alternative fuel labels may create consumer perception that higher octane fuels are more beneficial); Marathon, D–9, 2 (octane ratings for liquid alternative fuels will confuse consumers and diminish the potential value of information relating directly to performance); SIGMA, D–13, 1–2 (octane ratings for liquid alternative fuels may deceive consumers into thinking that a particular fuel is superior because of its higher octane rating); CFDC, D–14, 2–3 (octane ratings for liquid alternative fuels may confuse consumers whose vehicles function only on one fuel); PMAA, D–18, 1–2 (consumers may be deceived into believing that higher octane for liquid alternative fuels indicate better fuel quality and performance); CENEX, D–21, 2–3 (octane ratings for liquid alternative fuels may mislead consumers to believe the fuels are interchangeable with gasoline; unduly emphasizes perhaps the least important factor in the performance of such fuels; and will not help consumers choose among fuels); Chevron, D–5, 2 (octane posting inherently implies that a higher rating is better, and may cause consumers to think that a liquid alternative fuel is interchangeable with gasoline).

[62] AAMA, D–7, 1–2; RFA, D–1, 3; Phillips 66, D–3, 2–3; NYDAM, E–4, 1; Sun, D–8, 2; Marathon, D–9, 2; CFDC, D–14, 2–3; CENEX, D–21, 2–3; Texaco, D–22, 1.

[63] Single-fuel or dedicated fuel vehicles are those that can operate only on one type of fuel. Dual-fuel vehicles can operate on two different types of fuels, but most have separate fuel tanks for the different fuels. Flexible-fuel vehicles can operate on various blends of fuel from a single tank. For example, a flexible-fuel vehicle might operate on any percentage of methanol from zero to 85 percent or more.

[64] Marathon, D–9, 2; Chevron, D–5, 2; CFDC, D–14, 2–3; PMAA, D–18, 1–2. See also Texaco, D–22, 1 (consumers choose fuel when they purchase or retrofit a vehicle for that fuel).

[65] ATFI, D–15, 2; Chevron, D–5, 1 (recommended that, if an octane label is adopted, it state that the octane rating of the fuel exceeds the octane ratings recommended by all motor vehicle manufacturers); RCT, E–2, 1 (addressed propane only); NPGA, D–19, 2 (same); Sun, D–8, 2.

[66] Phillips 66, D–3, 2–3; NYDAM, E–4, 1; Mobile, D–4, 1; Sun, D–8, 2.

[67] API, D–10, 3–4.

[68] API, D–10, 3; Phillips 66, D–3, 2; Chevron, D–5, 1–2; Mobil, D–4, 1.

[69] API, D–10, 3; Phillips 66, D–3, 2; Chevron, D–5, 1–2; ATFI, D–15, 2.

[70] Only three of these comments clearly supported requiring posting of octane ratings for all alternative liquid automotive fuels, as other than an interim measure. See ABDI, E–6, 1 (stated, without providing supporting information, that octane is a measure of performance for alternative liquid automotive fuels and that significant differences in octane could occur); AMI, D–23, 1 (suggested that erroneous perceptions about octane could be addressed through education); PCC, E–3, 3 (recommended providing octane ratings with information on energy content, driving ranges, and unit pricing per BTU). One trade association supported posting of octane ratings for oxygenated fuels, but not for LPG or LNG. AIAM, D–17, 2. See text for discussion of comments filed by DOE, and comments jointly filed by AGA and NGVC, recommending octane ratings as an interim measure.

[71] DOE, E–5, 2–3. The Commission considers section 406 to require disclosures different than the certification and posting of a fuel rating.

[72] AGA/NGVC, D–11, 3, 8.

2. Fuel Composition: Hydrocarbon, Propane and Methane Content Option

As a second option, the Commission proposed requiring the disclosure of fuel composition.[73] Specifically, for the liquefied gas fuels, the Commission proposed a requirement that the minimum propane content of LPG and the minimum methane content of LNG be certified and posted.[74] The NPR estimated that the LPG most often used in automotive applications is 95% propane and 5% butane and that the LNG most often used in automotive applications is composed of several gases—methane, ethane, propane, and nitrogen, but with methane typically accounting for 88–99% of the fuel's composition.[75] Disclosure of the minimum propane content of LPG and the minimum methane content of LNG might, in conjunction with information from the vehicle manufacturer or converter, provide consumers with comparative quality information needed for fuel purchase decisions. Under this option, consumers would be able to compare like fuels. For example, for LNG, one station may post a methane content of 90. Another station may post 95. Depending on their vehicle's requirements, consumers could then determine which fuel is better for their purposes.

For the alcohol fuels, the Commission proposed requiring certification and posting of the hydrocarbon content of each fuel.[76] The alcohol fuels are either composed entirely of methanol or fuel ethanol or are blends of methanol or fuel ethanol with up to 15% or more hydrocarbons, usually in the form of gasoline. The NPR explained that hydrocarbon content relates to the cold start property of alcohol fuels, which differs significantly from that of gasoline. Alcohol is more difficult to vaporize than gasoline and therefore more difficult to ignite in a cold engine. The addition of hydrocarbons to the alcohol fuels improves their cold start characteristics. For example, cold starts are significantly improved by using M–85 and E–85 instead of M–100 and E–100. The NPR suggested that, for each alcohol fuel, hydrocarbon content disclosures might give consumers some information about the fuel's cold starting ability. For example, consumers might want to select a fuel with a higher or lower hydrocarbon content, depending on climatic conditions or geographic region.

[73] 58 FR 16464, 16470.

[74] *Id*

[75] *Id*

[76] *Id*

The Commission proposed that the hydrocarbon content of these fuels be certified and posted in terms of a range, rather than a fixed number.[77] Hydrocarbon content of alcohol fuels can vary, primarily because some varieties of these fuels can at different times of the year also contain hydrocarbon-containing oxygenates (basically, other alcohols and ethers) in varying amounts. The Commission reasoned that disclosure of a range could eliminate the need for changing labels at various times of the year to accommodate seasonal changes in the hydrocarbon contents of the alcohol fuels.

The Commission sought comment on the following labels, each of which is pertinent to a particular alternative fuel, and asked whether they would satisfy EPA 92's intent:

1. "Liquefied Propane Gas/Minimum _____% Propane"
2. "Liquefied Natural Gas/Minimum _____ % Methane"
3. "M–100 Fuel Methanol/X%–Y% Hydrocarbons"
4. "E–100 Fuel Ethanol/X%–Y% Hydrocarbons"
5. "M–85 Fuel Methanol/X%–Y% Hydrocarbons"
6. "E–85 Fuel Ethanol/X%–Y% Hydrocarbons"

The Commission sought comment on the advantages and disadvantages of requiring such disclosures. The Commission also sought comment on whether the Commission should specify a methodology or methodologies for determining the propane, methane, and hydrocarbon contents and, if it did so, what methodology or methodologies should be specified.[78] For alcohol fuels, the Commission asked whether requiring the disclosure of any factor(s) other than the hydrocarbon content of the fuels would better assist consumers in avoiding cold-start problems.[79]

Twelve comments discussed the Commission's proposal to require composition disclosures for LPG and LNG.[80] Two contended that the petroleum gas fuel that is now used in automobiles should be classified as a gas rather than a liquid and therefore should not be regulated in this proceeding.[81] Two others urged the Commission to make clear that the P in LPG (and CPG) stands not for propane, but for petroleum, because butane, another petroleum gas, is often also used along with propane as an ingredient in these fuels.[82] RCT, however, asked the Commission to use the term 'propane' instead of 'LPG' because propane is always the principal component of the fuel and consumers are already familiar with that term.[83]

Six of the twelve comments making recommendations on this option for LPG and LNG opposed the Commission's proposed requirement for composition disclosures. Four contended that such information would not benefit consumers in any meaningful way,[84] and two argued for alternative approaches.[85] Four comments approved of the proposal to require composition disclosures for liquefied gas fuels, contending such disclosures would help consumers in making fueling choices.[86]

Two comments made other suggestions. AGA/NGVC said they were not opposed to requiring fuels to be labeled according to their composition, but preferred a disclosure requirement that "will have the greatest ability to convey the most pertinent information," which would be "the testing of energy content in the form of gasoline equivalent gallon."[87] NPGA believed the proposed rulemaking will not achieve the Commission's objectives in the most efficient and cost-effective manner possible and argued that all consideration of comparison labeling for liquefied gas fuels should be deferred until the section 406 rulemaking.[88]

Five comments addressed what items should be included when disclosing

[77] *Id.*

[78] *Id.*

[79] *Id.* at 16475.

[80] Phillips 66, D–3, 3; AAMA, D–7, 2; Sun, D–8, 2; Marathon, D–9, 2–3; AGA/NGVC, D–11, 7; W&B, D–12, 2–3, 6; ATFI, D–15, 2–4; AIAM, D–17, 3–4; NPGA, D–19, 2–3; CENEX, D–21, 3; Texaco, D–22, 1–2; RCT, E–2, 3.

[81] NPGA, D–19, 1–2; RCT, E–2, 1–2.

[82] Phillips 66, D–3, 3; W&B, D–12, 2–3.

[83] RCT, E–2, 4.

[84] AAMA, D–7, Att. A, 2 (does not provide meaningful information to the consumer); Sun, D–8, 2 (would not provide useful information to the consumer and would be confusing to most consumers); Marathon, D–9, 3 (probably too complex for most consumers); CENEX, D–21, 3 (average consumer lacks the technical expertise needed to make an informed purchasing decision on the basis of posted fuel content.)

[85] Texaco, D–22, 1 (suggested requiring a statement that the fuel meets commonly accepted industry standards); RCT, E–2, 3 (recommended that the Commission adopt a market approach by providing consumer education on the advantages that have been identified for LPG, rather than regulations).

[86] Phillips 66, D–3, 3 (the minimum fuel composition option provides the most valuable public information for making a refueling choice); W&B, D–12, 5 (supported the proposal to disclose fully the possible range of contents in alternative fuels); ATFI, D–15, 2 (fuel composition information is the most relevant to vehicle manufacturers, fuel suppliers, and the consuming public); AIAM, D–17, 2–3 (fully supported this proposal because such information would certainly be beneficial to the vehicle operator).

[87] AGA/NGVC, D–11, 7.

[88] NPGA, D–19, 2–3.

propane gas content, i.e., whether the posting and certification requirement for LPG should specify that the propane component be disclosed as all "special duty grade" propane (i.e., suitable for all automobiles using petroleum gas) or only commercial grade propane (which may not be suitable for most automobiles) or as a mixture of the two.[89] No comments addressed the issue of whether the Commission should require certain methods for determining the methane or propane/butane gas contents of the liquefied gas fuels.

With respect to the alcohol fuels, 20 comments discussed the proposal to require hydrocarbon range disclosures for methanol and fuel ethanol. Five approved of such a requirement.[90] Fifteen opposed such a requirement.[91]

Some opposing comments said that consumers lacked the technical competence to utilize the information,[92] others said that factors other than hydrocarbon content are more relevant to predicting cold start performance,[93] and still others said they would prefer different approaches.[94] NYDAM emphasized that the costs of testing and labeling necessitated by the seasonal variations in the hydrocarbon content of the alcohol fuels designed to forestall cold-starting problems would make a hydrocarbon content disclosure requirement too burdensome.[95] Two other comments said that, until there is more empirical data on cold start problems and their solutions, it would be premature to require disclosure of any factors relating to cold-start performance.[96] CENEX also urged having disclosures that simply advise consumers to follow the instructions from their vehicles' manufacturers.[97] Three comments preferred a disclosure that the fuels meet all relevant industry standards.[98] Mobil argued that requiring disclosures of ranges of hydrocarbons might give incentives to manufacturers to aim for the lowest percentage of hydrocarbons because consumers might think that fuels with the highest alcohol fuel content are always best for their vehicles.[99] Two comments approved of principal ingredient disclosures, but not hydrocarbon content disclosures.[100] Only one comment addressed the issue of whether the Commission should prescribe certain methods for determining the composition of the alcohol fuels. ATFI supported the designation of an appropriate methodology to determine fuel composition, but did not recommend any specific methodology.[101]

Based on all the comments received in this proceeding, the Commission has determined to require a modified version of the fuel composition option proposed in the NPR. As discussed in detail in Part III.A.5, below, the Commission is requiring for each alternative liquid automotive fuel the disclosure of the principal fuel ingredient by percentage of volume. The Commission has determined not to require disclosures of ranges of hydrocarbon content for alcohol fuels because the record does not show sufficiently that knowledge of hydrocarbon content would provide consumers benefits in avoiding cold-start problems or even that most consumers would understand the reason for such disclosures.

The Commission has included in the Fuel Rating Rule as an alternative liquid automotive fuel the petroleum gas fuel now used by automotive vehicles because the fuel is stored and dispensed to consumers at least substantially in a liquefied state.[102] In the NPR, the Commission proposed describing this fuel with the term "Liquified Propane Gas."[103] As explained above, several comments raised concerns about proposed disclosure requirements for LPG in light of this designation. The Commission now uses the term "Liquified Petroleum Gas" because that is the term used in the definition of "alternative fuel" in section 301 of EPA 92. The certification and posting provisions of the Fuel Rating Rule, however, as explained in Part III.A.5., below, do not require choosing between the terms "Liquified Petroleum Gas" and "Liquefied Propane Gas." Either of those designations or just the expression "LPG" or any other commonly accepted designation may be used to describe the fuel so long as the minimum percentage by volume of the propane content (*i.e.*, the principal component of the fuel) is disclosed. Finally, because the Fuel Rating Rule does not require adherence to particular fuel specifications, it is unnecessary to require that marketers specify whether LPG contains special duty grade propane or commercial grade propane, as was suggested by some of the comments.[104]

3. Heating Value (Energy Content) Option

As another option, the Commission proposed requiring a label comparing each alternative liquid automotive fuel to gasoline in terms of the approximate mileage a car would get by using an equivalent volume of each fuel.[105] The comparison would be based on the heating value, or energy content, of each fuel. The Commission proposed two alternative labels for this option: the first compared how many gallons of a given alternative liquid automotive fuel were needed to drive as far as one could drive on a gallon of gasoline, and the second compared how far one could drive on a gallon of a given alternative liquid automotive fuel as compared to how far one could drive on a gallon of gasoline. The Commission stated that the advantage of this type of label was that the disclosed information, coupled with the price of the fuel, would give consumers with flexible fuel vehicles the ability to make choices among different fuels.

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[89] W&B, D–12, ATFI, D–15, 2–3, NPGA, D–19, 2; Texaco, D–22, 2; RCT, E–2, 3.

[90] RFA, D–1, 4 (the suggested labeling format provides sufficient information for the consumer); W&B, D–12, 5 (supported fully disclosing the possible range of contents in alternative fuels); CFDC, D–14, 3–5 (a label with the type and percentage of the fuel composition has merit); ATFI, D–15, 2–3 (supported using fuel composition labeling to inform consumers about the quality of each alternative fuel); AIAM, D–17, 2–3 (fully supported this proposal because such information is beneficial to the vehicle operator).

[91] Mobil, D–4, 2–3; Chevron, D–5, 2–3; AAMA, D–7, 3–4 and Att. A, 2–3; Sun, D–8, 2–3; Marathon, D–9, 2–3; API, D–10; 4; AGA/NGVC, D–11, 7–8; SIGMA, D–13, 2–3, NSDB, D–16, 6; CENEX, D–21, 3; Texaco, D–22, 1–2; AMI, D–23, 1–2; NYDAM, E–4, 2; DOE, E–5, 3; ABDI, E–6, 1.

[92] Mobil, D–4, 2–3; Marathon, D–9, 2–3; API, D–10, 4; CENEX, D–21, 3, NYDAM, E–4, 2.

[93] Chevron, D–5, 2–3; Sun, D–8, 2–3; AMI, D–23, 1–2.

[94] AAMA D–7, 3–4 (contended there are no agreed upon methods of measuring fuel compositions); AGA/NGVC, D–11, 7–8 (not opposed to this option, but would prefer listing of energy content in the form of gasoline equivalent gallon); SIGMA, D–13, 2–3 (urged Commission to require only the posting of the type of alternative liquid fuel dispensed); NSDB, D–16, 6 (recommended the fuel descriptor option); Texaco, D–22, 1–2 (suggested simply requiring a statement that the fuel meets commonly accepted industry specifications); DOE, E–5, 3 (recommended the option of requiring posting of octane ratings for all alternative fuels); ABDI, E–6, 1 (recommended the octane posting option for all fuels).

[95] NYDAM, E–4, 2.

[96] SIGMA, D–13, 3; CENEX, D–21, 3.

[97] CENEX, D–21, 3.

[98] AAMA, D–7, 1–2; Marathon, D–9, 2; Texaco, D–22, 1.

[99] Mobil, D–4, 2.

[100] Marathon, D–9, 2–3; SIGMA, D–13, 2–3.

[101] ATFI, D–15, 2.

[102] Some comments urged the Commission to wait until the section 406 rulemaking to address the liquefied petroleum gas fuels at the same time the compressed natural gas fuels are considered. Others urged the Commission to treat the compressed natural gas fuels now along with the liquefied petroleum fuels. The Commission, however, lacks the discretion to alter the provisions of EPA 92 in this regard.

[103] For LPG, The California Air Resources Board uses the term "Liquefied Petroleum Gas." However, based on discussions the Commission's staff had with Department of Energy staff and staff at the National Propane Gas Association, in the NPR the Commission proposed using the term "Liquefied Propane Gas."

[104] See note 89, *supra*.

[105] 58 FR 16464, 16470–71.

The Commission received 24 comments regarding this option,[106] all of which opposed or criticized it.[107] Some comments stated that the heating values in the Commission's proposed Heating Values Chart (based on information obtained from the Interagency Commission on Alternative Motor Fuels and the Department of Energy) were incorrect.[108] Chevron stated that the chart did not account for the fact that heating values vary with fuel composition.[109] Two comments contended that the Heating Values Chart should list a range of values for LPG (to reflect its composition),[110] while three others contended that measuring Btu content was expensive and not appropriate for a particular batch of any of the fuels.[111] AMI commented that "a simple means of clarifying the different energy densities of the fuels is needed."[112]

Some comments stated that the proposal would not provide consumers with useful information. PMAA stated that the purported benefits to consumers were speculative and not worth the costs to industry.[113] RFA stated that posting a label declaring that ethanol has a lesser fuel economy than gasoline would incorrectly lead gasohol purchasers into believing they would suffer fuel economy penalties.[114] Other comments stated that the information was useful to consumers only when choosing a new vehicle or deciding whether to convert an existing vehicle to an alternative fuel, and not when refueling.[115]

Numerous comments stated that labels based on heating values would be confusing or misleading to consumers, for various reasons. First, they argued that driving range and fuel economy (miles per gallon) are the function of many variables (e.g., engine design, engine efficiency, driving habits) and not simply the volumetric energy content of a fuel. As a result, Btu ratings do not always accurately reflect actual fuel economy.[116] Second, three comments stated that the volumetric comparisons ignored fuel cost, and that price comparisons were the most important factors driving which fuel a consumer would purchase.[117] Finally, six comments concluded that labels based on heating values would encourage consumers to purchase gasoline (leading to engine damage if used in engines not designed for gasoline), because this labeling option makes the alternative liquid automotive fuels appear less efficient than gasoline.[118]

Some comments raised concerns with the proposed labeling formats. Mobil commented that the proposed labeling formats were flawed because they were long and cumbersome.[119] AAMA noted that both labeling options incorrectly assume that vehicle efficiencies are the same for gasoline and alternative liquid automotive fuels.[120] AGA/NGVC stated that the fuels should be rated and compared in terms of price, either by Btu's per gasoline equivalent gallon or fuel cost per fixed Btu.[121] RFA and Phillips 66 favored posting the actual heat content of the fuels in Btu's rather than comparing the fuels to gasoline.[122] Two other comments proposed disclosing the reduction in toxins and other pollutants expected by using a particular fuel.[123]

After considering the record, the Commission has decided not to require labels based on heating values. Instead of helping consumers make informed purchasing decisions, the comments indicate that this option would not benefit consumers and might instead be confusing or misleading. This is because the volumetric energy content of a fuel, as measured by its Btu rating, is an imprecise gauge of that fuel's actual fuel economy. In light of this and the other concerns and objections noted, the Commission has decided not to adopt this option.

4. Fuel Descriptor Option

As another option, the Commission proposed requiring that the alternative liquid automotive fuel pumps identify the fuels for consumers.[124] The fuel descriptors the Commission proposed were based on the terms developed by and included in the California Air Resources Board's proposed specifications for the alternative fuels. Those terms are:

"M–100 fuel methanol;"
"M–85 fuel methanol;"
"E–100 fuel ethanol;"
"E–85 fuel ethanol;"
"Liquefied Propane Gas;"[125] and,
"Liquefied Natural Gas."

The Commission proposed that the fuels would have to meet certain technical specifications, such as those proposed by the State of California, as a condition to the descriptor posting. The Commission noted that additional specifications are likely to be developed by alternative vehicle manufacturers and fuel suppliers in conjunction with ASTM (as has been done for gasoline). Noting that ASTM and DOE specifications for the alternative liquid automotive fuels may not be completed within the time allotted for this rulemaking, the Commission asked whether, as an alternative to the ASTM specifications, it should adopt specifications analogous to California's as interim specifications until ASTM or others develop and approve specifications.[126]

The Commission noted in the NPR that descriptor labeling in conjunction with fuel specifications could direct consumers to the correct fuel dispenser and assure consumers that they are purchasing a product that satisfies automobile engine minimum content

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[106] RFA, D–1; Phillips 66, D–3; Mobil, D–4; Chevron, D–5; AAMA, D–7; Sun, D–8; Marathon, D–9; API, D–10; AGA/NGVC, D–11; W&B, D–12; SIGMA, D–13; CFDC, D–14; ATFI, D–15; AIAM, D–17; PMAA, D–18; NPGA, D–19; AEC, D–20; CENEX, D–21; AMI, D–23; RCT, E–2; PPC, E–3; NYDAM, E–4; DOE, E–5; ABDI, E–6.

[107] Mobil opposed additional labeling generally but concluded that this option has "the most meaning to the public" and "has the most merit." Mobil, D–4, 2.

[108] AAMA, D–7, Att. A, 3, (heating values for LPG and LNG are incorrect; values in chart should be based on net, not gross, heating values); API, D–10, 6 (same); W&B, D–12, 4 (heating value for LPG is incorrect); AEC, D–20, 1 (same); CENEX, D–21, 3 (heating value of LNG may vary widely); ABDI, E–6, 2 (chart should be based on lower, not higher, heating values).

[109] Chevron also stated that reporting heating values to the nearest one Btu/gallon "far exceeds the accuracy of the determinations." Chevron, D–5, 3.

[110] W&B, D–12, 5; AEC, D–20, 1.

[111] Chevron, D–5, 3; AAMA, D–7, Att. A, 3; API, D–10, 5.

[112] AMI further stated that the average volume of fuel required to drive the same distance as gasoline is "commonly accepted," and that the Commission should adopt "the same approach and values as California." AMI, D–23, 1. AMI did not further explain its reasons for supporting for this option.

[113] PMAA, D–18, 2.

[114] RFA, D–1, 5.

[115] Phillips 66, D–3, 3–4; Sun, D–8, 2–4; Marathon, D–9, 3; API, D–10, 5; SIGMA, D–13, 3; CFDC, D–14 4; CENEX D–21, 3; NYDAM, E–4, 2. See also AIAM, D–17, 3 (stating generally that the information would not be useful to consumers in comparing which fuel to purchase).

[116] RFA, D–1, 5; Chevron, D–5, 3; Sun, D–8, 3–4; Marathon, D–9, 3; API, D–10, 5; AGA/NGVC, D–11, 7; CFDC, D–14, 4; NPGA, D–19, 2; CENEX, D–21, 3; RCT, E–2, 3–4; NYDAM, E–4, 2; ABDI, E–6, 1.

[117] AGA/NGVC, D–11, 5–6 (labels should disclose the cost per set amount of Btu's for all fuels); PCC, E–3, 1–2 (same); NYDAM, E–4, 2 (consumers will measure each fuel's performance to make valid price comparisons).

[118] Phillips 66, D–3, 4; API, D–10, 5; CFDC, D–14, 4; ATFI, D–15, 3; NPGA, D–19, 2; RCT, E–2, 3.

[119] Mobil, D–4, 2.

[120] AAMA, D–7, 23.

[121] AGA/NGVC, D–11, 4, 6.

[122] RFA, D–1, 5 (opposed this option generally but favored posting minimum Btu content only "if the [C]ommission finds it necessary to post some sort of information relative to energy content"); Phillips 66, D–3, 4 (same).

[123] NPGA, D–19, 2; RCT, E–2, 4. See also discussion in Part II. D., above.

[124] 58 FR 16464, 16471.

[125] See note 103 and accompanying text, *supra*.

[126] 58 FR 16464, 16471.

requirements, which may be specified in their owner's manuals. Thus, the descriptors and accompanying specifications could constitute a "rating" for the alternative liquid automotive fuels pursuant to section 1501(b) of EPA 92.[127] Under this option, the Commission suggested that it could require certification and posting of the descriptors and develop and publish in the final rule minimum specifications for the alternative fuels. The Commission specifically asked for comments on what specifications would be appropriate for each fuel.

Fifteen comments discussed the fuel descriptor option.[128] Three generally opposed the option, stating it provided little or no benefit to consumers.[129] Nine generally supported the descriptor approach, but only if use of the descriptor were based on consensus fuel standards or specifications.[130] Two comments supported the descriptor approach if the dispenser label also included a disclosure of the minimum percentage of the principal component of the fuel.[131]

Another commenter, SGMA, suggested requiring the disclosure only of a fuel descriptor, without accompanying specifications. SGMA stated that the most important information for consumers of an alternative fuel is that their vehicles will function properly using the fuel dispensed. SIGMA contended, therefore, that the pump need only be labeled to disclose that it dispenses the fuel identified by the automobile manufacturer as being appropriate for operating the consumer's vehicle.[132]

Six comments suggested that, in selecting standards on which to base use of the descriptors, the Commission should adopt ASTM or other consensus standards.[133] Under this approach, disclosure of a particular fuel descriptor would indicate that the fuel meets technical specifications established by a recognized standards-setting organization. Standards established under this process would have the advantage of being developed with input from and approval of engine manufacturers, fuel suppliers, users, and regulators. Such an approach would benefit consumers, because they could determine easily whether alternative liquid automotive fuels marketed under these descriptors are compatible with the original vehicle equipment manufacturer's requirements. In addition, this approach would allow an alternative liquid automotive fuel supplier to improve the fuel beyond the minimum specifications and promote the improved fuel over those of its competitors.[134]

As anticipated by the Commission, however, the primary objection to this option was that neither ASTM nor any other consensus standards-setting organization has developed and adopted specifications and standards for most of the alternative liquid automotive fuels.[135] Commenters noted that ASTM has developed a standard for LPG (D 1835) and has proposed a standard for M–85 (ASTM proposed specification P232).[136] ASTM's LPPG specifications may change, however, as data are collected on LPG mixtures with higher butane contents.[137] ASTM has not proposed or developed fuel specifications for E–100, M–100, E–85 or LNG. With respect to E–85, commenters noted that General Motors ("GM") has developed a standard for use with its E–85/Flexible Fuel vehicles (GM standard GM 4729M).[138] AAMA also indicated that GM has developed a standard for use with its M–85/Flexible Fuel vehicles. AAMA's comment, which incorporates comments from GM, recommended that the Commission adopt GM's E–85 and M–85 specifications on an interim basis until ASTM standards for E–85 and M–85 are accepted by the industry.[139]

Four comments also opposed Commission adoption of the alternative liquid automotive fuel specifications proposed by the California Air Resources Board, because they were not developed by a consensus process, are technically flawed, and were developed for California's particular needs and therefore could be overly restrictive for other parts of the country.[140] For example, AAMA commented that because California has a moderate climate, its specifications do not fully address the low temperature starting requirements for M–85 and E–85 in the rest of the country.[141] Also, AAMA stated that California's specifications fail to control contaminants for these fuels at a sufficiently low level to ensure good vehicle fuel system durability. AAMA states that, for example, experience with M–85 in California shows that vehicle problems, such as filter plugging, were encountered due to contaminants introduced into the alternative fuel by the dispensing system.[142]

Disclosure of a fuel descriptor based on accepted and approved fuel specifications and standards could provide meaningful information to consumers relating to the quality of the fuel they are purchasing. After considering the aforementioned comments, however, the Commission finds that adequate, generally accepted standards and specifications suitable for nationwide use do not presently exist for most alternative liquid automotive fuels. Further, the Commission has an insufficient record and basis on which to establish specifications for alternative liquid automotive fuels. Therefore, the Commission has determined not to require the certification and posting of uniform fuel descriptors, as originally proposed.

The Commission favors the development of specifications and standards that define alternative liquid automotive fuels by a consensus standards-setting organization, such as ASTM, or by a government agency with appropriate engineering and technical expertise to set such specifications and standards for nationwide use. This would permit participation by affected parties such as alternative fuel producers and providers, engine manufacturers, regulators, and consumers, among others. It would provide opportunities for review by individuals and organizations with acknowledged technical expertise, and would provide a mechanism for evaluation of any proposed test methods and procedures necessary to determine compliance with the standards. Although the Commission is not adopting the fuel descriptor option as proposed, it is adopting a variation of the fuel description and composition proposals, as discussed in detail in Part III.A.5., below.

5. Final Rule

After considering all the comments received in light of the purposes of EPA

[127] Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821).

[128] RFA, D–1, 5; Phillips 66, D–3, 4; Mobil, D–4, 2; Chevron, D–5, 2; AAMA, D–7, 2, 4; Sun, D–8, 4; Marathon, D–9, 3; API, D–10, 1, 6; SIGMA, D–13, 2; CFDC, D–14, 4; ATFI, D–15, 3; NPGA, D–19, 3; CENEX, D–21, 3; RCT, E–2, 4; NYDAM, E–4, 1.

[129] Mobile, D–4, 2; NPGA, D–19, 3, RCT, E–2, 1.

[130] RFA, D–1, 5; Chevron, D–5, 4; AAMA, D–7 4; Sun, D–8, 2; Marathon, D–9, 2; API, D–10, 6; ATFI, D–15, 3; CENEX, D–21, 3; NYDAM, E–4, 1.

[131] Phillips 66, D–3, 3 CFDC, D–14, 5.

[132] SIGMA, D–13,2.

[133] Chevron, D–5, 4; AAMA, D–7, 4; Marathon, D–9, 2; API, D–10, 2; CENEX, D–21, 2–3; Texaco, D–22, 1.

[134] API, D–10, 6; RFA, D–1, 6.

[135] Chevron, D–5, 2; AAMA, D–7, 4; CFDC, D–14, 3.

[136] Chevron, D–5, 4; AAMA, D–7, 4; Sun, D–8, 2; API, D–10, 4–7; NPGA, D–19, 2.

[137] Sun, D–8, 4.

[138] RFA, D–1, 6; Chevron, D–5, 4; AAMA, D–7, 4; Sun, D–8, 4.

[139] AAMA, D–7, 2.

[140] Chevron, D–5, 4; AAMA, D–7, 4; Sun, D–8, 5; API, D–10, 6.

[141] AAMA, D–7, 2.

[142] *Id.*

92 and of PMPA, as amended, the Commission has determined that the automotive fuel rating for alternative liquid automotive fuels should be the commonly used name of the fuel with a disclosure of the amount, expressed as a minimum percentage by volume, of the principal component of the fuel. Those covered by the Fuel Rating Rule also may include a disclosure of other components as a minimum percentage by volume, if desired. To simplify the labels, however, the Commission is not requiring that the words "by volume" appear on the label. Those who determine the automotive fuel rating for an alternative liquid automotive fuel must have a reasonable basis, consisting of competent and reliable evidence, for the claimed percentage by volume of the principal component and any other component, of the alternative liquid automotive fuel that they certify or post.

This rating approach for the alternative liquid automotive fuels will provide consumers with information necessary to make informed fuel purchasing decisions. It also will provide fuel producers and marketers with the flexibility to develop and blend fuels appropriate for location and climate, consistent with U.S. Environmental Protection Agency and original equipment manufacturer requirements. The Commission's action, therefore, will assist in the development and use of alternative liquid automotive fuels and alternative fueled vehicles.

The Commission recognizes that the selection process between competing alternative liquid automotive fuels essentially is concluded when the alternative fueled vehicle is acquired, because the vast majority of such vehicles will not have the capability to operate on more than one fuel. Thus, efforts to provide consumers with extensive information comparing various different types of alternative fuels is best done prior to the time the vehicle is acquired, not at the refueling station. Once the alternative fueled vehicle has been purchased, the vehicle owner primarily needs information indicating that the fuel available from a particular dispenser is suitable for that vehicle.[143]

The rating requirement adopted today is consistent with many comments the Commission received on the four options proposed in the NPR, in particular comments relating to the "fuel descriptor" option. But, not all comments favor the automotive fuel rating approach the Commission is taking. Three commenters generally opposed a fuel composition label, two stating that the average consumer lacks the technical expertise needed to make an informed fuel selection decision on the basis of posted fuel content,[144] and the other stating that it does not provide meaningful information to consumers.[145]

Many of the comments, however, stressed that consumers of alternative fuels need information that directs them to the correct fuel dispenser by clearly identifying the type of fuel being dispensed, and providing information that can help them determine whether the fuel satisfies their automobile engine's minimum requirements.[146] These comments stated that such a disclosure approach, used in conjunction with the owner's manual containing the vehicle manufacturer's fuel recommendations, would provide consumers with the information necessary to select the fuel on which their vehicle has been designed to perform optimally. By allowing consumers to choose among different blends of fuels (e.g., LNG with a methane content of 90 versus 95), the Commission's approach provides a "rating" measure consistent with the purpose of the statute.[147]

W&B, for example, in its discussion of a proposed label for LPG and LNG, stated that it generally supported a requirement to disclose fully the possible range of contents in alternative fuels.[148] ATFI supported the use of fuel composition labeling to inform consumers about the quality of each alternative fuel they are purchasing. ATFI commented further that fuel composition is the most relevant information for vehicle manufacturers, fuel suppliers, and the consuming public.[149] AIAM commented that it fully supported the Commission's proposal to require a disclosure of the minimum percentage by volume of the principal component of LPG and LNG.[150] CFDC stated that requiring that a label be posted by type and percentage of fuel composition has merit. It said that a label that simply discloses what the type of fuel is, accompanied by a disclosure of the minimum percentage of the main component of the fuel, would provide assurances to consumers that the fuel purchased meets certain requirements relating to vehicle performance.[151] Phillips 66 stated that consumers of alternative fuels will pay particular attention to the fueling recommendations of the owner's manual or the directions provided by the fuel conversion center. Phillips 66 concluded, therefore, that a minimum fuel composition disclosure requirement would provide the most valuable public information for making a refueling choice. Phillips 66 further concluded that since the alternative fuels being considered are principally compounds, in contrast to gasoline and diesel fuels, which are blends, a consumer benefit could be gained by the posting of a minimum percentage of the principal compound.[152]

The fuel composition disclosure required by the Fuel Rating Rule has the further advantage of being easily applied to fuels that may be offered in the future (within the limits of the definition of "alternative fuel") that are not specifically discussed in this Notice. For example, fuel producers may market various blends of alcohols and gasoline, such as M–80 or M–90, or various combinations of liquefied petroleum gases. The Fuel Rating Rule will provide the framework for proper disclosure of the automotive fuel rating of such fuels, blends, or combinations. Because the disclosure requirements of the Fuel Rating Rule are generic and easily complied with, and because the labels are standardized for alternative liquid fuels, the Rule should assist in advising consumers about the availability of alternative liquid fuels and thus help promote development of these fuels. Further, the Fuel Rating Rule requirement that marketers disclose the principal component of each fuel should encourage the industry to develop uniform consensus specifications for all alternative liquid automotive fuels both to provide a standardized "reasonable basis" for required disclosures and to ensure the uniform quality of the fuels sold.

In addition, market forces should operate to keep any differences among sellers offering the same type of fuel, but using different test methods, within reasonable bounds. Cooperation between fuel producers and engine manufacturers is necessary to ensure that new engine developments and new fuels can be accommodated. In this respect, fuel quality and engine design depend on each other.[153] Engine

[143] Marathon, D–9, 1.

[144] API, D–10, 4; CENEX, D–21, 3.

[145] AAMA, D–7, 2.

[146] Sun, D–8, 4; Marathon, D–9, 1–3; SIGMA, D–13, 1; CFDC, D–14, 5; AIAM, D–17, 1.

[147] Section 1501(b) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821(17)).

[148] W&B, D–12, 5.

[149] ATFI, D–15, 2.

[150] AIAM, D–17, 2.

[151] CFDC, D–14, 3–5.

[152] Phillips 66, D–3, 3–4.

[153] See AAMA, D–7, 1 (acceptance of alternative fueled vehicles depends on availability of high quality fuels). Those involved with the production and marketing of these fuels understand that fuel quality aspects can influence market share and

designers must be aware of what fuels will be available in a particular market and the fuel producers must know the fuel requirements of vehicles on the road. In any event, the use of alternative fuels and their acceptance will depend on the development of and adherence to fuel quality standards. Such standards also would include standard test methods for determining all the necessary specified properties.

Two comments stated, however, that a required fuel composition label will increase testing costs and labeling problems for the industry. One comment stated that labels for the alcohol fuels will have to be changed on a seasonal basis as the fuels' contents change to address cold-start problems.[154] The other stated that seasonal LPG labels might be necessary due to varying butane/propane concentrations.[155] The Commission's requirement that the disclosure of the amount of the principal component of the fuel be expressed as a *minimum* percentage by volume should obviate the need for frequent label changes, yet allow for seasonal label changes, if desired.

While some commenters preferred having fuel specifications set in the rule, the Commission has determined that there is not now a sufficient basis for imposing single, nationwide specifications for most of these fuels. Neither ASTM nor any other standards-setting entity has developed and adopted consensus specifications and test methods for most of the liquid alternative fuels. Nor do federal specifications currently exist. ASTM has developed a standard for LPG and has proposed a standard for M–85, but has not developed or proposed fuel specifications for E–100, M–100, E–85, or LNG. GM has developed specifications for M–85 and E–85[156] and the State of California has issued final alternative liquid automotive fuel specifications. However, there are definitional inconsistencies among these standards with respect to the contents of the alternative liquid automotive fuels. For example, ASTM's proposed specification for M–85 fuel methanol requires a minimum 85% methanol by volume, California's proposed specification requires a minimum 84% methanol, and GM's proposed specification suggests a range of minimum methanol content from 74–84%, depending on the average temperature. Although the Commission could adopt one of these specifications, there is an insufficient basis on the record for determining which is preferable. Further, in the absence of more extensive information, which may not yet exist, mandating the use of any individual proposed alternative liquid automotive fuel specifications could have unforeseen adverse effects on competition, the environment, or vehicle performance.[157]

For the same reasons, the Commission is not requiring that sellers use specific standards as their "reasonable basis" for determining the percentage by volume of each component of the fuel that they certify or post.[158] Consensus specifications that define alternative liquid automotive fuels, and that include the test methods used to determine whether fuel samples comply with the specifications, have not been developed, except for liquefied petroleum gas.[159] Further, at least one cementer suggested that ASTM's specification for LP gases may change.[160]

Nevertheless, sellers may rely upon existing standards to determine and verify the ratings for alternative liquid automotive fuels, where such standards are appropriate. For example, ASTM's proposed specification for M–85 fuel methanol contains a proposed test method for determining methanol content in fuel methanol M–85 by gas chromatography.[161] ASTM's standard specification for liquefied petroleum gases also contains a test method for analysis of liquefied petroleum gases and propane concentrates by gas chromatography. Other test methods or calculations also may constitute competent and reliable evidence to satisfy the reasonable basis requirement for determining the ratings for alternative fuels.

If test methods for determining ratings for alternative liquid automotive fuels or fuel specifications are developed in the future by consensus or are issued by an appropriate Federal agency, the Commission will consider whether they constitute a reasonable basis. The Commission expects that industry compliance with the Fuel Rating Rule, in conjunction with the need to avoid uncertainty about whether particular test methods or calculations constitute a reasonable basis, will encourage development of standardized test methods and specifications. The development of standardized test methods and standard specifications for alternative liquid automotive fuels should help facilitate widespread acceptance of these fuels.

The Fuel Rating Rule also gives sellers the discretion to disclose information about more than one component of the fuel, if this is deemed relevant. The comments suggested that liquefied petroleum gas fuels, in particular, could be developed with higher butane concentrations and that future LPG fuels may have different ranges of propane/butant compositions than current LPG fuels.[162] The Rule allows industry the flexibility necessary to develop such variations.

The specifications and layout for the automotive fuel rating label for alternative liquid automotive fuels appear in § 306.12 of the Fuel Rating Rule. The alternative liquid automotive fuels labels will be subject to many of the same specifications that are required for current octane labels. The automotive fuel ratings for the alternative fuels, however, must be lettered in black type on an orange background. The Commission chose the different color to help consumers distinguish the octane rating for gasoline (black type on a yellow background) from the ratings for the alternative liquid automotive fuels to assist consumers in making the proper fuel choice for their alternative fueled vehicles and to help them avoid misfueling.[163] In designing the label requirements, the Commission decided that requiring a different color label for each different type of alternative fuel

affect the performance of the vehicles that are designed to use them.

[154] NYDAM, E–4, 2.

[155] Sun, D–8, 2.

[156] AAMA, D–7, 4.

[157] An analysis of the proposed specifications also indicates that, to ensure fuel quality and proper automobile performance, disclosing fuel composition in terms of the minimum percentage by volume of the principal component of the fuel is important and helpful. For example, Annex A1.5 of ASTM's Proposed Specification for Fuel Methanol (M–85) for Automotive Spark-Ignition Engines states that the production of fuel methanol (M–85) requires knowledge of the methanol content to ensure acceptable commercial fuel quality. The methanol content of M–85 affects the performance of an automobile designed to run on M–85.

[158] In its comment, Chevron stated that proven standard test methods are not available for determining all of the properties necessary for alternative fuels to perform properly. Chevron commented further that this is one of the reasons that ASTM cannot develop specifications for the various fuels. Chevron, D–5, 2.

[159] RFA, D–1, 6; Chevron, D–5, 2; API, D–10, 2; CFDC, D–14, 3.

[160] Sun, D–8, 4.

[161] The proposed specification states, however, that verification of the appropriateness of this test method is underway.

[162] Phillips 66, D–3, 3; Sun, D–8, 2–4.

[163] Phillips 66, D–3, 5 (alternative fuel labels should be a distinctive color such as blue); API, D–10, 7 (alternative fuel labels should use same style and background color and should use color other than yellow to distinguish from gasoline labels); CENEX, D–21, 4 (alternative fuel labels should use format that clearly differentiates them from gasoline).

would confuse consumers and make compliance unnecessarily burdensome.

To encourage standardization in alternative liquid automotive fuel labels, the Commission is specifying a width and length for the labels. There are two sets of specifications; one is for when only the principal component is disclosed, and the other is for the principal and one additional component. However, to accommodate those desiring to disclose more information than will fit on the specified labels, the Commission has included language in § 306.12(a) (ii) and (iii), explaining that those wishing to use labels with different dimensions may petition the Commission for a variance from the Fuel Rating Rule's label specifications.[164]

B. Cetane Ratings of Diesel Fuel Oil

Section 1501 of EPA 92 amended PMPA to include a definition for "automotive fuel rating" that includes the "cetane rating" of diesel fuel oils "if provided for by the Federal Trade Commission."[165] "Cetane rating" is defined as a measure, as indicated by a cetane index or a cetane number, of the ignition quality of diesel fuel oil and of the influence of the diesel fuel oil on combustion roughness.[166] This amendment gives the Commission the discretionary authority under PMPA to add the disclosure of cetane ratings of diesel fuel oils to the requirements of the Octane Rule.

A significant quantity of diesel fuel oil is sold for vehicle use nationally, and preliminary information available to the Commission suggested that the posting of cetane ratings for the diesel fuel oil used for vehicle applications might be helpful. Further, because information suggested that higher cetane fuels can make engines start better in cold weather and run more quietly with reduced emissions, the Commission considered that there might be market incentives to produce higher cetane fuels and to make available a variety of fuels with different cetane levels. The Commission's preliminary analysis also suggested, however, that accurate posting of cetane levels nationwide at retail outlets could be difficult to achieve, and that the costs of posting might outweigh the benefits.

To obtain information about whether to amend the Octane Rule to require the certification and posting of minimum cetane ratings, the Commission in the NPR proposed amendments that would require cetane certification and posting for diesel fuel oil intended for vehicle use. The NPR asked whether the proposed regulation would have benefits and costs corresponding to those of the Octane Rule. The NPR also solicited information about the marketing, classifications, and characteristics of diesel fuel oil distributed in the United States. In addition, the NPR solicited information on the extent of the burden the proposed amendments would place on the industry if they were promulgated.

Seventeen comments addressed the cetane disclosure issue. Ten were from members of the petroleum industry,[167] four were from members of the automobile manufacturing industry,[168] two were from state agencies involved with the regulation of petroleum products marketing,[169] and one was from an organization involved in the promotion of diesel fuel from biomass.[170] Seven comments favored the proposed amendments.[171] Ten opposed their adoption.[172]

The comments that favored the proposed amendments generally stated that because there is a range of diesel fuel oil with different cetane ratings, a posting requirement would enable consumers to determine which fuels have higher cetane ratings. EMA and AAMA both commented that the higher cetane diesel fuels would start better in cold weather, run more quietly, and produce fewer emissions, although AAMA noted that consumers may have to be educated about these facts.[173]

Several commenters stated that different engines may require different, higher cetane ratings, and noted that, for those engines, diesel fuel oil with higher cetane ratings will perform better.[174] EMA and Sun said that engine manufacturers often recommend fuels with higher cetane levels because of the improvement in engine performance associated with those fuels.[175] Sun also noted that there is a range of cetane ratings of between 40 and 50 available at retail stations.[176] EMA commented that, to the extent consumers can identify the relative cetane number of diesel fuels, they will be in a better position to improve engine performance and to decide whether the more expensive high-cetane fuels are cost effective.[177]

On the other hand, four of the oil companies stated that cetane levels in excess of 40 are not necessary for diesel engines to run well.[178] Marathon distinguished between the effect of cetane rating changes in diesel fuel on diesel engines and the effects of octane changes in gasoline on gasoline engines, noting that, in general, diesel engines are not nearly as sensitive to differences in cetane quality as gasoline engines are to differences in octane.[179]

Generally, the ten comments that opposed a requirement to certify and post cetane ratings stated that the posting at retail of cetane level information is not needed, that accurate disclosure of cetane ratings at retail outlets would be very difficult to achieve, and that the requirement would, therefore, be unduly burdensome. Eight comments contended that cetane posting will be unnecessary as of October 1, 1993, when U.S. Environmental Protection Agency regulations that restrict the sulfur content of diesel fuel and establish a mandatory minimum cetane level of 40

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[164] See § 1.25 of the Commission's rules of practice, 16 CFR 1.25.

[165] Section 1501(b), Pub. L. 102-486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821(17)).

[166] A cetane number is a cetane rating derived by testing the fuel directly. Cetane index is a cetane rating derived through calculation. See ASTM Standard Specification for Diesel Fuel Oils, D975-91, ASTM Standard Test Methods for Calculating Cetane Index of Distillate Fuels, D976-91 and D4737-90, and ASTM Standard Test Method of Ignition Quality of Diesel Fuels by the Cetane Method, D613-86.

[167] Phillips 66, D-3; Mobil, D-4; Chevron, D-5; Sun, D-8; Marathon, D-9; API, D-10; SIGMA, D-13, PMAA, D-18; CENEX, D-21; Texaco, D-22.

[168] ATAI, D-2, EMA, D-6; AAMA, D-7; AIAM, D-17.

[169] NCDA, E-1; NYDAM, E-4.

[170] NSDB, D-16.

[171] EMA, D-6, 1-3; AAMA, D-7, 2-3; Sun, D-8, 3, 5-6; NSDB, D-16, 3-4, 5; AIAM, D-17, 3; NC, E-1, 1-3; NYDAM, E-4, 3.

[172] ATAI, D-2, 2-3; Phillips 66, D-3, 6; Mobil, D-4, 3; Chevron, D5, 1, 5-6; Marathon, D-9, 3-4; API, D-10, 1, 7-8; SIGMA, D-13, 3-5; PMAA, D-18, 2-7; CENEX, D-21, 4; Texaco, D-22, 1-2.

[173] EMA, D-6; 1; AAMA, D-7, 3. These higher cetane level benefits were noted also by two other commenters who opposed the Commission's adoption of the proposed amendments. PMAA, D-18, 2; SIGMA, D-13, 4. The potential benefits that diesel fuel with higher cetane ratings can contribute were articulated by EMA as including control of white smoke emissions, reduction of engine noise, improvement of cold-starting capabilities and assistance in the reduction of emissions of nitrogen oxides, particulate matter, hydrocarbons and carbon monoxide. EMA, D-6, 1.

[174] AAMA, D-7, 3; Sun, D-8, 5; EMA noted that its 31 member internal combustion engine manufacturers are concerned with the quality of fuel used in the engines they produce and with consumers' ability to identify the differences in cetane ratings so they can improve engine performance. EMA, D-6, 1.

[175] EMA, D-6, 2; Sun, D-8, 5.

[176] Sun, D-8, 5.

[177] EMA, D-6, 1.

[178] Phillips 66, D-3, 6; Mobil, D-4, 3 ("cetane in excess of 40 is not commonly required by motor vehicles."); Chevron, D-5, 1 ("Diesel engines are designed to run on 40 cetane number."); Marathon, D-9, 3-4.

[179] Marathon stated that while a minimum cetane rating is necessary for cold starting and warm-up, most diesel fuels marketed today meet the ASTM D-975 minimum cetane of 40, which provides adequate cold-starting performance in modern diesel engines. Marathon, D-9, 3-4.

become effective.[180] These comments indicated that the Environmental Protection Agency's regulations will result in consumer benefits (reduced emissions and a minimum cetane standard) regardless of the Commission's Fuel Rating Rule.[181]

Further, several commenters said that diesel fuel consumers (who were usually identified in the comments as truck drivers) are now and have been for years more familiar with diesel fuel than gasoline consumers are with gasoline. Because of this knowledge, diesel fuel oil consumers do not need cetane information.[182] Three associates said that diesel fuel customers (whom they identify as primarily truck drivers) generally purchase their fuel at private facilities throughout contractual arrangements that specify such items as cetane. According to the comments, these customers are often not aware of the cetane level of the fuel, do not appear interested in knowing it, and would not be likely to go "cetane shopping."[183]

According to four comments, cetane information alone could confuse or even mislead consumers as to the relative importance of cetane as a quality of diesel fuel oil.[184] Most indicated that such qualities as detergency, cold flow properties, specific gravity, cloud point, viscosity, sulfur, and additives are of at least equal significance to cetane. Phillips 66 noted that two major diesel engine suppliers reference ASTM for the fuel recommendations, which encompasses many more aspects of the fuel than just cetane, and further suggested that either viscosity, sulfur, or additives may be important considerations for consumers.[185]

In addition, SIGMA pointed out that higher cetane ratings means lower energy content, which could result in lower mileage. SIGMA speculated that consumers unaware of this fact could mistakenly think that use of more expensive, higher cetane diesel fuel oil will result in greater engine efficiency.[186] SIGMA also noted that, to the extent diesel fuel marketers sell fuel with higher cetane ratings, they are already informing their customers of this fact as a marketing tool.[187] SIGMA concluded that the number of consumers that would find cetane ratings useful is very small, and that the Commission should weigh the benefits to this small group of consumers against the costs of a posting requirement.[188]

PMAA and Chevron commented that the way diesel fuel is distributed and subjected to cetane-enhancing additives will render it extremely burdensome for distributors to determine the cetane of diesel fuel from delivery to delivery.[189] Sun noted that cetane levels at retail could change because of many factors, such as refiner capability, co-mingling of product, marketing decisions, and use of additives, and could change as frequently as each shipment, by as much as 10 points, but usually only by 2 to 4 points.[190]

As noted earlier, the authority Congress granted the Commission in section 1501(b) of EPA 92 to regulate diesel fuel oil is discretionary, and is not tied to the mandate to amend the Octane Rule to require automotive fuel ratings for alternative liquid automotive fuels.[191] Further, the time limitations in section 1502(d)(2) of EPA 92 pertaining to the alternative liquid automotive fuels proceeding do not apply to the Commission's discretionary authority to regulate diesel fuel oil.[192]

The Commission has considered whether the record supports the conclusion that the burdens on the diesel fuel oil marketing industry that would result from cetane rating certification and posting requirements for diesel fuel oil would outweigh the benefits that would accrue to diesel fuel oil consumers as a result of the requirements. The Commission has decided that it would be premature to make this cost-benefit decision at this time given current regulatory developments in the industry. In particular, the Commission is interested in how, if at all, the maximum sulfur/minimum cetane regulations of the U.S. Environmental Protection Agency will affect the marketing, use, and cetane levels of diesel fuel oil after October 1, 1993. Consequently, the Commission has decided to postpone its decision on the cetane rating proposal contained in the NPR, and to solicit further information in a second Notice of Proposal Rulemaking to be published after the public has had significant experience with the Environmental Protection Agency regulations.

IV. Regulatory Flexibility Act

The Commission stated in the NPR that the provisions of the Regulatory Flexibility Act[193] requiring a regulatory analysis were not applicable to the proposed amendments because they did not appear to have a significant economic impact on a substantial number of small entities.[194] Based on available information, the Commission stated that the amendments it proposed would have a minimal effect on all business entities within the affected industries, regardless of their size. It stated that very few companies produce and distribute these alternative liquid automotive fuels or diesel fuel oil, and that, of those that do, most are not "small entities" as that term is defined in section 601 of the Regulatory Flexibility Act and in the regulations of the Small Business Administration, found in 13 CFR part 121.

The Commission further explained that although there are some "small entities" in the retailer sectors of those industries, the proposed amendments would likely have only a minimal impact on these small entities. It also stated that any such impact would likely consist of some additional recordkeeping and of retailers placing labels on dispensers (to the extent this is not done by distributors for their retailer customers). Therefore, the Commission stated that the impact on small entities appeared to be *de minimus* and not, therefore, significant.

The Commission requested information about these industries,

[180] The regulations will require a reduction of the maximum permissible level of sulphur in Grade 1–D diesel and Grade 2–D diesel. This will result in lower cetane levels than would otherwise be obtained. To compensate for this, the regulation will set a minimum cetane level of 40. 55 FR 34120, 34130–31 (Aug. 21, 1990). See comments of ATAI, D–2, 3; Phillips 66, D–3, 6; Mobil, D–4, 3; Marathon, D–9, 4; API, D–10, 6; SIGMA, D–13, 4; PMAA, D–18, 2–3; CENEX, D–21, 4. Several commenters also noted that ASTM Standard D975 requires Grade 2–D diesel to have a minimum cetane number of 40. See ATAI, D–2, 2; Phillips 66, D–3, 6; Chevron, D–5, 1, 6; AAMA, D–7, 2; Marathon, D–9, 4.

[181] See Phillips 66, D–3, 6.

[182] Phillips 66, D–3, 6; API, D–10, 6; CENEX, D–21, 4. None of these comments, however, discusses whether the EPA sulfur restriction regulations will change the characteristics of diesel fuel enough to have an effect on the familiarity these consumers have with the fuel.

[183] ATAI, D–2, 2 (ATAI's comment is based on "a survey of the maintenance executives of 25 trucking fleets, including the 5 largest running approximately 84,000 trucks and tractors"); SIGMA, D–13, 5; PMAA, D–18, 3.

[184] Phillips 66, D3, 6; API, D–10, 7–8; SIGMA, D–13, 2, 3–4; PMAA, D–18, 2, 5. See also AAMA, D–7, Att. A, 5 (AAMA supported the proposal, but noted the possibility that a cetane posting requirement could mislead customers).

[185] Phillips 66, D–3, 6.

[186] SIGMA, D–13, 4.

[187] "Some marketers currently market 'premium' grade diesel fuel that contains some additives and has a slightly higher cetane level. These marketers tend to inform consumers as a marketing tool about the higher cetane levels without a posting requirement. Therefore, it is unclear whether any benefits would result from a rule formulated to require them to post cetane ratings." SIGMA, D–13, 4–5.

[188] SIGMA, D–13, 5.

[189] PMAA, D–18, 4–6; Chevron, D–5, 6.

[190] Sun, D–8, 5–6.

[191] Section 1501(b), Pub. L. 102–486, 106 Stat. 2776, 2997 (codified at 15 U.S.C. 2821(17)).

[192] Section 1501(d)(2), Pub. L. 102–486, 106 Stat. 2776, 2997 (codified at 15 U.S.C. 2821 (notes)).

[193] 5 U.S.C. 603, 604.

[194] 58 FR 16464, 16473.

including the number and size of companies that produce, import and/or market (including the retail level) alternative liquid automotive fuels or diesel fuel oil. It asked whether the proposed amendments, if promulgated, would have a significant economic impact on a substantial number of small entities in these industries.

Most of the comments that discussed cost or burden addressed rating options for alternative liquid automotive fuels (octane and heating value options) the Commission has decided not to adopt, or addressed cetane posting for diesel fuel oil, on which the Commission has deferred a decision. Only Marathon, API, CFDC, NPGA, and RCT commented about the costs or burdens on small businesses of the existing Octane Rule or of other amendments the Commission proposed in the NPR.

Marathon and API addressed the costs and burden imposed by the existing Octane Rule. According to Marathon: "As it is currently implemented, we do not believe the Octane Rule places an undue economic burden on any segment of the petroleum industry, including operators of small businesses. Consequently, Marathon recommends the Octane Rule be continued in its current form." [195] API concurred, stating: "While the Octane Rule has an impact on a significant number of entities, the impact on each of those individual entities is not unreasonable, particularly in light of the consumer benefits achieved." [196] Neither Marathon nor API cited any specific figures.

CFDC, NPGA and RCT addressed the benefits and burdens of the proposed fuel composition or fuel descriptor options, which are similar to the option adopted today by the Commission. CFDC stated that posting a fuel descriptor "would provide assurances to consumers that the fuel purchased meets certain requirements, especially since the octane rating of the fuels indicated by type will not vary to any significant degree. Such a rating system would cost-effectively meet the requirements for alternative fuels of section 1501(b) of the Energy Policy Act of 1992." [197]

NPGA and RCT specifically addressed the impact on propane sellers of the four proposed amendment options. NPGA claimed: "Some 3,100 of our 3,400 member companies would classify as small businesses; these 3,100 members operate about 3,400 retail outlets for propane. Another 3,400 outlets are operated by 12 multistate corporations who are also member companies of this association. The proposed regulations would have a direct and adverse (e)ffect upon the ability of all these member companies to sell propane at retail as an alternative engine fuel." [198] RCT stated that it is: "Deeply concerned about the proposed changes. In our judgment, they would impose heavy costs on a fledgling [propane] industry while providing little or no benefit to consumers." [199] RCT further stated: "FTC's proposed rules would adversely affect 1,100 retail propane dealers in Texas alone. The proposed amendments could also adversely affect propane suppliers and consumers without providing commensurate benefits." [200] However, because the comments submitted by NPGA and RCT discussed primarily the octane and heating value posting options, and other issues not raised by the Commission, it appears that their general comments about the burdens of the options proposed in the NPR are not relevant to the amendments the Commission has adopted.

RCT also stated that a fuel composition posting requirement would require separate storage tanks and separate delivery systems to keep automotive grade HD–5 propane segregated from propane destined for residential and commercial customers, thus imposing costs on small businesses because of unnecessary duplication that "could cause some of them to turn away from the motor fuel market." [201] NPGA concurred with RCT's position.[202]

The statements by NPGA and RCT do not persuade the Commission that the posting option it has adopted will impose a significant economic impact on a substantial number of small entities. First, neither NPGA nor RCT cited specific cost or burden estimates or submitted supporting data. Second, the conclusions about cost and burden expressed by NPGA and RCT apply primarily to options (octane and heating value posting) the Commission has now rejected. Further, their comments about the burden of certification and posting fuel composition presume the Commission will require the posting of fuel composition of LPG based on tests to ensure the fuel meets test specifications for grade HD–5. For example, NPGA stated that the Commission should leave to other agencies the task of setting the specifications that fuels must meet, and recommended that the Commission limit its involvement to requiring posting the grade of the fuel being sold, or the specification it meets.[203]

The amendment adopted by the Commission requires only the certification and posting of the type of fuel and the minimum composition of its principal component, based on a reasonable basis standard. Retail outlets merely have to post consistent with the certifications they receive, so their burden is minimal. Retailers need not make the actual determinations unless they alter the fuel they receive before reselling it. Therefore, the Commission believes the certification and posting requirements it has adopted will minimize burdens on even small businesses.

On the basis of all the information now before it, including the written comments submitted in response to the NPR, the Commission has determined that the amendments will not have a significant impact on a substantial number of small entities. Consequently, the Commission concludes that a regulatory flexibility analysis is not required. In light of the above, the Commission certifies, under section 605 of the Regulatory Flexibility Act,[204] that the amendments it has adopted will not have a significant impact on a substantial number of small entities.

V. Paperwork Reduction Act

The Commission noted in the NPR that the proposed amendments contain provisions that constitute information collection requirements under the Paperwork Reduction Act.[205] The Commission explained that the proposed amendments would require refiners, producers, importers, distributors and retailers of alternative liquid automotive fuels to keep, for one year, records of any delivery tickets, letters of certification or tests upon which they based the automotive fuel ratings that they certify or post. It explained that these records would have to be open for inspection by Commission and Environmental Protection Agency staff members or by persons authorized by the Commission or the Environmental Protection Agency.

On the basis of available industry figures, the Commission estimated that, under the amendments proposed in the NPR, a total of approximately 85,000 refiners, producers, importers, distributors and retailers could possibly be affected by the recordkeeping

[195] Marathon, D–9, 4.
[196] API, D–10, 8.
[197] D–14, 5.
[198] NPGA, D–19, 3.
[199] RCT, E–2, 1.
[200] *Id.* at 4.
[201] RCT, E–2, 3.
[202] NPGA, D–19, 3.
[203] NPGA, D–19, 2–3.
[204] 5 U.S.C. 605(b).
[205] 44 U.S.C. 3501–3520.

requirements described above. It stated that certifications are usually noted on documents (shipping receipts, etc.) already in use, or are accomplished with a one-time letter of certification. It further stated that, in the case of refiners and importers, test records are typically retained for a period of one year.

The Commission noted that, in the past, the Commission estimated that the information collection burden associated with the Octane Rule's recordkeeping requirements was 20,000 hours per year (six minutes per year times 200,000 industry members).[206] This estimate was small because the records at issue were likely to be retained by the industry during the normal course of business, and the "burden," for OMB purposes, is defined to exclude effort that would be expended in any event.[207]

In the NPR the Commission stated that it believed that approximately 165,000 industry members currently were covered by the Octane Rule as it was in effect at that time (the drop in total industry members primarily being the result of closings by retail stations over the intervening years). The Commission estimated that approximately 85,000 industry members would be affected by the proposed amendments. Of these, the Commission concluded that approximately 60,000 currently sell gasoline (as well as diesel and some alternative fuels) and thus were already covered by the existing Octane Rule. For these 60,000 industry members, the Commission estimated that two additional burden minutes per member per year would cover the effort associated with coverage of the additional fuels (primarily diesel fuel oil). Further, approximately 25,000 additional industry members not currently covered by the Octane Rule would be covered by the proposed amendments because they sell only alternative liquid automotive fuels. These 25,000 would be affected by the Fuel Rating Rule's recordkeeping requirements for the first time under the proposed amendments. The Commission stated that it believed that the original estimate of six minutes per year each would be valid for these 25,000 additional industry members.

Based on these figures, the Commission estimated that the revised current total yearly burden of the existing Octane Rule's requirements would be 16,500 hours (six minutes per year times 165,000 industry members). The Commission estimated that the total additional yearly burden that would be imposed by the proposed amendments would be 4,500 hours (two minutes per year times 60,000 industry members, plus six minutes per year times 25,000 industry members). Consequently, the Commission estimated that the total burden associated with complying with the Rule's recordkeeping requirements, if amended as proposed, would be a total of approximately 21,000 hours per year for all affected industry members.

The Commission concluded that the recordkeeping burden associated with these proposed amendments is minimal. However, to ensure that no additional burden had been overlooked, the Commission requested public comment on the extent of the paperwork burden that the proposed requirements applying to alternative liquid automotive fuels and diesel fuel oil might impose, especially in terms of how many hours per year would be expended by industry members. None of the commenters challenged or specifically addressed the paperwork burden projections the Commission made in the NPR. Therefore, the Commission sees no reason to revise its projections of burden per year per covered industry member. However, because the Commission has deferred a decision about cetane posting for diesel fuel oil, the total yearly burden for all affected industry members due to the amendments adopted today will be less than the Commission estimated in the NPR.

Because the Commission is deferring a decision on certification and posting of cetane ratings for diesel fuel oil until further information has been obtained, the Commission revises its estimated total additional yearly burden imposed by today's amendments to be 2,500 hours (six minutes per year times 25,000 newly covered industry members), rather than 4,500 hours, as initially estimated. The Commission estimates the total yearly burden on gasoline sellers who already were covered by the Octane Rule to be approximately 16,500 hours (six minutes per year times 165,000 industry members). Thus, the Commission estimates the total yearly burden imposed by the Fuel Rating Rule to be approximately 19,000 hours.

Because these requirements would involve the "collection of information" as defined by the regulations of the Office of Management and Budget ("OMB"), 5 CFR 1320.7(c)(1) (1992), the Commission was required to submit the proposed requirements to OMB for clearance. 5 CFR 1320.13. The Commission did so as part of this proceeding. OMB approved the request, and assigned control number 3084–0068 to the information collection requirements.[208] This approval will expire on February 28, 1996, unless it has been extended before that date.

VI. Regulatory Review

As part of the Commission's ten-year regulatory-review plan for existing rules and guides, the Commission also specifically solicited comments in the NPR on the costs and benefits of the existing Octane Rule.[209] Based on the discussion in Parts IV and V, above, the Commission concludes that the Fuel Rating Rule will not have a significant economic impact on covered parties, and that there is a need for the Fuel Rating Rule. As explained in Parts III–V, above, the Commission has designed the amendments to minimize burdens imposed on covered industry members, including small businesses.

VII. Metric Measurements

In accordance with the Omnibus Trade and Competitiveness Act ("OTCA"), 15 U.S.C. 205b, and Executive Order 12770 ("Metric Usage in Federal Government Programs"), 56 FR 35801 (July 25, 1991), the Commission must consider metric measurements in addition to inch-pound measurements in measurement sensitive regulations. Only API addressed metric measurement issues. API recommended that the Commission specify label dimensions in both inches/picas and appropriate soft-conversion (calculated) metric units.[210] However, API stated that, because the average consumer's awareness of metric is minimal at this time, providing alternative fuel information to the consumer in metric units would not significantly benefit consumers.[211] Neither the original Octane Rule nor the amendments adopted today require disclosures to consumers of inch/pound measurement ratings. However, in accordance with OTCA and Executive Order 12770, § 306.12 of the Fuel Rating Rule includes both inch-pound and

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[206] See, e.g., Request for OMB Review of January, 1984, and Accompanying Supporting Statement for Information Collection Provisions of the Octane Certification and Posting Rule.

[207] Section 1320.7(b)(1) of the regulations implementing the Paperwork Reduction Act, 5 CFR 1320.7(b)(1), states:

> The time and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records) will be excluded from the "burden" if the agency demonstrates that the reporting or recordkeeping activities needed to comply are usual and customary.

[208] Notice of Office of Management and Budget Action to Carl Hevener, Federal Trade Commission, dated May 13, 1993.

[209] 58 FR 16464, 16477.

[210] API, D–10, 8.

[211] *Id.*

metric measurements in the specifications for label size.

VIII. Amendments to the Rule

A. Discussion of Amendments

The certification and posting requirements for alternative liquid automotive fuels have been discussed in Part III.A5. As indicated in the NPR, many of the amendments to the Octane Rule involve substituting "automotive fuel" for "gasoline" and "automotive fuel rating" for "octane rating." In this section, several additional amendments to the Rule are discussed. Pursuant to EPA 92, these amendments become effective at the end of the one-year period beginning on the date of the enactment of the Act, which was on October 24, 1992.[212] However, October 24, 1993 falls on a Sunday. When an effective date falls on a weekend or holiday, the next Federal business day is used as the effective date.[213] Therefore, these amendments are effective on Monday, October 25, 1993.

Section 306.0 Definitions

The Octane Rule currently does not have a section containing definitions. Because these amendments result in an expanded and more complex regulation, the Commission is including definitions in the Fuel Rating Rule. Most of the definitions that the Commission has adopted are definitions from PMPA that are pertinent to the Fuel Rating Rule. A few other definitions were adopted from other sources (principally, EPA 92), as explained below.

Section 306.0(2) contains references to the applicable ASTM standards that contain the methodologies for determining the research octane number and motor octane number. These references to the ASTM standards are different from the references in the prior version of the Rule because they are to current versions of the standards. The ASTM references are from the "Conforming Amendments" section of section 1501 of EPA 92,[214] with the addition of the suffix that ASTM uses to indicate the year of the standard's promulgation. This suffix is part of the reference to the standard in the Fuel Rating Rule to conform with the procedures for incorporation by reference in 5 U.S.C. 552(a)(1) and 1 CFR part 51.

In § 306.0, the definitions of refiner, distributor and retailer are based on the PMPA definitions of these terms. In § 306.0(4), the Commission has added a definition for "producer" that the Commission developed from language in the PMPA definition of "refiner" and the Commission's description of "producers" that was published with the announcement of the final Octane Rule.[215]

In § 306.0(9), the Commission uses the PMPA definition for "automotive fuel." As amended by EPA 92, PMPA currently defines "automotive fuel" as "liquid fuel of a type distributed for use as a fuel in any motor vehicle." To provide more guidance to industry, the Commission has supplemented this definition by drawing on the definition for "alternative fuel" contained in section 301(2) of EPA 92[216] and specifically listing (without limiting coverage) the liquid fuels that are presently covered. The Commission also has added in this section a definition for gasoline that lists (without limiting coverage) the fuels that are presently considered "gasoline," including gasohol and reformulated and oxygenated gasolines.[217]

Section 306.4 Preemption

Section 1502(a) of EPA 92 amends section 204 of PMPA to authorize the states to use whatever investigative and enforcement action they find necessary to enforce state laws that require the certification and posting of automotive fuel ratings.[218] The purpose of this amendment is to facilitate state enforcement of any state or local regulation pertaining to automotive fuel rating disclosure by permitting the use of any remedy or penalty authorized by law. The Commission has inserted new language in § 306.4 of the Fuel Rating Rule to conform with EPA 92's amendment of section 204 of PMPA.

Section 306.5 Automotive Fuel Rating

The references to the ASTM standards have been changed in § 306.(0)(2)—Definitions to reflect the current versions of the standards, as contained in section 1501(c)(1)(B) of EPA 92.[219] The Octane Rule contained language (§ 306.4(b)(2)) detailing a procedure for updating the Rule whenever ASTM modifies the octane determination standards referenced in this section. The amendments announced today delete this section. If there are subsequent amendments to the standards that are pertinent to the Rule, any person may petition the Commission to adopt the amended version or the Commission on its own motion may initiate a proceeding to adopt the revision.

List of Subjects in 16 CFR Part 306

Energy conservation, Gasoline, Incorporation by reference, Labeling, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, title 16 of the Code of Federal Regulations will be amended as follows:

PART 306—AUTOMOTIVE FUEL RATINGS, CERTIFICATION AND POSTING

1. The authority citation for part 306 of 16 CFR is revised to read as follows:

Authority: 15 U.S.C. 2801 *et seq.*

2. Part 306 of 16 CFR is amended by revising the heading to read as set forth above.

§§ 306.0 through 306.11 [Redesignated as §§ 306.1 through 306.12]

3. Sections 306.0 through 306.11 of 16 CFR are redesignated as §§ 306.1 through 306.12, respectively.

4. Part 306 of 16 CFR is amended by adding a new § 306.0, to read as follows:

§ 306.0 Definitions.

As used in this part:

(a) *Octane rating* means the rating of the anti-knock characteristics of a grade or type of gasoline as determined by dividing by 2 the sum of the research octane number plus the motor octane number.

(b) *Research octane number* and *motor octane number* have the meanings given such terms in the specifications of the American Society for Testing and Materials ("ASTM") entitled "Standard Specification for Automotive Spark-Ignition Engine Fuel" designated D4814–92c and, with respect to any grade or type of gasoline, are determined in accordance with test methods set forth in ASTM D2699–92, "Standard Test Method for Knock Characteristics of Motor Fuels by the Research Method" and ASTM D2700–

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[212] Section 1501(d)(1) of Pub. L. 102–486, 106 Stat. 2997 (codified at 15 U.S.C. 2821 (notes)).

[213] 1 CFR 18.17.

[214] Section 1501(c)(1)(B) of Pub. L. 102–486, 106 Stat. 2776, 2996 (codified at 15 U.S.C. 2821).

[215] See 44 FR 19172 (March 30, 1979). The original proceeding to promulgate the Octane Rule revealed that there is a sector of the petroleum industry that combines component elements of gasoline into the finished product. Producers are a small group within the petroleum industry who are the originating sellers of automotive gasoline but who do not import or receive gasoline or refine it from crude oil. Rather, they purchase component parts and combine them to produce finished gasoline.

[216] Sec. 301(2), Pub. L. 102–486, 106 Stat. 2776, 2866 (codified at 42 U.S.C. 13211).

[217] Reformulated and oxygenated gasolines are produced to comply with the requirements of the Clean Air Act, 42 U.S.C. 7545 (k), (m). These fuels and gasohol were specifically discussed as gasoline in the NPR. 58 FR 16464, 16466.

[218] Section 1502(a) of Pub. L. 102–486, 106 Stat. 2776, 2997–98 (codified at 15 U.S.C. 2824).

[219] Section 1501(c)(1)(B) of Pub. L. 102–486, 106 Stat. 2776. 2998 (codified at 15 U.S.C. 2821).

92, "Standard Test Method for Knock Characteristics of Motor and Aviation Fuels by the Motor Method." These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of ASTM D4814–92c, ASTM D2699–92, and ASTM D2700–92 may be obtained from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA, 19103, or may be inspected at the Federal Trade Commission, Public Reference Room, room 130, 600 Pennsylvania Avenue, NW., Washington, DC., or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(c) *Refiner* means any person engaged in the production or importation of automotive fuel.

(d) *Producer* means any person who purchases component elements and combines them to produce and market automotive fuel.

(e) *Distributor* means any person who receives automotive fuel and distributes such automotive fuel to another person other than the ultimate purchaser.

(f) *Retailer* means any person who markets automotive fuel to the general public for ultimate consumption.

(g) *Ultimate purchaser* means, with respect to any item, the first person who purchases such item for purposes other than resale.

(h) *Person*, for purposes of applying any provision of the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*, with respect to any provision of this Part, includes a partnership and a corporation.

(i) *Automotive fuel* means liquid fuel of a type distributed for use as a fuel in any motor vehicle, and the term includes, but is not limited to:

(1) Gasoline, an automotive spark-ignition engine fuel, which includes, but is not limited to, gasohol (generally a mixture of approximately 90% unleaded gasoline and 10% denatured ethanol) and fuels developed to comply with the Clean Air Act, 42 U.S.C. 7401 *et seq.*, such as reformulated gasoline and oxygenated gasoline; and

(2) alternative liquid automotive fuels, including, but not limited to:

(i) Methanol, denatured ethanol, and other alcohols;

(ii) Mixtures containing 85 percent or more by volume of methanol, denatured ethanol, and/or other alcohols (or such other percentage, but not less than 70 percent, as determined by the Secretary of the United States Department of Energy, by rule, to provide for requirements relating to cold start, safety, or vehicle functions), with gasoline or other fuels;

(iii) Liquefied natural gas;

(iv) Liquefied petroleum gas;

(v) Coal-derived liquid fuels.

(j) *Automotive fuel rating* means—

(1) For gasoline, the octane rating; or

(2) For an alternative liquid automotive fuel, the commonly used name of the fuel with a disclosure of the amount, expressed as a minimum percentage by volume, of the principal component of the fuel. A disclosure of other components, expressed as a minimum percentage by volume, may be included, if desired.

5. Section 306.1 of 16 CFR is revised to read as follows:

§ 306.1 What this rule does.

This rule deals with the certification and posting of automotive fuel ratings in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.* It applies to persons, partnerships, and corporations. If you are covered by this regulation, breaking any of its rules is an unfair or deceptive act or practice under section 5 of that Act. You can be fined up to ten thousand dollars each time you break a rule.

6. Section 306.2 of 16 CFR is revised to read as follows:

§ 306.2 Who is covered.

You are covered by this rule if you are a refiner, importer, producer, distributor, or retailer of automotive fuel.

7. Section 306.4 of 16 CFR is revised to read as follows:

§ 306.4 Preemption.

The Petroleum Marketing Practices Act ("PMPA"), 15 U.S.C. 2801 *et seq.*, as amended, is the law that directs the FTC to enact this rule. Section 204 of PMPA, 15 U.S.C. 2824, provides:

(a) To the extent that any provision of this title applies to any act or omission, no State or any political subdivision thereof may adopt or continue in effect, except as provided in subsection (b), any provision of law or regulation with respect to such act or omission, unless such provision of such law or regulation is the same as the applicable provision of this title.

(b) A State or political subdivision thereof may provide for any investigative or enforcement action, remedy, or penalty (including procedural actions necessary to carry out such investigative or enforcement actions, remedies, or penalties) with respect to any provision of law or regulation permitted by subsection (a).

8. Section 306.5 of 16 CFR is revised to read as follows:

§ 306.5 Automotive fuel rating.

If you are a refiner, importer, or producer, you must determine the automotive fuel rating of all automotive fuel before you transfer it. You can do that yourself or through a testing lab.

(a) To determine the automotive fuel rating of gasoline, add the research octane number and the motor octane number and divide by two, as explained by the American Society for Testing and Materials ("ASTM") in ASTM D4814–92c, entitled "Standard Specifications for Automotive Spark-Ignition Engine Fuel." To determine the research octane number, use ASTM standard test method D2699–92, and to determine the motor octane number, use ASTM standard test method D2700–92.

(b) To determine automotive fuel ratings for alternative liquid automotive fuels, you must possess a reasonable basis, consisting of competent and reliable evidence, for the percentage by volume of the principal component of the alternative liquid automotive fuel that you must disclose. You also must have a reasonable basis, consisting of competent and reliable evidence, for the minimum percentages by volume of other components that you choose to disclose.

9. Section 306.6 of 16 CFR is revised to read as follows:

§ 306.6 Certification

In each transfer you make to anyone who is not a consumer, you must certify the automotive fuel rating of the automotive fuel consistent with your determination. You can do this in either of two ways:

(a) Include a delivery ticket or other paper with each transfer or automotive fuel. It may be an invoice, bill of lading, bill of sale, terminal ticket, delivery ticket, or any other written proof of transfer. It must contain at least these four items:

(1) Your name;

(2) The name of the person to whom the automotive fuel is transferred;

(3) The date of the transfer;

(4) The automotive fuel rating. Octane rating numbers may be rounded off to a whole or half number equal to or less than the number determined by you.

(b) Give the person a letter or written statement. This letter must include the date, your name, the other person's name, and the automotive fuel rating of any automotive fuel you will transfer to that person from the date of the letter onwards. Octane rating numbers may be rounded to a whole or half number equal to or less than the number determined by you. This letter of certification will be good until you transfer automotive fuel with a lower

automotive fuel rating. When this happens, you must certify the automotive fuel rating of the new automotive fuel either with a delivery ticket or by sending a new letter of certification.

(c) When you transfer automotive fuel to a common carrier, you must certify the automotive fuel rating of the automotive fuel to the common carrier, either by letter or on the delivery ticket or other paper.

10. Section 306.7 of 16 CFR is revised to read as follows:

§ 306.7 Recordkeeping.

You must keep records of how you determined automotive fuel ratings for one year. They must be available for inspection by Federal Trade Commission and Environmental Protection Agency staff members, or by people authorized by FTC or EPA.

11. Section 306.8 of 16 CFR is revised to read as follows:

§ 306.8 Certification.

If you are a distributor, you must certify the automotive fuel rating of the automotive fuel in each transfer you make to anyone who is not a consumer.

(a) In the case of gasoline, if you do not blend the gasoline with other gasoline, you must certify the gasoline's octane rating consistent with the octane rating certified to your. If you blend the gasoline with other gasoline, you must certify consistent with your determination of the average, weighted by volume, of the octane ratings certified to you for each gasoline in the blend, or consistent with the lowest octane rating certified to you for any gasoline in the blend. Whether you blend gasoline or not, you may choose to certify the octane rating of the gasoline consistent with your determination of the octane rating according to the method in § 306.5. In cases involving gasoline, the octane rating may be rounded to a whole or half number equal to or less than the number certified to you or determined by you.

(b) If you do not blend alternative liquid automotive fuels, you must certify consistent with the automotive fuel rating certified to you. If you blend alternative liquid automotive fuels, you must possess a reasonable basis, consisting of competent and reliable evidence, for the automotive fuel rating that you certify for the blend.

(c) You may certify either by using a delivery ticket with each transfer of automotive fuel, as outlined in § 306.6(a), or by using a letter of certification, as outlined in § 306.6(b).

(d) When you transfer automotive fuel to a common carrier, you must certify the automotive fuel rating of the automotive fuel to the common carrier, either by letter or on the delivery ticket or other paper. When you receive automotive fuel from a common carrier, you also must receive from the common carrier a certification of the automotive fuel rating of the automotive fuel, either by letter or on the delivery ticket or other paper.

12. Section 306.9 of 16 CFR is revised to read as follows:

§ 306.9 Recordkeeping

You must keep for one year any delivery tickets or letters of certification on which you based your automotive fuel rating certifications. You must also keep for one year records of any automotive fuel rating determinations you made according to § 306.5. They must be available for inspection by Federal Trade Commission and Environmental Protection Agency staff members, or by persons authorized by FTC or EPA.

13. Section 306.10 of 16 CFR is revised to read as follows:

§ 306.10 Automotive fuel rating posting.

(a) If you are a retailer, you must post the automotive fuel rating of all automotive fuel you sell to consumers. You must do this by putting at least one label on each face of each dispenser through which you sell automotive fuel. If you are selling two or more kinds of automotive fuel with different automotive fuel ratings from a single dispenser, you must put separate labels for each kind of automotive fuel on each face of the dispenser.

(b) (1) The label, or labels, must be placed conspicuously on the dispenser so as to be in full view of consumers and as near as reasonably practical to the price per unit of the automotive fuel.

(2) You may petition for an exemption from the placement requirements by writing the Secretary of the Federal Trade Commission, Washington, DC 20480. You must state the reasons that you want the exemption.

(c) In the case of gasoline, if you do not blend the gasoline with other gasoline, you must post the octane rating of the gasoline consistent with the octane rating certified to you. If you blend the gasoline with other gasoline, you must post consistent with your determination of the average, weighted by volume, of the octane ratings certified to you for each gasoline in the blend, or consistent with the lowest octane rating certified to you for any gasoline in the blend. Whether you blend gasoline or not, you may choose to post the octane rating of the gasoline consistent with your determination of the octane rating according to the method in § 306.5. In cases involving gasoline, the octane rating must be shown as a whole or half number equal to or less than the number certified to you or determined by you.

(d) If you do not blend alternative liquid automotive fuels, you must post consistent with the automotive fuel rating certified to you. If you blend alternative liquid automotive fuels, you must possess a reasonable basis, consisting of competent and reliable evidence, for the automotive fuel rating that you post for the blend.

(e)(1) You must maintain and replace labels as needed to make sure consumers can easily see and read them.

(2) If the labels you have are destroyed or are unusable or unreadable for some unexpected reason, you can satisfy the law by posting a temporary label as much like the required label as possible. You must still get and post the required label without delay.

(f) The following examples of automotive fuel rating disclosures for some presently available alternative liquid automotive fuels are meant to serve as illustrations of compliance with this part, but do not limit the Rule's coverage to only the mentioned fuels:

(1) "Methanol/Minimum _____% Methanol"
(2) "Ethanol/Minimum _____% Ethanol"
(3) "M–85/Minimum _____% Methanol"
(4) "E–85/Minimum _____% Ethanol"
(5) "LPG/Minimum _____% Propane" or "LPG/Minimum _____% Propane and _____% Butane"
(6) "LNG/Minimum _____% Methane"

(g) When you receive automotive fuel from a common carrier, you also must receive from the common carrier a certification of the automotive fuel rating of the automotive fuel, either by letter or on the delivery ticket or other paper.

14. Section 306.11 of 16 CFR is revised to read as follows:

§ 306.11 Recordkeeping.

You must keep for one year any delivery tickets or letters of certification on which you based your posting of automotive fuel ratings. You also must keep for one year records of any automotive fuel rating determinations you made according to § 306.5. These records may be kept at the retail outlet or at another, reasonably close location. They must be available for inspection by Federal Trade Commission and Environmental Protection Agency staff members or by persons authorized by FTC or EPA.

15. Section 306.12 is revised to read as follows:

§306.12 Labels.

All labels must meet the following specifications:

(a) Layout.—(1) For gasoline labels. The label is 3" (7.62 cm) wide x 2½" (6.35 cm) long. The illustrations appearing at the end of this rule are prototype labels that demonstrate the proper layout. "Helvetica Black" type is used throughout except for the octane rating number on octane labels, which is in Franklin gothic type. All type is centered. Spacing of the label is ¼" (.64 cm) between the top border and the first line of text, ⅛" (.32 cm) between the first and second line of text, ¼" (.64 cm) between the octane rating and the line of text above it. All text and numerals are centered within the interior borders.

(2) For alternative liquid automotive fuel labels (one principal component). The label is 3" (7.62 cm) wide × 2½" (6.35 cm) long. "Helvetica black" type is used throughout. All type is centered. The band at the top of the label contains the name of the fuel. This band should measure 1" (2.54 cm) deep. Spacing of the fuel name is ¼" (.64 cm) from the top of the label and 3/16" (.48 cm) from the bottom of the black band, centered horizontally within the black band. The first line of type beneath the black band is ⅛" (.32 cm) from the bottom of the black band. All type below the black band is centered horizontally, with ⅛" (.32 cm) between each line. The bottom line of type is 3/16" (.48 cm) from the bottom of the label. All type should fall no closer than 3/16" (.48 cm) from the side edges of the label. If you wish to change the dimensions of this single component label to accommodate a fuel descriptor that is longer than shown in the sample labels, you must petition the Federal Trade Commission. You can do this by writing to the Secretary of the Federal Trade Commission, Washington, DC 20580. You must state the size and contents of the label that you wish to use, and the reasons that you want to use it.

(3) For alternative liquid automotive fuel labels (two components). The label is 3" (7.62 cm) wide × 2½" (6.35 cm) long. "Helvetica black" type is used throughout. All type is centered. The band at the top of the label contains the name of the fuel. This band should measure 1" (2.54 cm) deep. Spacing of the fuel name is ¼" (.64 cm) from the top of the label and 3/16" (.48 cm) from the bottom of the black band, centered horizontally within the black band. The first line of type beneath the black band is 3/16" (.48 cm) from the bottom of the black band. All type below the black band is centered horizontally, with ⅛" (.32 cm) between each line. The bottom line of type is ¼" (.64 cm) from the bottom of the label. All type should fall no closer than 3/16" (.48 cm) from the side edges of the label. If you wish to change the dimensions of this two component label to accommodate additional fuel components, you must petition the Federal Trade Commission. You can do this by writing to the Secretary of the Federal Trade Commission, Washington, DC 20580. You must state the size and contents of the label that you wish to use, and the reasons that you want to use it.

(b) *Type size and setting*—(1) *For gasoline labels.* The Helvetica series is used for all numbers and letters with the exception of the octane rating number. Helvetica is available in a variety of phototype setting systems, by linotype, and in a variety of computer desk-top and phototype setting systems. Its name may vary, but the type must conform in style and thickness to the sample provided here. The line "Minimum Octane Rating" is set in 12 point Helvetica Bold, all capitals, with letterspace set at 12½ points. The line "(R+M)/2 METHOD" is set in 10 point Helvetica Bold, all capitals, with letterspace set at 10½ points. The octane number is set in 96 point Franklin gothic condensed with ⅛" (.32 cm) space between the numbers.

(2) *For alternative liquid automotive fuel lables (one principal component).* All type should be set in upper case (all caps) "Helvetica Black" throughout. Helvetica Black is available in a variety of computer desk-top and phototype setting systems. Its name may vary, but the type must conform in style and thickness to the sample provided here. The spacing between letters and words should be set as "normal." The type for the fuel name is 50 point (½" (1.27 cm) cap height) "Helvetica Black," knocked out of a 1" (2.54 cm) deep band. The type for the words "MINIMUM" and the principal component is 24 pt. (¼" (.64 cm) cap height.) The type for percentage is 36 pt. (⅜" (.96 cm) cap height).

(3) *For alternative liquid automotive fuel labels (two components).* All type should be set in upper case (all caps) "Helvetica Black" throughout. Helvetica Black is available in a variety of computer desk-top and phototype setting systems. Its name may vary, but the type must conform in style and thickness to the sample provided here. The spacing between letters and words should be set as "normal." The type for the fuel name is 50 point (½" 1.27 cm) cap height) "Helvetica Black," knocked out of a 1" (2.54 cm) deep band. All other type is 24 pt. (¼" (.64 cm) cap height.)

(c) *Colors*—(1) *For gasoline labels.* The basic color on all octane labels is process yellow. All type is process black. All borders are process black. All colors must be non-fade.

(2) *For alternative liquid automotive fuel labels.* The background color on all the labels is Orange: PMS 1495. The knock-out type within the black band is orange PMS 1495. All other type is process black. All borders are process black. All colors must be non-fade.

(d) *Contents.* Examples of the contents are shown in the sample labels. The proper octane rating for each gasoline must be shown. The proper automotive fuel rating for each alternative liquid automotive fuel must be shown. No marks or information other than that called for by this rule may appear on the labels.

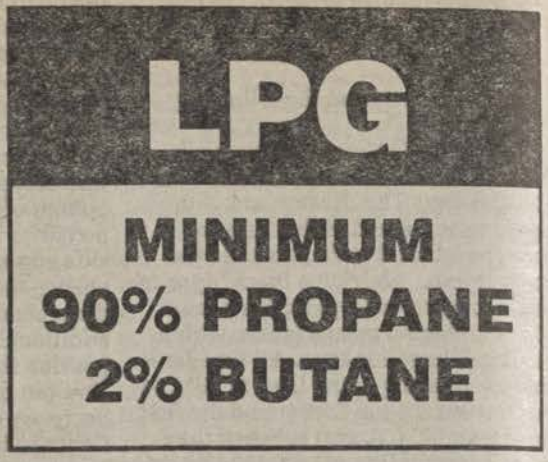
(e) *Special label protection.* All labels must be capable of withstanding extremes of weather conditions for a period of at least one year. They must be resistant to automotive fuel, oil, grease, solvents, detergents, and water.

(f) *Illustrations of labels.* Labels should meet the specifications in this section, and should look like these examples, except the black print should be on the appropriately colored background.

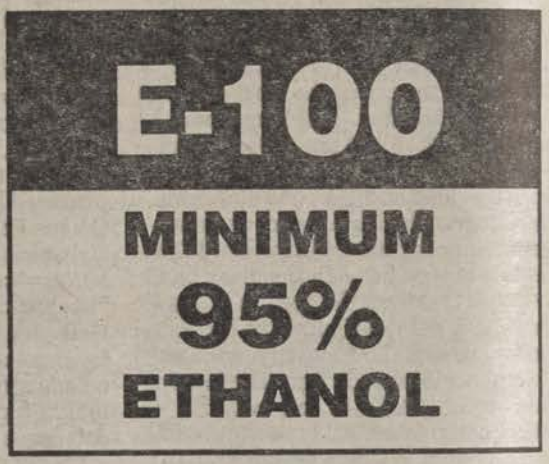
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By direction of the Commission.

Donald S. Clark,

Secretary.

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