Kiselica

COMMONWEALTH OF PUERTO RICO
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY

February 29, 2000

Mr. Bruce Kiselica, Chief
Public Water Supply Section
US EPA REGION II
290 Broadway
New York, New York 10007-1866

Att: Mr. Mike Lowy

Re : Adoption by Reference

Dear mister Kiselica:

By February 4, 2000, the Department of Health, submitted to the Puerto Rico Department of State, the General Regulation of Environmental Health. This regulation abolished the Regulation #50, "To Protect the Purity of Drinking Water of Puerto Rico" and their amendments. The number of regulation is 6090, according to the Department of State, and will be effective 30 days after the submission (March 6, 2000).

The Drinking Water Regulation Amendments will be adopted by reference according to the Code of Federal Regulation Tittle 40, Parts 141, 142 and 143.

The above is submitted for your information and corresponding action.

Any questions, please feel free to contact me at (787) 754-6370, 6650.

Cordially,

Olga I Rivera
Director
Public Water Supply Supervision Program

Cf:
Jorge Martínez , US EPA CEPD
Mr. Douglas Mckenna - US EPA REGION II

U.S. EPA, REGION II
2000 MAR 17 PM 2:08
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DEPARTAMENTO DE SALUD
GOBIERNO DE PUERTO RICO

PUBLIC WATER SUPPLY SUPERVISION PROGRAM

FAX COVER

Date : July 11, 2000

Num. of Pages : 4

To : Mike Lowy

Location : EPA R2

From : Oneida Santiago

Subject : General Rule of Environmental Health #6090

Message :

Pages 24, 25 & 26
Article II - Drinking water
Section 1.01 - Primary Standards
1.02 - Implementation
1.03 - Secondary Standards
1.04 - DWSRF
1.05 - V&E
1.06 - Additional Requirements

Phone No. (787) 754-6350 - 754-6370

Fax No. (787) 754-6010

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Núm. 6090
Fecha: FEB - 4 2000
Aprobado: Angel Morey
Por: Secretario Auxiliar de Servicios

GOBIERNO DE PUERTO RICO
DEPARTAMENTO DE SALUD
SAN JUAN, PUERTO RICO

REGLAMENTO GENERAL

DE

SALUD AMBIENTAL

VIGENCIA

AGUA POTABLE 787 754 6144 07/11 '00 15:52 NO.566 02/05

conclusiones en un informe que constituirá parte de la prueba del Departamento en la vista administrativa. En ese caso, los datos analíticos quedarán reservados para ser sometidos a las vistas administrativas o al tribunal en juicio abierto, excepto en caso del mandamiento judicial en otro sentido.

13. Si un alimento contiene una substancia preservativa aplicada exteriormente para su conservación, que en nada afecte la naturaleza de dicho alimento, deberá estar rotulado con instrucciones claras y explícitas para su remoción.

Sección 5.00 CUALIDADES NUTRICIONALES DE LOS ALIMENTOS

Se aplicarán como norma, los requisitos y las guías sobre cualidades nutricionales de los alimentos para consumo humano del Título 21, Parte 104, del "CFR", según sea enmendado.

Sección 6.00 BUENAS PRACTICAS DE MANUFACTURA, EMPAQUE Y ALMACENAJE DE ALIMENTOS PARA CONSUMO HUMANO

A todo establecimiento público, según definido en este Reglamento, donde se manufacturen, empaquen o se almacenen alimentos para consumo humano, se aplicarán las disposiciones incluidas en Título 21 Parte 110 del CFR, según sea enmendado.

ARTICULO II. AGUA POTABLE.

Sección 1.00 SISTEMAS PUBLICOS DE AGUA POTABLE

1.01 Requisitos sobre Estándares Primarios.

1. Todos los sistemas de agua potable existentes y todos aquellos que se establecerán a partir de la fecha de aprobación de este Reglamento, deberán cumplir con los requisitos sobre contaminantes primarios.

2. Los estándares primarios de agua potable en Puerto Rico estarán regulados conforme a lo dispuesto en el Título 40 Parte 141 del Código de Regulaciones Federales, según sea enmendado.

1.02 Implantación de la Reglamentación para Estándares Primarios.

1. La implantación de los estándares sobre Contaminantes Primarios en Agua Potable en Puerto Rico estará sujetos a lo dispuesto en el Título 40 Parte 142 del "CFR", según sea enmendado.

1.03 Requisitos sobre Estándares Secundarios.

1. Los contaminantes secundarios de agua potable estarán regulados conforme a lo establecido en el Título 40 Parte 143 del "CFR", según sea enmendado.

1.04 Fondo Rotatorio.

1. Previo al inicio de sus operaciones, el Secretario queda facultado para requerirle a los sistemas de agua potable, ya existentes o nuevos que comiencen a operar a partir del 1ro. de octubre de 1999, ya sean éstos comunales o no comunales no transitorios, el cumplir con las secciones 1419 y 1420 de la Ley Federal de Agua Potable Segura, según enmendada; así como con las disposiciones del Título 40 del Código de Regulaciones Federales aplicables a la primacía del Programa de Agua Potable del Departamento; y con las regulaciones federales del Programa de Fondo Rotatorio y sus Sub-programas. El Secretario también tendrá facultad para ordenar la paralización de la operación de sistemas de agua potable que no cumplan con estos requisitos.

2. Los sistemas de agua a ser construidos con fondos bajo el programa de Fondo Rotatorio deberán cumplir con lo establecido en la sección 1452, 1419 y 1420 de la Ley Federal de Agua Potable Segura (Safe Drinking Water Act), según sea enmendada; también deberá cumplir con las guías federales o disposiciones del Código de Regulaciones Federales, que sean aplicables; así como con los procedimientos establecidos por el Departamento bajo dicho programa.

1.05 Variaciones y Exenciones.

1. El Departamento podrá otorgar variaciones y exenciones de determinadas provisiones a tenor con el Título 40, Parte 141.4 del "CFR" y conforme a las disposiciones de la Ley Federal de Agua Potable Segura (Safe Drinking Water Act), del 16 de diciembre de 1974, según sea enmendada.

1.06 Requisitos adicionales.

1. Lo dispuesto en la Sección 1 de este Artículo no deberá, de ninguna manera, interpretarse como una limitación a la facultad del Secretario para establecer requisitos adicionales y/o estándares más estrictos a lo dispuesto en la Ley Federal de Agua Potable de 1974, según sea enmendada, y en el Código

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de Regulaciones Federales, según sea enmendado, con el fin de proteger la salud pública.

Sección 2.00 AGUA EMBOTELLADA

2.01 Requisitos de Procesamiento y Embotellado.

1. Toda planta embotelladora de agua para consumo humano en Puerto Rico deberá cumplir con los requisitos de procesamiento y embotellado de agua dispuestos en el Título 21, Parte 129, del Código de Regulaciones Federales, según sea enmendado.

2.02 Requisitos Específicos para Agua Embotellada.

1. El agua embotellada en Puerto Rico y toda agua embotellada importada deberá cumplir con los estándares de calidad y requisitos específicos para agua embotellada establecidos en Título 21 Parte 165.110 del "CFR", según sea enmendado.

2.03 Rotulación de Envases de Agua y Productos de Agua Embotellada.

1. Toda agua embotellada que se envase en Puerto Rico y toda aquella que se importe de plantas localizadas fuera de Puerto Rico deberá cumplir con lo dispuesto en Título 21 Parte 101, del "CFR", según sea enmendado.

2.04 Buenas Prácticas de Manufactura.

1. Las disposiciones sobre buenas prácticas de manufactura contenidas en el Título 21 Parte 110, del "CFR" aplicarán a las plantas embotelladoras de agua en Puerto Rico.

2.05 Plantas Embotelladoras fuera de Puerto Rico.

1. El agua de todas las plantas de agua embotellada localizadas fuera de Puerto Rico, que se venda, exponga, distribuya, transporte, se ofrezca en venta o donación en Pueto Rico, deberá cumplir con los estándares de calidad establecidos en este Reglamento.

2.06 Control de Calidad

1. Será responsabilidad del operador velar por que se tomen muestras representativas deL agua embotellada por la planta y se analicen en un laboratorio certificado, con la frecuencia establecida y para los parámetros especificados en el título 21, Parte 129, Sección 129.80, sub-parte E, del "CFR".

PUERTO RICO DEPARTMENT OF HEALTH

DEPARTAMENTO DE SALUD
GOBIERNO DE PUERTO RICO

PUBLIC WATER SUPPLY SUPERVISION PROGRAM

FAX COVER

Date : Julio 7, 2000

Num. of Pages : 4

To : Mike Lowy

Location : EPA R2

From : Olga Rivera

Subject : Primacy Revision Application

Message : **Lowy:** We are working on the State Primacy Revision Application for the first six (6) rules, according to your fax dated 5/10/00. There are some doubts on its:

(1) We are working on the special requirements on the IESWTR, D/DBP's and CCR. Are special primacy requirements for the other rules?

(2) Analytical Methods for Radionuclides, PWS definition and Variances/Exemptions, can be covered by the adoption by reference, recently adopted by PR?

(3) For all these rules, only <u>one</u> Attorney general Statement will be enough?

(4) Regarding Penalties (Administrative Penalty Authority) is necessary to amend our current law in order to increase the amount of penalty. We expect to request an extension for this requirement. (See letters sent to Doug regarding this issue).

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GOVERNMENT OF PUERTO RICO
DEPARTMENT OF HEALTH

September 10, 1997

Mr. Doughlas G. Mckenna, Leader
Public Water Supply Enforcement Team
U.S. E.P.A. REGION II
290 Broadway
New York, N.Y. 10007-1866

Dear mister Mckenna :

This letter is in regard to the requirement for State administrative penalty authority under the Safe Drinking Water Act (SDWA) Amendments of 1996.

The Section 9 of the Act. No. 5 of July 21, 1977 known as the "**Act to Protect the Purity of Drinking Water of Puerto Rico**" reads as follows:

> **Section 9 - Penalties** - Any person who willfully violates the provisions of Section 7 of this Act, who violates the Regulations promulgated by the Secretary, or who willfullly violates or refuses to comply with an order issued by the Secretary, shall be subject to a civil penalty not greater that five thousand dollars ($5,000.00) for each day of such violation or failure to comply with Regulations.
>
> The Secretary may file a petition for a restraining order or injunction to prevent the violation of any order or Regulations issued under this Act. Copy of the Act is enclosed.

After review the new provisions of the SDWA amendments of 1996 in section 1413(a)(6) we understand that the Section 9 of the Act. No. 5 up to certain extent considers or covers this provison. Nevertheless, we have determined that Act. No. 5 must be amended to meet additional new requirements.

We base our determination on the following :

- The actual penalty requirement establishes a maximum quantity no matter the type of violation and the size of the population served by the public water system. It was established at $5,000.00. The establishment of penalty cap is under evaluation.

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Safe Drinking Water Act (SDWA)

September 10, 1997

- There is no minimum penalty established. The actual penalty has the authority to assess for less than $1,000.00 dollars, then the act must be amended.

- The wording "per day per violation" is not expressed in those terms.

- Provides the flexibility to the State in dealing with the smaller systems. As you know, this is very critical for the Non-PRASA systems that have difficulty in complying with the Drinking Water Regulation.

In order for the Department of Health to continue with the primary responsibility of watching for the purity of the drinking water and the health of the people of Puerto Rico and thus retaining its primacy we will initiate the process of amending the Section 9 of the Act. No.5 in accordance with Section 1413(a)(6) of the SDWA.

As soon as we have available a draft copy of the proposed amendment with the statement of motives and the State Attorney General Opinion, we will send it for your review and comments.

Should you have any questions on this regard, please do not hesitate to contact me.

Cordially,

Mrs. Olga I. Rivera, MEH
Acting Director
Public Water Supply Supervision Program

cf: Mr. Hernán Horta Cruz, MSS -DOH
Eng. Víctor Trinidad, USEPA DECA

GOVERNMENT OF PUERTO RICO
DEPARTMENT OF HEALTH

December 24, 1997

Mr. Doughlas McKenna, Leader
Public Water Supply Enforcement Team
US EPA Region II
290 Broadway
New York, NY 10007-1866

Dear mister McKenna:

Regarding your request about an assessment of our authority to issue Administrative Orders, assess and collect administrative penalties against water systems that violate drinking water regulations, I will like to inform you, the following: Our current law establishes that any person who willfully violates the provisions of Section 7 of this Act , violates the Regulations promulgated by the Secretary of Health. Likewise, any person who willfully violates or refuses to comply with an order issued by the Secretary, shall be subject to a penalty not greater than five thousand dollars ($5,000.00) for each day of such violation or failure to comply with the Regulation (Act No.5 of July 5,1977, Section 9) .

In addition, the Department of Health (DOH) adopted regulations to establish the norms for regulating the adjudgement procedures according to Act No. 170 of August 12, 1988, known as *Uniform Administrative Procedure Act.*

All public water supply owners who violate, among other, the drinking water regulation and/or any other procedure or agreement, including Administrative Orders, Bilateral Agreement, Action Plans will be subject to DOH's enforcement actions, as established in Act No.170.

If you have any comments or need further information, do not hesitate to contact me at (787) 754-6010/6370.

Cordially,

OIRivera /bv

Olga I. Rivera
Acting Director
Public Water Supply Supervision Program

P.O. Box 70184 • San Juan, Puerto Rico 00936 • 787-274-7602 • Fax: -250-6547

AGUA POTABLE 787 754 6144 07/07 '00 15:40 NO.505 04/04

Kiselica

COMMONWEALTH OF PUERTO RICO
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY

May 5, 2000

Mr. Mike Lowy
Division of Environmental
Planning and Protection
Water Programs Branch
Drinking Water Section
290 Broadway
New York, New York 10007

Re: General Regulation of Environmental Health – Adoption by Reference

Dear Mr. Lowy:

Regarding your request on when exactly the adoption by reference will be effective, I am sending you the following documents:

1. Newspapers notice (November 23, 1999) on the Department of Health proposal to adopt a General Regulation of Environmental Health. This notice contains a list of all regulations that DOH intended to repeal, among which the Regulation # 50.

2. Copy of the General Regulation of Environmental Health as PR Department of State approved on February 4, 2000. The regulation is in effective since March 06, 2000 (30 days after Department of State approval).

3. Copy of February 29, 2000 letter, addressed Mr. Bruce Kiselica on this matter.

My interpretation about your concern is that the current drinking water federal requirements are covered with the General Regulation of Environmental Health. Any future regulation will be adopted by reference with the federal regulation. The General Regulation provides to be stricter than the federal regulation or add any requirement.

I am working in the other requirements that you point out in the fax.

Any questions please feel free to contact me at (787) 754-6370/6650.

Cordially,

ORivera

Olga I. Rivera

C: Bruce Kiselica – EPA Region II, Jorge Martínez EPA-CEPD

U.S. EPA, REGION II
2000 MAY 12 AM 11:05
WATER PROGRAMS BRANCH

CALL BOX 70184 SAN JUAN, PUERTO RICO 00936

From: MICHAEL LOWY
To: Olga Rivera
Date: 4/6/00 10:19am
Subject: Adopt By Reference Legislation, LT1/FBR proposal

Olga:

(I'll also FAX this to you as I have no idea if the email is working)

Could you forward to me a copy of the legislation that was passed regarding the adoption by reference change that did away with PRDOH Regulation #50 (I think that's the right number for PRDOH DW regulations).

We need to determine exactly when the "adoption by reference" kicks in, i.e., is it retroactive.

Also, on the Primacy Rule (primacy submittal pkg due April 28th, 2000), there are around 3 items within that rule of importance to States:

Administrative Penalty
Emergency Language
PWSS Definition

According to our latest status, (the tracking of PR's progress in adopting the various new rules), it is indicated that PRDOH will submit a final pkg on these items (collectively - the "primacy rule") by September 2000. Final submittal of a primacy pkg includes the AG Statement. Is this still the schedule you see? We may need an extension agreement request from PRDOH since the primacy rule 2 year period for final pkg submittal is up at the end of this month.

It is possible that your Admin Penalty language, from the original granting of primacy would cover what EPA is requiring under the new regs. Can you forward a copy of the pertinent section of the original granting of primacy so we can check that out? I realize this may be diffficult to obtain. Let me know.

On LT1, as you know, the proposal has come out (I believe the actual federal register for it is not yet published, but a "pre-publication" version is on the web).

R2 is arguing for the proposed one time warmest weather applicability monitoring event to be moved back to 2003, and have the profiling, if needed, based on TTHM/HAA5 results, begin 4th quarter 2004. Do you support this? Essentially what this does is to move requirements on these small systems (the LT1 PWSs, i.e., those less than 10K) to sample from before the rule is required to be adopted (November 2002) to after adoption (and final primacy pkg submittal is due - 11/03).

The other issue is of combined filter effluent (cfe) versus individual filter effluent (ife) requirements for LT1 systems. R2 believes that for any system with up to 2 filters, they should only be required to take cfe sampling. We are also examining the idea of allowing small systems with up to 3 filters to take the same. Do you know if 3 is a rare number in PR? Do you support our intention to require only those with 2 (or 3) filters to just take cfe?

2/3

Michael Lowy
07/10/00 12:16 PM

To: orivera@salud.gov.pr

cc: Douglas McKenna/R2/USEPA/US@EPA, Robert Poon/R2/USEPA/US@EPA, Matthew Garamone/R2/USEPA/US@EPA, Bruce Kiselica/R2/USEPA/US@EPA, Gerard McKenna/R2/USEPA/US@EPA

Subject: Primacy Applications

Olga:

I'll also FAX this to you as I don't know if this email works for you.

In response to your questions, I relist them and provide answers.

Q: You ask if there are "special primacy requirements" for rules other than the IESWTR/Stage 1 and the CCR.

A: No.

Q: You ask if **Analytical Methods for Radionuclides**, **PWS Definition**, and **V&E** can be covered by the "adopt by reference".

A: Overall, we need an English version of the new PRDOH regulation pertaining to the "adopt by reference" so our legal people can determine if in fact the above items are covered by the new law. I'm sure that it is, but we need to have that ground covered. If you can send that to me as soon as possible, that would be helpful in determining such.

- for Radiological Analytical Methods, I don't know exactly how PRDOH deals with new methods, you may put it in your regs (which I guess is what is happening with "adopt by reference") or you may address it some other way. Assuming the "adopt by reference" is OK with the lawyers, the primacy package for this rule (whether bundled with other rules or not) would just need to indicate that the new methods are in the regs since they are adopted by reference, and some indication to EPA in the primacy package as to how PRDOH ensures that these new methods are among those that are now approved for radionuclide analysis.

- for the PWS Definition, since it is adopt by reference, it should be OK.

- for V and Es, I'm still trying to sort this out, but it is my understanding that PRDOH does not give variances or exemptions. If that is the case, than this may not be required to be adopted (although again, you already have "adopted by reference"), as it is less stringent than what you already have on the books (i.e., the initial V and E rule). I'll get back to you on this. You can also let me know if indeed, PRDOH does not grant V and Es.

Q: You ask if one AG statement can cover all these rules.

A: Depending on how you chooes to bundle which rules and submit them, one AG statement per bundle. For example, if you submit the primacy packages for MDBP and the CCR together with an indication that you have changed the PWS Definition, one AG Statement can cover these 3 items with indication on the statement that it does so.

Q: You indicate that you are in the process of requesting an extension for amending the Admin Penalty Auth.

Comment: According to you r attached leter to Doug (9/10/97), you indicate that PRDOH must amend the Admin Penalty portion. I believe the thinking here is that PRDOH's Admin Penalty requirements do meet the requirement of 1000 per day per violation. I'll have t o get back to you on this.