Consideration of Rulemaking Petitions Regarding Water Fluoridation

Environmental Quality Board Meeting

Oct. 21, 2014
On July 11, 2014, Beverly DeCer filed two petitions for rulemaking with the Environmental Quality Board to:

1. Discontinue water fluoridation in the Commonwealth of Pennsylvania, and
2. Require the listing of fluoride concentrations on bottled water labels.
The petition requests that water fluoridation should cease immediately until such time as:

1. The FDA approves fluoride chemicals for ingestion,

2. Controlled studies prove that fluoride chemicals are harmless, and

3. Water fluoridation meets standards of informed consent.
The 2^{nd} petition requests that bottled water labels should include the fluoride concentration of the bottled water.
DEP reviewed the EQB petition processing policy and determined the petitions meet the following conditions:

- The petitions are complete as required by Section 23.1.
- The petitions request an action that can be taken by the EQB.
- The requested actions do not conflict with federal law.
On Aug. 13, 2014, the department sent a letter to Ms. DeCer notifying her that the petitions meet the completeness criteria.

DEP recommends that the EQB **not accept** the petitions for further study.
The following slides outline DEP’s basis for this recommendation.

• Discontinuation of water fluoridation is referred to as Petition #1.

• Bottled water labeling is referred to as Petition #2.
Fluoride in water can be naturally-occurring as a result of the geological composition of soils and bedrock.

Fluoride can also be added to public drinking water supplies as a public health measure for reducing cavities among the treated population.
The current state drinking water standard (MCL – maximum contaminant level) for fluoride is 2.0 mg/L.

**Note:** This is more stringent than the federal MCL for fluoride of 4.0 mg/L. There is also a non-enforceable federal secondary MCL of 2.0 mg/L for esthetic effects.
The current federal standards were set in 1986 to be protective of the following:

- A level of 2.0 mg/L is protective of tooth discoloration and/or pitting in children; and
- A level of 4.0 mg/L is protective of an increased risk of crippling skeletal fluorosis, a condition characterized by pain and tenderness of the major joints.
Neither the federal or state Safe Drinking Water Act (SDWA) mandates (or prohibits) the fluoridation of community water systems (CWS).

Currently, more than 100 CWSs in Pennsylvania fluoridate their water. This represents 6 percent of all CWSs in Pennsylvania, and 5 million Pennsylvanians.
DEP is neutral regarding water fluoridation.

DEP’s role:

• Review proposals for the addition (or removal) of fluoridation treatment through the permitting process; and

• Ensure compliance with the federal and state SDWAs and regulations.
DEP supports local decision making on the issue of water fluoridation.

An application submitted to the department for the addition (or removal) of water fluoridation must include evidence that the public has been involved in the decision-making process.
Once a permit application has been received and deemed complete, DEP will provide notice of the submission in the *Pennsylvania Bulletin* and requests public comments. This process provides an additional opportunity for the public to provide input on a permit application.
The permitting process includes safe-guards, such as:

- All chemicals and materials must meet ANSI/NSF Standard 60 & 61
- Permit conditions are set to ensure:
  - Fluoride concentrations meet more stringent state standards
  - On-going efficacy is tracked through performance and compliance monitoring
As per the SDWA and Chapter 109 regulations, water fluoridation chemicals must be acceptable to DEP.

Chemicals which are certified for conformance with ANSI/NSF Standards 60 or meet the food grade standards of the *U.S. Pharmacopeia* are deemed acceptable.
Additional safe-guards are in place in the form of routine monitoring, surveillance (e.g., DEP inspections), compliance and enforcement activities.

Information about fluoride concentrations is also provided to consumers in an Annual Water Quality Report, and in public notices, as needed.
DEP recommends that the petition not be accepted for further study because the public safety and health objectives outlined in the petition are being met and water fluoridation is a matter of local choice.
Bottled water within Pennsylvania must meet the requirements of the department under the SDWA, and of the Food and Drug Administration as a beverage.

Existing DEP labeling requirements require that artificially-fluoridated water must include the words “fluoridated water.”
DEP recommends that the petition not be accepted for further study because:

• Fluoridated bottled water must meet SDWA standards and be labeled as “fluoridated water”.

• The addition of the fluoride concentration on the label is not necessary, and it would add to the cost/complexity of labeling.
Kelly Heffner, Deputy Secretary
Office of Water Management

David Mittner, Division Chief
Bureau of Safe Drinking Water

Bill Cumings, Assistant Counsel
Bureau of Regulatory Counsel