

DEPARTMENT OF THE TREASURY**Bureau of Alcohol, Tobacco and Firearms****27 CFR Part 16**

[Notice No. 917]

RIN 1512-AC12

Alcohol Beverage Health Warning Statement (99R-507P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is considering amending the regulations concerning the placement, legibility, and noticeability of the congressionally mandated health warning statement required to appear on the labels of all containers of alcohol beverages. Based on a petition we have received, we wish to gather information by inviting comments from the public and industry as to whether the existing regulations should be revised.

DATES: Comments must be received on or before August 20, 2001.

ADDRESSES: Send written comments to: Chief, Regulations Division; Bureau of Alcohol, Tobacco and Firearms; P.O. Box 50221; Washington, DC 20091-0221; ATTN: Notice No. 917. Written comments must be signed, and may be of any length.

E-mail comments may be submitted to: nprm@atfhq.atf.treas.gov. E-mail comments must contain your name, mailing address, and e-mail address. They must also reference this notice number and be legible when printed on not more than three pages 8½" × 11" in size. We will treat e-mail as originals and we will not acknowledge receipt of e-mail. See the Public Participation section at the end of this advance notice for requirements for submitting written comments by facsimile.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202-927-8210).

SUPPLEMENTARY INFORMATION:**Background**

Title VIII of the Anti-Drug Abuse Act of 1988, Public Law 100-690 (enacted November 18, 1988), amended the Federal Alcohol Administration Act (FAA Act) by designating the existing sections of the FAA Act as "Title I," and

by adding at the end a new title, "Title II—Alcoholic Beverage Labeling." This title, cited as the "Alcoholic Beverage Labeling Act of 1988" (ABLA), requires that the following health warning statement appear on the labels of all containers of alcohol beverages for sale or distribution in the United States:

GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

The health warning statement requirement applies to alcohol beverages bottled on or after November 18, 1989, and applies both to interstate and intrastate sale and distribution of alcohol beverages. In addition, the health warning statement must appear on containers of alcohol beverages that are sold, distributed, or shipped to members or units of the U.S. Armed Forces, including those located outside the United States. For purposes of the ABLA, the term "alcoholic beverage" includes any beverage in liquid form which contains not less than one-half of one percent (.5%) of alcohol by volume and is intended for human consumption.

The law specifies that the health warning statement "shall be located in a conspicuous and prominent place on the container of such beverage, as determined by the Secretary [of the Treasury], shall be in type of a size determined by the Secretary, and shall appear on a contrasting background."

On February 14, 1990, we issued final regulations in 27 CFR Part 16 implementing the provisions of the ABLA (T.D. ATF-294; 55 FR 5414). These regulations became effective on November 14, 1990. The final rule was preceded by a notice of proposed rulemaking (Notice No. 678, February 16, 1989; 54 FR 7164), which solicited comments on our temporary regulations (T.D. ATF-282, February 16, 1989; 54 FR 7160). The temporary regulations applied to products bottled between November 18, 1989, and November 13, 1990.

The final regulations provide that the health warning statement must appear on the brand label or separate front label, or on a back or side label, separate and apart from all other information. It must be readily legible under ordinary conditions, and must appear on a contrasting background. Furthermore, labels bearing the health warning statement must be firmly affixed to the container. In order to ensure that the consumer's attention is drawn to the health warning statement, the

regulations require that the words "GOVERNMENT WARNING" appear in capital letters and in bold type. The remainder of the warning statement may not appear in bold type.

The regulations specify the maximum number of characters (i.e., letters, numbers, marks) permitted per inch in which the health warning statement may appear. This requirement is intended to ensure that the warning statement is more easily read by the average consumer. Additionally, the regulations prescribe minimum type size requirements for the health warning statement.

Petition

We have received a petition, dated November 17, 1999, filed on behalf of the Center for Science in the Public Interest (CSPI), four members of Congress, the National Council on Alcoholism and Drug Dependence, Inc. (NCADD), and 119 other organizations, requesting an amendment of the regulations regarding the legibility, clarity, and noticeability of the health warning statement. The petitioners included citations to research to support their proposed amendments. Specifically, the petitioners request that the regulations in Part 16 be amended to require the following:

1. *The health warning statement must appear in a prominent place on the front of the container in a horizontal position.* The petitioners contend that many alcohol producers position the warning statement vertically on the margin of the label, thus making the label difficult to read when the container is placed on a shelf. The petitioners also allege that the warning statement often appears crowded and is embedded in the surrounding information, making it hard to locate and read. According to the petitioners, warnings that contain fewer characters per inch, occupy a larger area on the label, and appear less embedded in surrounding information tend to be noticed more readily. The petitioners further state that for maximum effectiveness the warning information should be easy to locate and should appear in the same relative position on all labels. Finally, the petitioners claim that label messages appearing horizontally are significantly more noticeable than warnings that are printed in a vertical position.

2. *The health warning statement must appear in red or black type on a white background, and be surrounded by a lined border.* In addition to placement on the front of the container, the petitioners claim that the research suggests two other elements that would

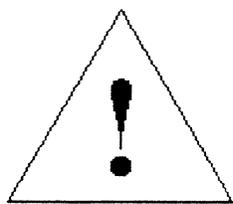
dramatically improve consumer awareness of the alcohol warning statement, i.e., a clear, lined border surrounding the statement and text in a highly contrasting color. The petitioners refer to one study that found that graphic devices such as boxes help consumers recognize and process a warning message. They refer to another study that found that color helps immensely to increase awareness of warning labels; in fact, the higher the contrast between text and background, the more likely consumers are to notice them.

3. *The first two words of the health warning statement, i.e.,*

“GOVERNMENT WARNING,” must appear in capital letters and boldface type that is at least 15 percent larger than the remaining text of the statement. The text of the remaining portion of the warning statement must be in upper and lower-case lettering. A particular type font should be required to maximize legibility. According to the petitioners, one researcher found that the degree to which the phrase “GOVERNMENT WARNING” stood out from the rest of the label was a significant predictor of the consumer response time. In this regard, the petitioners note that in both the statute and the regulations the words

“GOVERNMENT WARNING” appear in capital letters while the text of the statement appears in upper and lower-case letters. However, the regulations do not specify that the text of the warning statement must appear in upper and lower-case letters. The petitioners maintain that it is harder to read the warning when the entire statement appears in capital letters.

4. *The warning statement must appear together with a red pictorial device or icon that is a triangle with an exclamation mark inside.* As proposed by the petitioners, the warning statement would appear as follows:



GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

According to the petitioners, several studies have shown that the inclusion of an icon or pictorial element substantially heightens consumer recognition of a warning label. In studies of the way consumer eye-movements track warning labels, the petitioners state that one researcher specifically studied a triangular icon with an exclamation mark inside it and found that this icon produced significantly faster response times than warnings without the icon.

With the above modifications, the petitioners believe that the health warning statement will be “more noticeable, more effective, and will help insure that the labels on alcoholic-beverage containers meet the standards for the warning statement as originally set out by Congress.”

Review of Petition by Other Federal Agencies and the Surgeon General

By letters dated December 3, 1999, ATF asked the Food and Drug Administration (FDA), the National Institute on Alcohol Abuse and Alcoholism, the Surgeon General, and the Federal Trade Commission (FTC) to review the petition and provide us with their comments. We also asked for available information regarding the latest scientific studies dealing with the design of alcohol warning labels, as well

as any research on warning labels in general.

In his letter of February 15, 2000, the Surgeon General (on behalf of the Food and Drug Administration, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration) noted that it has been more than a decade since the alcohol health warning statement and implementing regulations were adopted. As such, revisiting this issue would be a valuable contribution to the public health as the abuse of alcohol beverages continues to represent a serious public health problem. The Surgeon General stated the following:

If the current mandatory health warning is to serve a public function of informing consumers, it is important that periodic efforts be made to evaluate the placement of the label, its legibility, the extent to which manufacturers are complying with current label requirements, and the level of consumer awareness of the label, particularly under expected conditions of use.

In addition, the Surgeon General indicated that over the last 10 years there has been an abundance of practical experience and science about ways to design and disseminate health information on product packaging. For example, he notes that in Canada and Australia much work has been done to

assess the most effective placement of health warnings on tobacco products. He also notes that the FDA has unique and relevant experience in this area through the development and evaluation of food label and nutrient requirements.

By letter dated March 13, 2000, the FTC advised us that it has experience with respect to health warnings, including the “Surgeon General’s” warnings required on cigarettes and the warnings required on smokeless tobacco products. In addition, the FTC recently recommended to Congress that cigar manufacturers and marketers be required to comply with a system of multiple rotating warnings, similar to those now in place for cigarettes and smokeless tobacco. The FTC also provided us with citations to some of the relevant research on warning labels with respect to size, placement, pictorials, borders, etc. If ATF decides to explore modifying the requirements with respect to the health warning statement, the FTC recommends that we conduct consumer testing of any proposed changes. Based on its experience, the FTC states that such research is often useful in assessing the prominence, noticeability, and understandability of warnings.

Discussion

ATF is requesting information from consumers, consumer groups, interest groups, associations, and industry members on the desirability of amending the regulations with regard to the legibility and noticeability of the mandated Government health warning statement. Although we are soliciting comments on the following specific questions, we are also requesting any relevant information on the subject.

1. Are consumers aware that the health warning statement must appear on the labels of all alcohol beverages sold in the U.S.?

2. Do consumers look for the warning statement on alcohol beverage containers?

3. Do consumers notice the health warning statement on alcohol beverage containers? Explain.

4. Do consumers read the warning statement on labels of alcohol beverages? Why or why not?

5. Are consumers familiar with the information contained in the alcohol health warning statement?

6. Do consumers find the warning statement on alcohol beverages difficult to read? Explain.

7. Do consumers have examples of alcohol beverages where the warning statement is legible and noticeable? What makes the warning statement legible and noticeable?

8. Do consumers believe the regulations need to be amended to make the warning statement more legible? Explain.

9. What would be the costs associated with adopting any or all of the changes recommended by the petitioners, to the industry and, ultimately, the consumer?

As indicated by the Surgeon General, over the last 10 years there has been an abundance of practical experience and science about ways to design and disseminate health information on product packaging. Accordingly, we are requesting scientific information, i.e., scientific studies, reports, consumer surveys, research literature, etc., that might be useful in assessing the changes suggested by the petitioners concerning the legibility of the health warning statement. As mentioned in the FTC's letter to us, the question of whether any particular warning is clear and prominent is an empirical one. Information submitted should not be limited to that completed within the last few years. Although we believe that such information may be more valid, we are seeking any pertinent information on the subject.

We are also interested in studies that are currently in progress and, if

available, any interim findings. We would also like to be advised of any studies currently underway which may not be completed within the 90-day comment period, along with a projected target date for completion.

Executive Order 12866

It has been determined that this advance notice is not a significant regulatory action as defined by Executive Order 12866. Accordingly, this advance notice is not subject to the analysis required by this Executive Order.

Public Participation

We are requesting comments on the petition from all interested persons. We are specifically requesting comments on the clarity of this advance notice and how it may be made easier to understand.

Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

ATF will not recognize any material in comments as confidential. Comments may be disclosed to the public. Any material that the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of the person submitting a comment is not exempt from disclosure.

You may submit written comments by facsimile transmission to (202) 927-8602. Facsimile comments must:

- Be legible;
- Reference this notice number;
- Be 8½" × 11" in size;
- Contain a legible written signature; and
- Be not more than three pages long.

We will not acknowledge receipt of facsimile transmissions. We will treat facsimile transmissions as originals.

Disclosure

Copies of the petition, this notice, and the comments received will be available for public inspection during normal business hours at: ATF Public Reading Room, Room 6480, 650 Massachusetts Avenue, NW, Washington, DC.

Drafting Information

The author of this document is James P. Ficaretta, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 16

Alcohol and alcoholic beverages, Consumer protection, Health, Labeling, Penalties.

Authority and Issuance

This notice is issued under the authority of 27 U.S.C. 205 and 215.

Dated: April 25, 2001.

Bradley A. Buckles,
Director.

Approved: April 25, 2001.

Timothy E. Skud,
Acting Deputy Assistant Secretary,
(Regulatory, Tariff and Trade Enforcement).
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD116-3067b; FRL-6979-5]

Approval and Promulgation of Air Quality Implementation Plans; State of Maryland; Repeal of Petroleum Refinery Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Maryland. This action proposes to approve Maryland's repeal of its petroleum refinery regulation. EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

DATES: Comments must be received in writing by June 21, 2001.