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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0436]

Food and Drug Administration Draft Study Report; Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing for comment a draft study report on the feasibility of appropriate methods of informing customers of the contents of bottled water, as required by the Safe Drinking Water Act Amendments. This draft feasibility study report evaluates and identifies appropriate methods that may be feasible for conveying information about bottled water to customers.

DATES: Written comments must be received by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Buckner, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4081.

SUPPLEMENTARY INFORMATION: The text of the draft study report on the feasibility of appropriate methods of informing customers of the contents of bottled water follows:

FDA Draft Study Report: Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

I. Background

On August 6, 1996, the President signed into law the Safe Drinking Water Act (SDWA) Amendments (Public Law 104–182). Under the Public Notification section of the Amendments, the Environmental Protection Agency (EPA) was required to issue regulations mandating that each community water system provide each customer of the system with an annual report, referred to as a consumer confidence report (CCR), on the level of contaminants in the drinking water purveyed by that system. A complete description of the information contained in a CCR can be found in the next section of this document entitled “FDA’s Evaluation of Information about the Contents of Bottled Water.”

In the **Federal Register** of February 13, 1998 (63 FR 7606), EPA published a proposed rule to require local water systems to provide an annual CCR to their customers. Based on this proposal, EPA published a final rule on August 19, 1998 (63 FR 44512). Section 114(b) of the SDWA Amendments also required that, no more than 18 months after the date of its enactment, the Food and Drug Administration (FDA), in consultation with EPA, publish for notice and comment a draft study on the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water.

In a notice published in the **Federal Register** of November 12, 1997 (62 FR 60721) (hereinafter “the 1997 notice”), FDA requested comment on several matters relevant to the feasibility of appropriate methods of informing customers of the contents of bottled water. We have evaluated the information received and identified appropriate methods that may be feasible for conveying information about bottled water to customers. This draft feasibility study presents the agency’s evaluation of those methods. Congress, under the SDWA Amendments, did not expressly address FDA’s authority for implementing, by regulation, any appropriate methods deemed feasible. Should FDA, in the future, decide to engage in rulemaking on this subject, FDA would discuss, in such a rulemaking, the agency’s statutory authority for requiring any of the types of information or for requiring a specific method for conveying such information on the contents of bottled water to customers. However, such a discussion is outside the scope of this study. Comments received on this draft report will be evaluated and considered in preparation of the final report

on the feasibility of appropriate methods, if any, for providing information about the contents of bottled water to customers.

In the 1997 notice, FDA asked for specific information to use in generating the feasibility study. The agency considered this to be the most effective means of obtaining information from all segments of the general public (i.e., industries, trade associations, consumers, consumer advocacy groups, educational institutions) that are interested in the subject of the feasibility of appropriate methods of providing information on bottled water to customers. The following specific information was requested: (1) What methods, if any, may be appropriate for conveying information about the contents of bottled water to customers, and why they are appropriate; (2) for each method identified as being appropriate for conveying information to customers, whether such method is or is not feasible and the supporting reasons why the method is or is not feasible; and (3) the type of information about the contents of bottled water that should be provided to customers within the context of the SDWA Amendments and that would, to the extent possible, be analogous to the information provided in a CCR.

The agency received 51 letters in response to the 1997 notice. Many comments stated that it is not necessary to provide customers with more information than they currently receive on bottled water. Comments that expressed these opinions are beyond the scope of this report and are not discussed.

II. Information About the Contents of Bottled Water

In the 1997 notice, FDA requested comments on the type of information about the contents of bottled water that should be provided to customers that would, to the extent possible, be analogous to information provided in a CCR. To that end, the agency notes that a CCR, as outlined by EPA, contains: (1) Information about the source of drinking water; (2) definitions of “maximum contaminant level” (MCL), “maximum contaminant level goal” (MCLG), “exemption” and “variance”; (3) the MCL, MCLG, and contaminant level detected in the water for regulated contaminants and, for any contaminant detected that violates the MCL during the year, information on the health effects that led EPA to regulate that contaminant; (4) information on compliance with EPA’s National Primary Drinking Water Regulations and notice if the system operates under a variance or an exemption and the basis on which the variance or exemption was

granted; (5) information on the levels of unregulated contaminants for which monitoring by the system is required (including, for example, levels of *Cryptosporidium* and radon where States determine such levels may be found); and (6) a statement that the presence of contaminants in drinking water does not necessarily indicate that the drinking water poses a health risk, and that more information about contaminants and potential health risks can be obtained by calling the EPA hotline.

In the 1997 notice, we requested comments on what information analogous to that in a CCR should be provided to customers. We realize that not all of the information in a CCR is relevant to bottled water. For example, FDA establishes “allowable levels” for contaminants, not MCL’s (FDA has established allowable levels for 83 contaminants in bottled water).

A few comments stated that FDA was exceeding its congressional mandate in soliciting comments on information about the contents of bottled water that could be reported to customers. These comments stated that the agency was asked to study the feasibility of appropriate methods of informing customers about the contents of bottled water and was not asked to evaluate information about the contents.

We disagree with these comments. In order to consider the feasibility of appropriate methods of informing customers of the contents of bottled water, we must consider the type and amount of information on the contents of bottled water that may be included within the context of the SDWA Amendments. Many who commented indicated that it was possible to provide information similar to that found in a CCR for bottled water. However, several comments stated that a list of all detected contaminants should not be provided because this would be confusing to customers and indicated that only contaminants in violation of allowable levels should be listed.

Many comments stated that it was appropriate to discuss contaminant limits in bottled water in terms of allowable levels rather than MCL’s. MCL is the term used in EPA’s, but not FDA’s, regulations. However, a few comments maintained that bottled water contaminant limits should be expressed as MCL’s for the sake of consistency.

Several comments indicated that, in addition to the information contained in a CCR, bottled water information should include a mineral profile, hydrogen-ion concentration (pH) and hardness measurements

and sodium content. A “date bottled” statement and a statement of the type of treatment or disinfection that the water received also were suggested as information that would be of interest to customers. Some comments stated that treatment or disinfection information is important to immunocompromised individuals in determining whether the water has been treated by one of the methods recommended by the Centers for Disease Control and Prevention for the elimination of *Cryptosporidium*, a parasite that has caused serious waterborne illness outbreaks from the consumption of contaminated public drinking water.

FDA’s Evaluation of Information About the Contents of Bottled Water

We believe that much of the information contained in a CCR is applicable to bottled water. However, we recognize that certain information contained in a CCR is relevant only to public drinking water systems. Such information includes the definition and statement of MCLG’s and information on public drinking water systems operating under a variance and other information that is relevant only to public drinking water systems regulated by EPA, such as information on EPA’s drinking water hotline.

The agency notes that certain information not required in a CCR, e.g., “date bottled,” mineral profile, pH and type of treatment given to water (for immunocompromised consumers), may be of interest to some bottled water customers. However, with the exception of information related to the potential presence of *Cryptosporidium* in bottled water (type of treatment), this information is not analogous to information contained in a CCR. In soliciting comments on the type of information on bottled water that could be provided to customers, we specified in the 1997 notice (62 FR 60721 at 60722) that the information should be within the context of the SDWA Amendments and, to the extent possible, be analogous to that contained in a CCR. The agency’s intent in the 1997 notice was to solicit information that was analogous to that outlined by EPA for inclusion in a CCR (see above). Although we recognize that the SDWA Amendments provide for States to develop alternative requirements with respect to the form and content of a CCR, it was not our intent to solicit a broad range of information but rather to limit the discussion to information that is analogous to that outlined by EPA for inclusion in a CCR. Therefore, consideration of information that is not within the context of the SDWA Amendments (i.e., analogous to information outlined by EPA for inclusion in a CCR) is beyond the scope of this study.

III. Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

In the 1997 notice, FDA suggested several possible methods for conveying information, i.e., providing the information on the label of the bottle or in a pamphlet made available at point of sale, or listing a phone number or an address on the label that the customer could use to access information, or providing the information on an Internet site that customers could access. We also suggested that firms making bulk deliveries might provide their customers with the information directly or by mail. The agency recognized that the aforementioned methods do not represent all possible methods that may be appropriate and interested persons were asked to suggest other methods.

For each method identified as being appropriate for conveying information to customers about the contents of bottled water, FDA requested comments on whether the provision of information by the method is or is not feasible, i.e., is or is not “capable of being done or carried out” (Webster’s Third New International Dictionary, 1976). Although not explicitly stated in the 1997 notice, we note that practicality is an important element of feasibility. Additionally, interested persons were asked to state why a particular method would be feasible or not feasible, addressing costs and other relevant factors (e.g., label space) in their comments.

The agency received comments on the appropriateness and feasibility of six methods of informing customers of the contents of bottled water. These methods include the label, a phone number/address for company contact on the label, a combination of the two previous methods (some information on the label, some available through company contact), a pamphlet at point of purchase, an information package distributed with bulk water deliveries, and the Internet. The supporting reasons for why each method identified is appropriate and the feasibility of each method as described in comments are discussed in the subsequent sections. Further, FDA’s evaluation of each method is presented.

A. Information on the Label

Several comments identified the use of the label as an appropriate method because labels are designed specifically to convey information to customers. In fact, a few comments stated that the only appropriate

method was the label because it allows customers to have access to all available information at the point of purchase.

Alternatively, several comments stated that it would be inappropriate to place the information contained in a CCR on the label of bottled water. These comments noted that all food labels are required by law to carry certain pieces of information. Requiring additional information on the labels of bottled water would not be in keeping with labeling requirements for all other food products. Some comments also contended that additional information on the label might frighten or confuse customers because they would not understand the significance of information such as levels of trace contaminants in bottled water.

A few comments indicated that it would be feasible to include all of the information which would appear in a CCR on the label if the size of the label were increased or a fold-out label were used. However, the majority of comments indicated that it was not feasible to place significantly more information on a label based upon current label sizes.

1. Costs Associated With the Method.

One comment estimated that, because of the amount of information, the cost of adding comprehensive CCR information would cost significantly more than the cost of adding a nutrition facts panel to a label (i.e., would cost more than \$24,000 for a medium-sized bottled water company with eight product labels and three package sizes). Several comments stated that changing a label significantly could be an economic hardship for small companies.

We estimate the average cost of making a label change for firms in this industry to be between \$2,200 and \$17,900, depending upon the complexity of the label change, the number of labels a company uses, and the time parameters for implementing the changes. Costs would be higher if testing that the company currently does not perform was necessary to generate additional information that may be of interest to customers. These costs could be substantially greater if it became necessary to make multiple label changes in response to changing test results, for example, from ongoing monitoring for chemical and microbiological contaminants. Bottled water regulations for monitoring for chemical and microbiological contaminants

require weekly monitoring for some contaminants and yearly monitoring for others. A change in the levels detected from week-to-week or year-to-year would necessitate a label change.

2. FDA's Evaluation

We agree that placing information on the label is an appropriate method of informing customers about the contents of bottled water. However, we question the feasibility of placing all of the information on the contents of bottled water, that is analogous to that contained in a CCR, on the label of bottled water. The amount of information contained in a CCR, as outlined by EPA, is considerable (see section II of this document). We believe that the placement of all analogous CCR information on the label would lead to label clutter due to space requirements for such information. Therefore, we believe it is not feasible to place all such information on the contents of bottled water on the product label.

The agency also has concerns about the economic feasibility of placing information on a label that has the potential to change on a frequent basis as a result of ongoing monitoring that is required under its "Processing and Bottling of Bottled Drinking Water" regulations (21 CFR part 129). Labeling changes for information that may change frequently could result in an economic hardship to companies and, in addition, would result in the possibility that a product might bear a label that was no longer accurate, due to changing test results, which may cause the product to be misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343). Therefore, we believe placing all analogous CCR information on bottled water on the label is not economically feasible.

B. Information Available by Company Contact

Several comments considered an appropriate method for informing customers of the contents of bottled water to be through a customer request by calling a phone number or writing to an address provided on the label. It was noted that the customer would have to go to some effort to get the information in this case, but comments still considered the method to be appropriate because customers who were interested in receiving information could do so. Several comments indicated that historically there has been little customer interest in information on the contents of bottled water.

Comments also stated that this would be a feasible method of conveying information to customers. This method was considered feasible because it is already being employed by a number of bottlers and, therefore, neither costly label changes nor greatly increasing the size of the product label would be necessary.

1. Costs Associated With the Method

The costs associated with providing information in response to requests made by calling a phone number or writing to an address on the label depend upon how the company chooses to provide this information (e.g., operation of a toll number, a toll-free number, or a mail-response system), the volume of customer requests for information, and the amount of time required to answer requests. FDA estimates that costs for this option would be between \$1,200 and \$4,200 annually, depending on the method chosen. In addition, any product label that does not already provide contact information will have to be changed to provide that information. We estimate the average cost of making a simple one-time label change for firms in this industry to be between \$2,200 and \$12,800. Finally, FDA notes that the customer will incur costs for acquiring information on bottled water if a company chooses to provide a toll number, rather than a toll-free number, on the label.

2. FDA's Evaluation

We agree that a phone number or an address on the label directing customers on how to obtain information from the company is an appropriate method of providing information to customers. Telephones and mail are available to almost all customers. The information would be accessible to customers with this method, although the agency does note that some effort will be required on the part of the customer to obtain the information. Dissemination of information in this manner may be less likely to confuse customers if the system allowed customers to be selective by obtaining only information in which they have an interest rather than all the information that may be available. Information provided in this manner can also be kept current.

We believe that providing information through a phone number or an address is feasible. It is the least costly method to industry of providing information to customers because it does not require frequent

label changes and is therefore less costly to maintain. Moreover, the start up costs would only apply to a portion of the industry since many firms already provide information to customers in this manner.

C. Information Available by the Combination Approach

Many comments advocated placing certain individual pieces of information, such as information on source of the water, information about the suitability of the water for consumption by immunocompromised individuals or fluoride levels, on the label, while making other CCR-type information available to customers through contact with the company (i.e., a combination approach). Comments stated that this would be both appropriate and feasible and noted that this would give customers access to certain pieces of information that may be of interest to them at point of purchase.

1. Costs Associated With the Method

The costs associated with providing information in response to customer requests for the information through company contact would be similar to those listed in the previous section. This option would also entail a label change for companies, estimated to cost a minimum of between \$2,200 and \$12,800 for the initial change. Whether or not there would be additional costs for subsequent label changes would depend upon whether the information required to be on the label could change as a result of ongoing monitoring of the product.

2. FDA's Evaluation

We agree that the combination approach is an appropriate method of providing information to customers. We also agree that this method is feasible as long as the particular information that is placed on the label does not require frequent changes as a result of ongoing monitoring for contaminants.

Comments that advocated the combination approach requested that particular pieces of information, that may be of interest to customers at point of purchase, be placed on the label. The agency notes that, in order to fully explore the combination approach in the final feasibility report, advocates of the combination approach should provide information on which pieces of CCR-type information should go on the label and which should be available through company contact.

D. Information in a Pamphlet

None of the comments considered placement of a pamphlet containing information about bottled water at the point of purchase an appropriate method. The comments stated that retail establishments might not want to provide the necessary display space.

1. Costs Associated With the Method

Costs associated with providing information on bottled water to customers in a pamphlet depend upon the quality of the paper and printing, the size of the pamphlet, and the use of color. We estimate that it would cost a company between \$3,500 and \$16,500 per year to distribute 10,000 pamphlets.

2. FDA's Evaluation

The agency is not aware that retailers necessarily would not want to provide space for pamphlets. The agency does believe, however, that this would not be the most feasible method when other methods of conveying information are available. Information on bottled water contained in a pamphlet would be subject to the same frequent changes that may be necessary for label information due to changing test results from ongoing monitoring. In addition, there would be practical concerns regarding assuring that the pamphlets were consistently available at point of purchase. Therefore, we do not believe that pamphlets would be the most feasible method of providing information on the contents of bottled water to customers.

E. Distribution of an Information Package With Bulk Water Deliveries

The majority of the comments indicated that it would be appropriate for bulk water deliverers to include an information package with a bill or deliver it with an invoice. Comments also stated that this would be feasible since bulk water deliverers have regular contact with their customers.

1. Costs Associated With the Method

If an informal information package were prepared for delivery or inclusion with an invoice, we estimates the cost to be between \$1 and \$2 per package. If a firm makes 20 bulk deliveries per week, then the yearly cost would be \$1,000 to \$2,000.

2. FDA's Evaluation

The agency believes that it would be appropriate and feasible for bulk water deliverers to include an information package with a bill or deliver it with an invoice. An information package could be prepared in response to any changes in information about the delivered product, rather than printed in advance as labels typically are. The information also could be provided to customers by bulk deliverers only in response to customer request. This would reduce the chance for customers who are not seeking additional information on the contents of bottled water to be confused by information that may not be relevant to them or in which they have no interest.

F. Information Available on the Internet

A small number of comments indicated that the Internet was an appropriate method for conveying information to customers. However, the majority of comments stated that the internet was not appropriate as the sole source of information because some customers may not have access to it.

1. Costs Associated With the Method

The cost of creating and maintaining a web site also was considered prohibitive for small companies. Comments stated that the cost of creating a web site is approximately \$7,500.

We estimate the cost of creating and maintaining an Internet website to be between \$2,000 and \$7,500. For firms that already maintain a website, the cost of adding information on the contents of bottled water would be negligible.

2. FDA's Evaluation

Although the Internet is increasingly popular, FDA agrees that the internet may not be appropriate as the sole source of information about the contents of bottled water. According to the 1999 Economic Report of the President (Washington, DC, 1999), approximately 70 million Americans (26 percent of the U.S. population) have access to the Internet. Since many customers may not have access to the Internet, the agency believes that it may not be appropriate for the Internet to be the sole source of information on the contents of bottled water for customers. The Internet is an appropriate and feasible method of

providing information to customers; however, it may need to be used in combination with another method to ensure that all bottled water customers have access to the information.

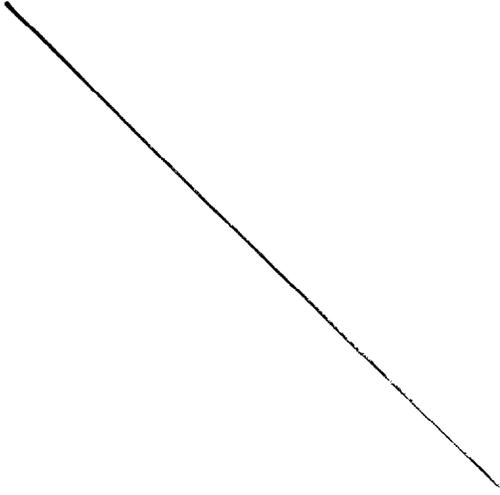
IV. Summary

We believe that much of the information contained in a CCR is applicable to bottled water. However, we recognize that certain information contained in a CCR is relevant only to public drinking water systems regulated by EPA. For example, a CCR includes the definition and statement of MCLG's, information on public drinking water systems operating under a variance, and information on EPA's drinking water hotline.

The agency has tentatively determined that certain methods are appropriate and feasible for informing customers of the contents of bottled water. We believe that providing analogous CCR information on bottled water by company contact through an address or phone number on the label is an appropriate and feasible method. We believe that the combination approach (providing some content information on the label along with a company contact) is an appropriate and feasible method of providing customers with information and, in addition, has the benefit of delivering certain pieces of information to customers at the point of purchase. The agency also believes that it would be an appropriate method and is feasible for bulk deliverers to provide an information package with a bill or an invoice.

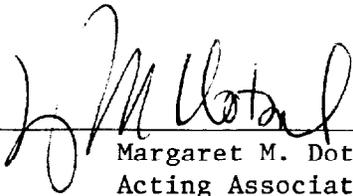
The agency has tentatively determined that certain methods are not appropriate and feasible for informing customers of the contents of bottled water. We believe that placing all of the information analogous to that contained in a CCR on the label of bottled water is not feasible. Moreover, there is a potential economic burden of frequent label changes if the particular information that is placed on the label requires frequent label changes as a result of ongoing monitoring of contaminants. We have the same concerns regarding changing test results for information provided in a pamphlet at point of purchase. We also question the practicality of ensuring that pamphlets are consistently available at retail. Further, the agency does not believe that the Internet may be appropriate as the sole method of providing information on the contents of bottled water to customers because not all customers may have access to it.

Comments received on this draft report will be evaluated and considered in preparation of the final report on the feasibility of appropriate methods, if any, for providing information about



the contents of bottled water to customers. Based on the comments received, the agency plans to discuss the possibility of further action on this subject, if any is necessary, in the final report.

Dated: 2/11/00
February 11, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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