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January 10, 1973

TO: All Members of the SPI-Food,  
Drug and Cosmetic Packaging  
Materials Committee

RE: Proposed Rulemaking for  
Bottled Water

Gentlemen:

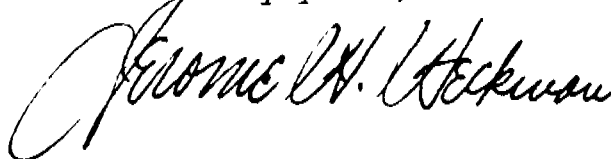
The Federal Register for Monday, January 8, 1973, contains a proposed quality standard for bottled water. Because of the obvious importance of this proposed action to our interests, we are enclosing a copy of this proposed rulemaking (38 F.R. 1019, 1020).

It is of interest to note that the first sentence in this proposal asserts the Food and Drug Administration's jurisdiction over bottled water for human consumption. Consistent with our present understanding, the regulation of water that is piped into homes is not being contemplated.

As we reviewed this proposed regulation there does not seem to us to be any need for comments on behalf of the Society. However, if any of you feel that comments should be made, please let us know before February 15 so that there will be sufficient time to prepare a suitable submission before March 9, 1973, the last day for filing comments.

We shall, of course, keep you informed about any further activity in this area. In the meantime if you have any questions or comments, please do not hesitate to contact us.

Cordially yours,



Enclosure

ASI-PR 0001699

# Proposed Rule Making

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[ 21 CFR Part 11 ]

### BOTTLED WATER

#### Proposed Quality Standards

Bottled water for human consumption is a food within the meaning of the Federal Food, Drug, and Cosmetic Act.

Bottled water is increasingly being used as a source of drinking water. Factors that have influenced this increase include consumer reaction to publicity of the potential pollution of some public water supplies, abnormal taste and odor of tap water in some areas, and increasing consumer affluence. The consumer expects bottled water to meet the minimum criteria established for public drinking water supplies.

The Food and Drug Administration has evaluated bottled water for human consumption using essentially the same criteria used in determining the acceptability of public water supplies. The criteria for evaluation of public water supplies are those of the U.S. Public Health Service Drinking Water Standards (1962), promulgated as regulations for drinking water and water supply systems used by interstate common carriers and others subject to the Federal interstate quarantine regulations. These standards set microbiological, physical, chemical, and radioactivity limits in drinking water based on health or esthetic factors. The standards are considered the minimum for public water supplies by the American Water Works Association and are the bases of State and local regulations pertaining to the control of public water supplies.

Analyses by the FDA and the Environmental Protection Agency (EPA) have shown that some bottled water fails to meet the criteria of the U.S. Public Health Service Drinking Water Standards (1962). A survey of bottled water in 1971, conducted by the FDA, revealed that 8 out of 85 samples tested contained coliform bacteria at levels in excess of the PHS Standards. In addition, the range of the geometric mean of the aerobic total plate count was 0 to 5.4 by  $10^7$  for the samples. Results of chemical tests on 85 samples revealed that none of the samples contained concentrations of heavy metals or pesticides that exceeded the PHS drinking water standards. As part of the EPA survey of the bottled water industry, bacteriological and chemical examinations were made of about 50 bottled water products from 25 bottling firms. Eight percent of the bottled water examined evidenced the presence of the

coliform organism. Standard plate counts ranged from zero to "too numerous to count". Gross changes in the standard plate counts were noted in the 25 samples that were examined during a 63-day storage test. While six samples remained at or near zero for the entire test period, four rose to levels that became too numerous to count, while the remainder fluctuated widely with no definite discernible pattern. Chemical analyses by EPA revealed that three samples exceeded the PHS Standards for total dissolved solids and that one sample exceeded the PHS Standard for copper while another sample exceeded the PHS Standard for lead.

The criteria of the U.S. Public Health Service Drinking Water Standards (1962) can be applied to bottled water with two notable exceptions: (1) The sampling plans of the PHS Standards are designed for the repetitive examination of public water supplies and are not appropriate for bottled water, and (2) the bacteriological limits set by the standards are based on repetitive examinations and also are not appropriate for bottled water.

The Environmental Protection Agency now has the responsibility for establishing drinking water standards. Extensive revisions of the drinking water standards are currently being developed by EPA. It is FDA's intention to revise the bottled water quality standards to keep them compatible with revisions of the EPA drinking water standards.

On the basis of the U.S. Public Health Service Drinking Water Standards (1962), survey data, and other available information, the Commissioner of Food and Drugs is of the opinion that reasonable grounds exist for proposing standards of quality for bottled water. Accordingly, in order to promote honesty and fair dealing in the interest of consumers the Commissioner proposes to establish quality standards for bottled water.

The Commissioner proposed in the FEDERAL REGISTER for September 23, 1972 (37 FR 20038), a new Part 11 for microbiological standards for foods for which there are no standards of identity. Although the proposal to establish quality standards for bottled water includes physical and chemical aspects as well as microbiological aspects, it is logical to include this proposal within that new part. The heading of the new part will be changed when the final order promulgating the regulations proposed in the September 23, 1972, FEDERAL REGISTER is issued, to reflect that quality standards may include provisions relating other than to microbiological aspects of a food.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 403(h), 701, 52 Stat. 1046,

1047 and 1055-1056, as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 343(h), 371) and under authority delegated to him (21 CFR 2.120) the Commissioner proposes to amend Part 11 (37 FR 20038) of Chapter I, of Title 21 of the Code of Federal Regulations by adding a new section to Subpart B as follows:

#### § 11.7 Bottled water.

(a) For purposes of this section, the following definitions shall apply:

(1) "Bottled water" is water that is sealed in bottles or other containers and intended for human consumption. Bottled water does not include mineral water or any food defined in § 31.1 of this chapter.

(2) A "sample" is 10 containers of water which are representative of the lot.

(3) An "analytical unit" is that portion of water taken from a container for purposes of analysis.

(b) *Microbiological quality.* Bottled water shall, when a sample is examined by the methods described in Part 400, of "Standard Methods for the Examination of Water and Wastewater," 13th Ed., 1971, American Public Health Association, meet standards of microbiological quality as follows:

(1) (i) *Multiple-tube fermentation method.* Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have a MPN of 9.2 or more coliform organisms per 100 milliliters, or:

(ii) *Membrane filter method.* Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed 500 per milliliter.

(2) The geometric average of the bacterial density (Standard Plate Count) of the 10 analytical units comprising the sample shall not exceed 500 per milliliter.

(c) *Physical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in Part 100 of the 13th Ed., 1971, of "Standard Methods for the Examination of Water and Wastewater," American Public Health Association, meet standards of physical quality as follows:

(1) The turbidity shall not exceed 5 units.

(2) The color shall not exceed 15 units.

(3) The odor shall not exceed threshold odor No. 3.

(d) *Chemical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in

Part 100 of the 13th Ed., 1971, of "Standard Methods of Examination of Water and Wastewater," American Public Health Association,<sup>1</sup> meet standards of chemical quality as follows:

(1) The bottled water shall not contain chemical substances in excess of the following concentrations:

| Substance              | Concentration in milligrams per liter |
|------------------------|---------------------------------------|
| Arsenic                | 0.05                                  |
| Barium                 | 1.0                                   |
| Cadmium                | 0.01                                  |
| Chloride               | 250.0                                 |
| Chromium (Hexavalent)  | 0.05                                  |
| Copper                 | 1.0                                   |
| Cyanide                | 0.2                                   |
| Iron                   | 0.3                                   |
| Lead                   | 0.05                                  |
| Manganese              | 0.05                                  |
| Nitrate                | 45.0                                  |
| Phenols                | 0.001                                 |
| Selenium               | 0.01                                  |
| Silver                 | 0.05                                  |
| Sulfate                | 250.0                                 |
| Total Dissolved Solids | 500.0                                 |
| Zinc                   | 5.0                                   |

(2) The bottled water shall not contain fluoride in excess of the levels in Table I and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water was filled.

TABLE I

| Annual average of maximum daily air temperatures: | Fluoride concentration in milligrams per liter |
|---------------------------------------------------|------------------------------------------------|
| 50.0-53.7                                         | 2.4                                            |
| 53.8-58.3                                         | 2.2                                            |
| 58.4-63.8                                         | 2.0                                            |
| 63.9-70.6                                         | 1.8                                            |
| 70.7-79.2                                         | 1.6                                            |
| 79.3-90.5                                         | 1.4                                            |

(e) *Radiological quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in Part 300 of the 13th Ed., 1971, of "Standard Methods for the Examination of Water and Wastewater," American Public Health Association,<sup>1</sup> meet standards of radiological quality as follows:

(1) The bottled water shall not contain radioactivity in excess of the following concentrations:

| Substance    | Concentration in micromicrocuries per liter |
|--------------|---------------------------------------------|
| Radium-226   | 3                                           |
| Strontium-90 | 10                                          |

(2) When it is known that the strontium-90 and alpha emitters are absent, the composite shall not contain a gross beta concentration in excess of 1,000 micromicrocuries per liter.

(f) *Label statements.* Bottled water, the quality of which is below that prescribed by this section, shall be labeled with a statement of substandard quality as follows:

(1) When the microbiological quality of bottled water is below that prescribed by paragraph (b) of this section, the

<sup>1</sup>"Standard Methods for the Examination of Water and Wastewater," 13th Ed., 1971, can be obtained from the American Public Health Association, 1015 18th Street NW., Washington, DC 20036.

label shall bear the statement of substandard quality specified in § 11.1(b).

(2) When the physical, chemical, and/or radiological quality of bottled water is below that prescribed by paragraphs (c) through (e) respectively of this section, the label shall bear the statement of substandard quality specified in § 11.1(b) except that, as appropriate, instead of or in addition to the words "Contains Excessive Bacteria" the following statement(s) shall be used:

(i) "Excessively Turbid", "Abnormal Color", and/or "Abnormal Odor" if the bottled water fails to meet the requirements of paragraph (c) (1), (2), and/or (3), respectively, of this section.

(ii) "Contains Excessive Chemical Substances", if the bottled water fails to meet any of the requirements of paragraph (d) of this section. The specific chemical(s) may be declared in lieu of the words "Chemical Substances" in the statement "Contains Excessive Chemical Substances". When a specific chemical is declared, that name by which the chemical(s) is designated in paragraph (d) of this section shall be used. Example: "Contains Excessive Copper".

(iii) "Excessively Radioactive" if the bottled water fails to meet the requirements of paragraph (e) of this section.

(g) Bottled water containing a substance at a level considered injurious to health under section 402(a) (1) of the act is deemed to be adulterated, regardless of whether or not the bottled water bears a label statement of substandard quality prescribed by paragraph (f) of this section.

Interested persons may, on or before March 9, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: December 22, 1972.

CHARLES C. EDWARDS,  
Commissioner of Food and Drugs.  
[FR Doc.73-316 Filed 1-6-73; 8:45 am]

#### National Institute of Education [ 45 CFR Ch. 14 ]

#### EDUCATIONAL RESEARCH AND DEVELOPMENT GRANTS

#### General Provisions of National Institute of Education

Pursuant to the authority contained in section 405 of the General Education Provisions Act, the Director of the National Institute of Education, with the approval of the Secretary of Health, Education, and Welfare, hereby proposes to amend Title 45 of the Code of Federal Regulations by adding a new Chapter XIV, Subchapter A, as set forth below.

In section 301(a) of the Education Amendments of 1972 (Public Law 92-318), Congress enunciated policies of the U.S. Government: (1) To provide to every person an equal opportunity to receive an education of high quality regardless of his race, color, religion, sex, national origin, or social class; (2) to provide leadership in the conduct and support of scientific inquiry into the educational process to achieve such equality of opportunity; and (3) to improve American education through its reform and renewal and through the strengthening of the scientific and technological foundations of education and the building of an effective educational research and development system (section 405(a) of the General Education Provisions Act).

To carry out these policies, Congress established, within the Education Division of the Department of Health, Education, and Welfare, the National Institute of Education, to conduct educational research, collect and disseminate the findings of educational research, train individuals in educational research; to assist and foster such research, collection, dissemination, or training through grants, contracts, technical assistance to, or jointly financed cooperative arrangements with, public or private organizations, institutions, agencies, or individuals; and to promote the coordination of such research and research support within the Federal Government. An interim statement of organization for the Institute was published at 37 FR 19158 (September 19, 1972).

This proposed subchapter establishes general rules and requirements, both substantive and procedural, for the award of assistance to eligible parties to support "educational research," which is broadly defined in the statute to include basic and applied research, planning, surveys, evaluations, investigations, experiments, developments, and demonstrations in the field of education (including career education).

Sections 1400.2 and 1400.4 of this proposed subchapter indicate that the award and administration of contracts by the Institute are not subject to this subchapter, but are instead covered by Chapters 1 and 3 of Title 41 of the Code of Federal Regulations. However, §§ 1400.2 and 1400.4 bear upon prospective contractors by providing that Department standards for the selection between contract and grant procedures and instruments (published at 41 CFR 3-1.53) shall govern such selection by the Institute, both with respect to solicitation of grant proposals or contract proposals and awards based upon unsolicited proposals. In addition, § 1400.4(e) provides that the provisions on eligible applicants in this subchapter (§ 1403.2) shall govern contracts, as well as grant awards, except that profitmaking institutions may also be eligible for contracts with the Institute. The body of this subchapter applies only to the award and administration of grants by the Institute.

The provisions of this proposed subpart would establish general rules and