

3177

Kathy Cooper

From: James Land <jamesjlandjr@comcast.net>
Sent: Monday, September 25, 2017 2:14 PM
To: IIRC
Cc: ecomment@pa.gov
Subject: REGULATION #7-521 (IIRC # 3177) PROPOSED CHANGES TO 25 PA CODE 109 SAFE DRINKING WATER GENERAL UPDATE AND FEES
Attachments: September 25 IIRC.docx

To whom it may concern:

Please accept the attached comments to the proposed changes to 25 PA Code 109.

To Summarize:

1. The Food Safety Act provides that the Secretary of the Department of Agriculture has the sole and exclusive authority to promulgate regulations regarding Food safety.
2. Bottled Water is a food defined under the statute and regulations promulgated under the statute,
3. The Food Safety Act legislates the fee structure for bottled water producers
4. The Dep has failed to consider the Food Safety Provisions in their Preamble or anywhere else in their submitted documents
5. The DEP is promulgating rules and regulations outside their statutory authority.

Respectfully

James J Land Jr
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Tower Springs Inc

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September 25, 2017

Pennsylvania Independent Regulatory Review Commission
333 Market St.
14th Floor
Harrisburg, PA 17101

RE: REGULATION #7-521 (IRRC # 3177)
PROPOSED CHANGES TO 25 PA CODE 109
SAFE DRINKING WATER GENERAL UPDATE AND FEES

To Whom It May Concerns:

We thank the Environmental Quality Board and the Regulatory Review Commission for the opportunity to comment on the proposed changes to 25 PA Code 109, and thank them in advance for their consideration. Please note that our comments are directed solely to the application of changes to the bottled water industry, and the sources related thereto, as we are unqualified to comment on Public Water Supply impacts and concerns.

We support The Water Supply Division's Mission to assure and support delivery of the highest quality drinking water to Commonwealth's Citizens. And applaud the successes over the last 30 years.

We share the Department's concern that many stakeholders are asked to achieve more with less in today's new order. We encourage the DEP to look deeper for internal savings, ways to efficiently measure exceptions rather than reporting the norm, reduce staff time spent clarifying confusing and conflicting policies that exist between different regions, reduce staff time focused on issues unrelated to drinking water quality and quantity, and to seek funding from the Legislature to fund the portions of the program our elected officials deem appropriate while jettisoning internal legacy initiatives that are not legislatively mandated or supported by the Commonwealth. Most

importantly, we would encourage the DEP to look outside itself and adopt best practices utilized in other comparative agencies.¹

However, we question the sufficiency of the DEP's statutory citations for the authority to impose the proposed changes upon the bottled water industry and their related water sources. Particularly, whereas here the DEP ignores the statutory changes to the regulation of bottled water introduced in the Commonwealth by the Food Safety Act, (Title 3 Pa.C.S.A., Part VII, Ch. 57, Subch. B).

Furthermore, The Department's reliance on Primary Enforcement Authority (Primacy), and more troubling The Environmental Protection Agency's evaluation of the proposed changes effecting the bottled water industry, is argumentative and unconvincing. By Federal Statute the EPA's authority in the field of bottled water is specifically limited to the development of Maximum Contaminant Levels and Treatment Techniques, any of which may be rejected by the Federal Food and Drug Administration as inapplicable to bottled water. (Safe Drinking Water Act Amendments of 1996. P.L. 104-182, see also Federal Food, Drug, and Cosmetic Act § 410, 21 U.S.C. § 349 (2005).) As such Primacy and the EPA's related input are not relevant in the discussion of bottled water regulation in the Commonwealth.

Please allow us to elaborate.

The FDA has developed a comprehensive and stringent regulatory framework for bottled water producers under their general statutory authority covering all food and beverage. Bottled Water is a packaged food product specifically recognized by the Federal Food and Drug Administration which defines it as "water that is intended for human consumption and that is sealed in bottles or other containers". 21 U.S.C. § 321(f). Furthermore, water when used as an ingredient in food and or drink is also a food. 21 U.S.C. § 201 (f). Further, FDA has promulgated product specific regulations for bottled water including Standards of Identity, Standards of Quality and specific Good Manufacturing Practices directed at bottled water.

As discussed earlier the Federal Government in 1996, limited EPA's statutory authority over bottled water to the promulgation of MCLs or treatment techniques for drinking water generally. This authority is limited however by the FDA's statutory power to set a different standard for bottled water or to reject outright an MCL or treatment technique proposed by the EPA.

¹ By way of example, and directly related to the bottled water industry, a quick cursory review of competitive state application forms for a bottled water facility range from one page to five pages. Interestingly, enough the Pennsylvania Department of Agriculture License Application is 5 pages including instructions for all food and beverage manufacturers including bottled water plants. The same application filed with the DEP includes over 100 pages of forms. Effectively, a DEP permitting specialist spends at a minimum 20 times more money reviewing forms than a Department of Agriculture Inspector and 100 times more than their counterpart in New York.

In 2010, The Commonwealth of Pennsylvania enacted the Pennsylvania Food Safety Act, which codified the above principles to standardize the regulation of food, including bottled water; produced in Pennsylvania with the competing 49 States. Among other things the Act provided the following pertinent to this discussion:

1. The Act adopted all regulations promulgated under the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.) related to bottled water as regulations of the Commonwealth of Pennsylvania
2. The Act provided that the Secretary of the Department of Agriculture would have sole jurisdiction over all food manufacturers, including bottled water producers in Pennsylvania (Title 3 Pa.C.S.A., Part VII, Ch. 57, Subch. B).
3. Statutorily sets the annual Fee for bottled water plants at \$35 dollars per annum (Title 3 Pa.C.S.A., Part VII, Ch. 57, Subch. B §5734(c))
4. The Act prohibited the secretary from ordaining or enforcing requirements relating to sanitation, food safety, food standards and labeling requirements of any kind or description other than those provided for in the Federal acts unless the proposed regulation meets all the following:
 - (1) is justified by compelling and unique local conditions;
 - (2) protects an important public interest that would otherwise be unprotected;
 - (3) relates to subject matter that is primarily local in nature and the Federal agency with responsibility over the subject matter is not exercising its jurisdiction with respect to the subject matter;
 - (4) would not cause a food to be in violation of any applicable requirements under the Federal acts; and
 - (5) would not unduly burden interstate commerce. (Id. §5736 (a))
5. Finally, the Act defined quality standards for ingredient water used in bottled water. Id. §5733 (g). Specifically, ingredient water must meet MCL's, treatment techniques and Maximum Residual Disinfection Limits promulgated in 25 PA Code 109.9. (Hereinafter "Quality Rules").

The DEP in proposing the new regulations relies solely on language found in the Pennsylvania Safe Drinking Water Act of 1984 that includes in the definition of Public Water System "a system which provides water for bottling or bulk hauling for human consumption" 35 P.S. § 721.3. Although the DEP has long interpreted this language to include portions of the bottled water industry, the Legislature under the 2010 Food Safety Act significantly limits the DEP's authority to the setting of Quality Rules.

It appears on its face that the DEP's position that 35 P.S. § 721.4 provided the statutory authority ignores the clear and concise language that the Secretary of the Department of Agriculture shall have exclusive authority to promulgate regulations effecting the bottled water industry, and even than upon the finding that the rule met the criteria in 4 above. Since none of the proposed regulations are defined by the DEP as Quality Rules, these rules, although perhaps meritorious,

are inappropriate under the current state of legislation in the Commonwealth; unless adopted by the Department of Agriculture as part of their regulatory initiative.

In past rulemaking, the DEP has relied on certain language in the FDA rules (effectively adopted under The Food Safety Act) that permits states to set rules for water sources used in the production of bottled water. One should reasonably assume the DEP will cite this exception in response to these comments.

Although we agree that the Commonwealth has the broad constitutional authority to protect the water resources of the Commonwealth, we disagree that the Safe Drinking Water Act and the staff responsible for its administration are the appropriate vehicle to do so. Safe Drinking Water Staff are limited in their authority to set regulations for Public Water Systems as defined under the Act.²

As such water sources used as a food or beverage ingredient does not by its definition meet the statutory or regulatory requirements of 15 connections or 25 individuals served.

We believe that the DEP has developed many terrific source protection tools that provide wise guidance beyond the public water system segment, and we strongly support the concept of adoption of many of these tools by food producers as part of sight specific HAACP development required under the Food Safety Act.

In conclusion, we would humbly request the Department reconsider the proposed rules impacting the bottled water industry or in the least reconcile the proposal with The Food Safety Provisions presented above.

Respectfully,

JLLJ

James J. Land Jr

Member

² 25 Pa. Code Chapter 109 require that a permit be obtained from DEP for the construction and operation of a public water system, which is defined as "[a] system which provides water to the public for human consumption which has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year." MC Resource Development v DEP, EHB Docket No. 2015-023-C, DEPARTMENT'S RESPONSE TO M.C. RESOURCES' MOTION FOR SUMMARY JUDGMENT