

The EPA Administrator, Gina McCarthy signed the following action on December 22, 2015, and EPA is submitting it for publication in the Federal Register (FR). While we have taken steps to ensure the accuracy of this Internet version of the action, it is not the official version of the final notice. Please refer to the official version in a forthcoming FR publication, which will appear on the Government Printing Office's FDsys website (<http://fdsys.gpo.gov/fdsys/search/home.action>) and on Regulations.gov (<http://www.regulations.gov>) in Docket No. EPA-HQ-OW-2012-0155. Once the official version of this document is published in the FR, this version will be removed from the Internet and replaced with a link to the official version.

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2012-0155; FRL-XXXX-X]

**Announcement of Final Regulatory Determinations for Contaminants on the Third
Drinking Water Contaminant Candidate List**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing final regulatory determinations not to issue national primary drinking water regulations for four of the 116 contaminants listed on the Third Contaminant Candidate List. The Safe Drinking Water Act, as amended in 1996, requires the EPA to make regulatory determinations every five years on at least five unregulated contaminants. A regulatory determination is a decision about whether or not to begin the process to propose and promulgate a national primary drinking water regulation for an unregulated contaminant. On October 20, 2014, the agency published its preliminary determinations not to regulate dimethoate, 1,3-dinitrobenzene, terbufos, terbufos sulfone and begin the process to regulate strontium. The agency requested public comment on the determinations, process, rationale and supporting technical information. The agency received comments from 14 individuals or organizations on the preliminary regulatory determinations. After careful review and consideration of the public comments, the agency is making a final determination not to regulate dimethoate, 1,3-dinitrobenzene, terbufos and terbufos sulfone. The agency, however, is delaying the final regulatory determination on strontium in order to consider

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additional data and decide whether there is a meaningful opportunity for health risk reduction by regulating strontium in drinking water.

DATES: In accordance with 40 CFR 23.7 for purposes of judicial review, the regulatory determinations in this notice are issued as of **[INSERT PUBLICATION DATE OF FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT: Zeno Bain, Standards and Risk Management Division, Office of Ground Water and Drinking Water, Office of Water (Mailcode 4607M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 564-5970; e-mail address: bain.zeno@epa.gov. For general information, contact the Safe Drinking Water Hotline, telephone number: (800) 426-4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 10 a.m. to 4 p.m., eastern time.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

These final regulatory determinations will not impose any requirements on anyone. Instead, this action notifies interested parties of the EPA's final regulatory determinations for four contaminants and provides a summary of the major comments received on the October 20, 2014, preliminary determinations (USEPA, 2014c).

B. How Can I Get Copies of This Document and Other Related Information?

Docket: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2012-0155. Publicly available docket materials are available either electronically at

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<http://www.regulations.gov> or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Water Docket Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

Electronic Access: You may access this *Federal Register* document electronically from the Government Printing Office under the “Federal Register” listings at <http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>.

ABBREVIATIONS USED IN THIS DOCUMENT

| | |
|--------|---|
| CCL | Contaminant Candidate List |
| CCL 3 | Third Contaminant Candidate List |
| CFR | Code of Federal Regulations |
| EPA | Environmental Protection Agency |
| FR | Federal Register |
| HRL | Health Reference Level |
| MCL | Maximum Contaminant Level |
| MCLG | Maximum Contaminant Level Goal |
| MRL | Minimum Reporting Limit |
| NPDWR | National Primary Drinking Water Regulation |
| PWS | Public Water System |
| RD | Regulatory Determination |
| RD 3 | Third Regulatory Determination |
| RSC | Relative Source Contribution |
| SDWA | Safe Drinking Water Act |
| STORET | Storage and Retrieval Data System |
| UCMR | Unregulated Contaminant Monitoring Regulation |

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| UCMR 1 | First Unregulated Contaminant Monitoring Regulation |
| UCMR 2 | Second Unregulated Contaminant Monitoring Regulation |
| UCMR 3 | Third Unregulated Contaminant Monitoring Regulation |
| USDA | United States Department of Agriculture |
| USGS | United States Geological Survey |
| µg/L | micrograms per Liter |

TABLE OF CONTENTS

- I. General Information
 - A. Does this Action Apply to Me?
 - B. How Can I Get Copies of This Document and Other Related Information?
- II. Purpose and Background
 - A. What is the Purpose of This Action?
 - B. What are the Statutory Requirements for the Contaminant Candidate List (CCL) and Regulatory Determinations?
 - C. What Contaminants did the EPA Consider for Regulations
- III. What Process did the EPA Use to Make the Regulatory Determinations?
- IV. Summary of the EPA's Findings on the Four Contaminants with Final Regulatory Determinations
 - A. Dimethoate
 - 1. Description
 - 2. Agency findings
 - B. 1,3-Dinitrobenzene
 - 1. Description
 - 2. Agency findings

C. Terbufos and Terbufos Sulfone

1. Description
2. Agency findings

D. Public Comments on Four Contaminants with Final Regulatory Determinations

V. Summary of Public Comments on Strontium and the Agency's Responses

- A. Background on Strontium and the EPA's Preliminary Determination
- B. What Comments Did the EPA Receive on Strontium?

VI. Next Steps

VII. References

II. Purpose and Background

A. What is the Purpose of This Action?

The purpose of this action is to present a summary of the EPA's findings related to the final regulatory determinations for four contaminants listed on the Third Contaminant Candidate List (CCL 3) (USEPA, 2009). The four contaminants include: dimethoate, 1,3-dinitrobenzene, terbufos and terbufos sulfone. Today's action briefly summarizes the statutory requirements for targeting drinking water contaminants for regulatory determination, provides an overview of the contaminants the agency considered for regulation and describes the approach used to make the final regulatory determinations. In addition, today's action summarizes the public comments received on the agency's preliminary determinations and the agency's responses to those comments, including the status of the EPA's evaluation of strontium.

B. What are the Statutory Requirements for the Contaminant Candidate List (CCL) and Regulatory Determinations?

The specific statutory requirements for the CCL and regulatory determinations can be found in the Safe Drinking Water Act (SDWA), section 1412(b)(1). The 1996 SDWA Amendments require the EPA to publish the CCL every five years. The CCL is a list of contaminants that are not subject to any proposed or promulgated national primary drinking water regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs) and may require regulation under SDWA. The 1996 SDWA Amendments also direct the agency to determine whether to regulate at least five contaminants from the CCL every five years. SDWA requires the agency to publish a Maximum Contaminant Level Goal (MCLG)¹ and promulgate an NPDWR² for a contaminant if the Administrator determines that:

- (a) The contaminant may have an adverse effect on the health of persons;
- (b) The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
- (c) In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

¹ The MCLG is the “maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. Maximum contaminant level goals are nonenforceable health goals” (40 CFR 141.2).

² An NPDWR is a legally enforceable standard that applies to public water systems. An NPDWR sets a legal limit (called a maximum contaminant level or MCL) or specifies a certain treatment technique for public water systems for a specific contaminant or group of contaminants.

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If the agency determines that all three of these statutory criteria are met, it makes a determination that a national primary drinking water regulation is needed. In that case, the agency has 24 months to publish a proposed MCLG and NPDWR. After the proposal, the agency has 18 months to publish a final MCLG and promulgate a final NPDWR (SDWA section 1412(b)(1)(E)).³

C. What Contaminants did the EPA Consider for Regulation?

On October 20, 2014, the EPA published preliminary regulatory determinations for five contaminants on the third Contaminant Candidate List (CCL 3) that had sufficient information to support a regulatory determination (USEPA, 2014c). The five contaminants are 1,3-dinitrobenzene, dimethoate, terbufos, terbufos sulfone and strontium. The agency is making final regulatory determinations not to regulate dimethoate, 1,3-dinitrobenzene, terbufos and terbufos sulfone. The agency is not making a final regulatory determination for strontium at this time. The agency's decision to delay a final determination for strontium is based on public comments received and the plan to further evaluate scientific information that became available after publication of the preliminary regulatory determinations. The agency is currently conducting additional scientific analyses to determine if there is a need to develop a national drinking water regulation for strontium. For more information about the comments the agency received on strontium and the analyses that are underway, see section V.A of this notice.

Information on the five contaminants can be found in the Regulatory Determinations 3 Support Document (USEPA, 2014b). More information is available at the Water Docket (Docket

³ The statute authorizes up to a nine-month extension of this promulgation date.

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ID No. EPA–HQ–OW–2012–0155) and also on EPA’s Regulatory Determination 3 website at <http://www2.epa.gov/ccl/regulatory-determination-3>.

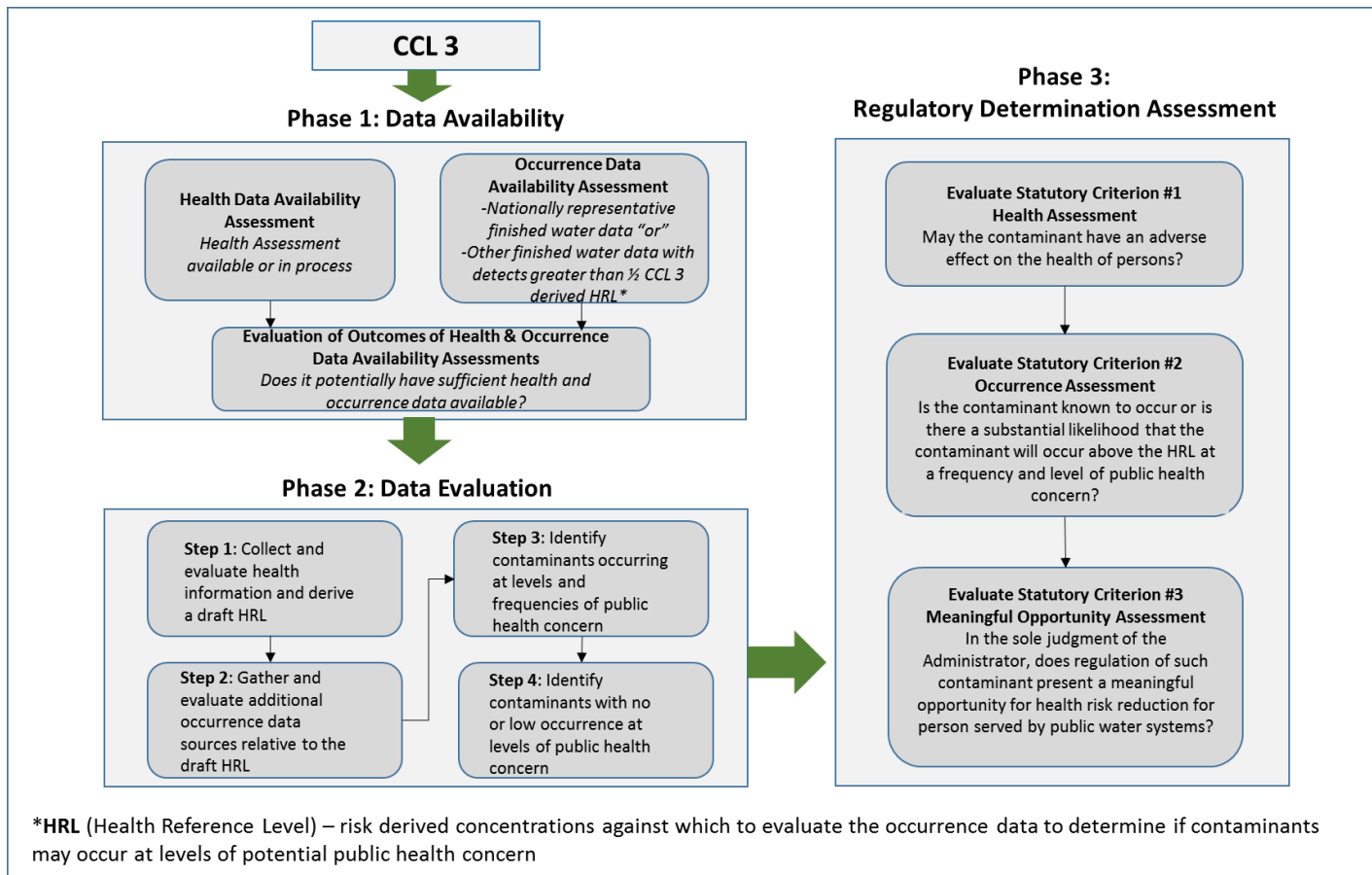
III. What Process did the EPA Use to Make the Regulatory Determinations?

This section gives a summary of the regulatory determination process the agency followed to identify and evaluate contaminants for the Third Regulatory Determination. For more detailed information on the process and the analyses performed, please refer to the “Protocol for the Regulatory Determination 3” document (USEPA, 2014a) and the *Federal Register* notice for the Preliminary Regulatory Determinations for Contaminants on CCL 3 (USEPA, 2014c).

The CCL 3 identified 116 contaminants that are currently not subject to any proposed or promulgated national drinking water regulation, are known or anticipated to occur in public water systems, and may require regulation under SDWA (USEPA, 2009). Since some of the CCL 3 contaminants do not have adequate health and/or occurrence data to evaluate against the three statutory criteria (see section II.B of this notice), the agency used a three-phase process to identify which of the contaminants are candidates for regulatory determinations. Priority was given to identifying contaminants known to occur or with substantial likelihood to occur at frequencies and levels of public health concern.

The three phases of the Third Regulatory Determination process are (1) the Data Availability Phase, (2) the Data Evaluation Phase and (3) the Regulatory Determination Assessment Phase. The overall process is displayed in **Exhibit 1**.

Exhibit 1: The Three Phases of the Regulatory Determination 3 Process



The purpose of the first phase, the Data Availability Phase, is to determine if the agency “may have” sufficient data to characterize the potential health effects and known or likely occurrence in drinking water. Although contaminants must have sufficient data to evaluate the statutory criteria in Phase 3, the agency does not want to rule out any contaminants too early in the process; therefore, if sufficient health and occurrence data are likely available, the contaminants are considered in the Data Evaluation Phase, the second phase of the regulatory determination process. From the 116 CCL 3 contaminants, the agency identified 37 contaminants

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(35 CCL 3 contaminants and two non-CCL 3 contaminants⁴) to further evaluate in the second phase.

During the second phase, the agency further evaluates each contaminant on the short list to identify those that have sufficient data (or are expected to have sufficient data within the timeframe allotted for the second phase) for the EPA to assess the three statutory criteria. As part of the second phase, the agency specifically focuses its efforts on identifying those contaminants or contaminant groups that are occurring or have substantial likelihood to occur at levels and frequencies of public health concern, based on the best available peer reviewed data. If the agency finds that sufficient data are not available or not likely to be available to evaluate the three statutory criteria during the first and second phases, then the contaminant is not considered a candidate for making a regulatory determination.

If sufficient data are available for a contaminant to characterize the potential health effects and known or likely occurrence in drinking water, the contaminant is evaluated against the three statutory criteria in the Regulatory Determination Assessment Phase, which is the third phase of the process. Of the 37 contaminants that were evaluated under Phase 2, 12 were designated for further evaluation in Phase 3.

Of the 12 contaminants that were evaluated in Phase 3, the agency did not make preliminary regulatory determinations for seven contaminants. The seven contaminants include chlorate and six nitrosamines. Chlorate and the six nitrosamines are disinfection byproducts, and the agency is further evaluating these contaminants as part of the regulatory review of existing Microbial and Disinfection Byproduct regulations, as announced in the Preliminary Regulatory Determination 3 *Federal Register* notice published on October 20, 2014 (USEPA, 2014c).

⁴ The non-CCL 3 contaminants, N-Nitroso-di-n-butylamine (NDBA) and N-Nitrosomethylethylamine (NMEA), were included because they are part of a larger group (nitrosamines) that also includes a number of CCL 3 contaminants.

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After evaluating the five remaining CCL 3 contaminants (dimethoate, 1,3-dinitrobenzene, terbufos, terbufos sulfone and strontium) against the three statutory criteria and considering other relevant information (such as level and frequency of occurrence, population exposed and information on sensitive populations and lifestages), the agency made preliminary regulatory determinations to regulate strontium and to not regulate the remaining four contaminants. These preliminary determinations, with their supporting analyses and documentation, were published in the *Federal Register* on October 20, 2014, for public comment (USEPA, 2014c).

The EPA received comments from 14 organizations and individuals on the October 20, 2014, *Federal Register* notice. These 14 organizations and individuals include four environmental organizations, six industry groups, one state association and three anonymous individuals. The agency prepared a Response to Comments document for this action that is available in the Public Docket at www.regulations.gov under Docket ID No. EPA-HQ-OW-2012-0155. Comments on specific contaminants, and the EPA's responses, are briefly summarized in the sections below.

IV. Summary of the EPA's Findings on the Four Contaminants with Final Regulatory Determinations

After considering the public comments, the EPA is making final regulatory determinations not to regulate dimethoate, 1,3-dinitrobenzene, terbufos and terbufos sulfone.

This notice provides a brief description of the agency findings on these contaminants. Details on the background, health and occurrence information and analyses used to evaluate and make final determinations for these contaminants can be found in the Regulatory Determinations 3 Support Document (USEPA, 2015b) and the *Federal Register* notice for the Preliminary Regulatory Determination 3 (USEPA, 2014c).

For each contaminant, the agency evaluated the available human and toxicological data, derived a health reference level (HRL),⁵ evaluated the potential and/or likely occurrence and examined the likely exposed population for the contaminant in public water systems. The agency also considered whether information was available on sensitive populations. The agency used the findings from these evaluations to determine whether the three SDWA statutory criteria are satisfied. **Table 1** gives a summary of the health and occurrence information for the four contaminants with final determinations under RD 3.

Table 1. Summary of the Health and Occurrence Information and the Final Determinations for Four of the Contaminants Considered for RD 3

| RD 3 Contaminants | Health Reference Level (HRL) (µg/L) | Occurrence Findings from Primary Data Sources | | | | | Final Determination |
|--------------------|-------------------------------------|---|---|--|---|--|---------------------|
| | | Primary Database | PWSs with at least 1 detection $\geq \frac{1}{2}$ HRL | Population served by PWSs with at least 1 detection $\geq \frac{1}{2}$ HRL | PWSs with at least 1 detection \geq HRL | Population served by PWSs with at least 1 detection \geq HRL | |
| Dimethoate | 15.4 | UCMR 2 | 0% (0 of 4140) | 0% (0 of 229M) | 0% (0 of 4140) | 0% (0 of 229M) | Do not regulate |
| 1,3-Dinitrobenzene | 0.7 | UCMR 2 | 0% (0 of 4139) | 0% (0 of 229M) | 0% (0 of 4139) | 0% (0 of 229M) | Do not regulate |
| Terbufos | 0.35 | UCMR 1 | 0% (0 of 295) | 0% (0 of 41M) | 0% (0 of 295) | 0% (0 of 41M) | Do not regulate |
| Terbufos sulfone | 0.35 | UCMR 2 | 0.02% (1 of 4140) | 0.01% (44.6K of 229M) | 0.02% (1 of 4140) | 0.01% (44.6K of 229M) | Do not regulate |

⁵ HRLs are risk derived concentrations against which to evaluate the occurrence data to determine if contaminants may occur at levels of public health concern. They are not the level of a contaminant in drinking water that must not be exceeded to protect any particular population (i.e., an HRL is not an MCL).

A. *Dimethoate*

1. Description

Dimethoate is an organophosphate pesticide, commonly used as an insecticide on field crops (e.g., wheat, alfalfa, corn and cotton), orchard crops, vegetable crops and in forestry. Synonyms for dimethoate include dimethogen, dimeton, dimevur and cygon (HSDB, 2010; USEPA, 2007). Dimethoate is considered highly mobile and relatively non-persistent in the environment (USEPA, 2007).

2. Agency findings

The agency is making a determination not to regulate dimethoate with an NPDWR. It does not occur at levels and frequencies of public health concern. As a result, the agency finds that an NPDWR does not present a meaningful opportunity for health risk reduction.

The primary data for dimethoate are the 2008-2010 nationally representative drinking water monitoring data, generated through the EPA's Second Unregulated Contaminant Monitoring Regulation (UCMR 2). Dimethoate was not detected in any of the 32,150 UCMR 2 samples collected by 4,140 PWSs (serving ~ 230 million people) at levels greater than the ½ HRL (7.7 µg/L), the HRL (15.4 µg/L), or the minimum reporting level (MRL) (0.7 µg/L) (USEPA, 2015c). Based on the results of the UCMR 2 samples, the estimated population exposed to dimethoate at levels of public health concern is 0%.

Other supplementary sources of finished water data from the State of California, the U.S. Department of Agriculture (USDA) and the U.S. Geologic Survey (USGS) indicate that the occurrence of dimethoate in PWSs is likely to be low to non-existent. Dimethoate occurrence data for ambient water from the USGS and the Storage and Retrieval (STORET) Data System

are consistent with those for finished water. These data sources are discussed in the October 2014 *Federal Register* notice of the Preliminary Regulatory Determination 3 (USEPA, 2014c).

B. 1,3-Dinitrobenzene

1. Description

1,3-Dinitrobenzene is a nitro aromatic compound that is used as an industrial chemical and formed as a by-product in the manufacture of munitions, as well as in the production of other substances (HSDB, 2009). There are no known natural sources of 1,3-dinitrobenzene. 1,3-Dinitrobenzene appears to be moderately persistent in environmental media and moderately mobile in soil and water, although in soils with high clay content it will be less mobile (USEPA, 2015b).

2. Agency findings

The agency is making a determination not to regulate 1,3-dinitrobenzene with an NPDWR. It does not occur at levels and frequencies of public health concern. As a result, the agency finds that an NPDWR does not present a meaningful opportunity for health risk reduction.

The primary data for 1,3-dinitrobenzene are the 2008-2010 nationally representative drinking water monitoring data generated through the EPA's UCMR 2 (USEPA, 2015c). UCMR 2 is the only dataset with finished water data for this contaminant. UCMR 2 collected 32,152 samples from 4,139 PWSs for 1,3-dinitrobenzene and it was not detected above the MRL (0.8 µg/L), which is only slightly higher than the HRL (0.7 µg/L). Based on the results of the UCMR 2 samples, the estimated population exposed to 1,3-dinitrobenzene at or above the MRL is 0%.

Findings from the available ambient water data for 1,3-dinitrobenzene are consistent with the results in finished water. Ambient water data in STORET included no measured results above 0.33 µg/L in 143 samples from 70 sites (USEPA, 2012). It should be noted that some occurrence above the HRL may have gone undetected since reporting levels are not documented. These data sources are discussed in the October 2014 *Federal Register* notice of the Preliminary Regulatory Determination 3 (USEPA, 2014c).

C. Terbufos and Terbufos Sulfone

1. Description

Terbufos is a phosphorodithioate pesticide (i.e., an organophosphate) used as an insecticide-nematicide to control a variety of insect pests, primarily used on corn and sugar beets (USEPA, 2006). Terbufos sulfone is a degradate of terbufos. Total toxic residues of terbufos and degradates are highly mobile and persistent in the environment, with terbufos sulfone being more mobile and substantially more persistent than terbufos (USEPA, 2006).

2. Agency findings

The agency is making determinations not to regulate terbufos and terbufos sulfone with NPDWRs. They do not occur at levels and frequencies of public health concern. As a result, the agency finds that an NPDWR does not present a meaningful opportunity for health risk reduction.

The primary data for terbufos are from the First Unregulated Contaminant Monitoring Regulation (UCMR 1) screening survey (2001-2003) (USEPA, 2008). The UCMR 1 screening survey collected 2,301 finished water samples from 295 PWSs for terbufos and it was not detected at levels at or above the MRL (0.5 µg/L), which is slightly higher than the HRL (0.35

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µg/L) (USEPA, 2008). Based on the results of the UCMR 1 screening survey, the estimated population exposed to terbufos at or above the MRL is 0%.

The primary data for terbufos sulfone are nationally representative finished water monitoring data generated through the EPA's UCMR 2 (2008-2010) (USEPA, 2015c). UCMR 2 collected 32,149 finished water samples from 4,140 PWSs (serving ~ 230 million people) for terbufos sulfone and it was detected in only one sample, at a concentration of 0.42 µg/L. The MRL is 0.4 µg/L, which is slightly higher than the HRL (0.35 µg/L) (USEPA, 2015c). Based on the results of the UCMR 2 samples, the estimated population exposed to terbufos sulfone at a level of public health concern (based on the HRL for terbufos) is 44,600 (0.02% of the population served by PWSs).

Finished water data for terbufos and terbufos sulfone from California, Iowa, USDA and USGS are consistent with the UCMR 1 and UCMR 2 data. Terbufos and (very limited) terbufos sulfone occurrence data for ambient water from the EPA, STORET and several USGS programs or studies are also consistent with those for finished water. These data sources are discussed in the October 2014 *Federal Register* notice of the Preliminary Regulatory Determination 3 (USEPA, 2014c).

D. Public Comments on Four Contaminants with Final Regulatory Determinations

The agency received comments in support of the agency's preliminary determinations not to regulate dimethoate, 1,3-dinitrobenzene, terbufos and terbufos sulfone. The agency did not receive any comments to the contrary.

Agency Response: EPA agrees with the comments and, as previously explained, is making final determinations not to regulate dimethoate, 1,3-dinitrobenzene, terbufos and terbufos sulfone.

V. Summary of Public Comments on Strontium and the Agency's Responses

A. Background on Strontium and the EPA's Preliminary Determination

Strontium is a naturally occurring element (atomic number 38) and a member of the alkaline earth metals (ANL, 2007). There are several radioactive strontium isotopes formed by nuclear fission of uranium or plutonium. Since drinking water contamination by radioactive isotopes, including beta particle emitters, is covered under the existing Radionuclides Rule, this section describes the stable ^{88}Sr isotope.

In October 2014, the agency made a preliminary determination to regulate strontium with an NPDWR after evaluating the available health, occurrence and other related information against the three SDWA statutory criteria. Specifically, EPA made a preliminary determination that (a) strontium may have an adverse effect on the health of persons, (b) it is known to occur or there is substantial likelihood that strontium will occur in public water systems with a frequency and at levels of public health concern and (c) regulation of strontium with an NPDWR presents a meaningful opportunity to reduce health risks for persons served by PWSs. EPA describes the underlying science in support of these criteria in the *Federal Register* notice of the Preliminary Regulatory Determination 3 (USEPA, 2014c).

In the *Federal Register* notice of the Preliminary Regulatory Determination 3, EPA calculated a non-cancer HRL of 1500 $\mu\text{g/L}$ for strontium using the reference dose of 0.3

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mg/kg/day, a default Relative Source Contribution (RSC) of 20% and age-specific exposure factors (i.e., drinking water intake expressed as liters per kg of body weight) for the sensitive population of birth through 18 years to reflect the most active period of bone growth and development. The RSC is the level of exposure believed to result from drinking water when compared to other sources (e.g., food, ambient air). In the Preliminary Regulatory Determination 3 EPA used the default 20% RSC to calculate the HRL. For more detailed information see the October 20, 2014, *Federal Register* notice of the Preliminary Regulatory Determination 3 (USEPA, 2014c).

After consideration of public comments on the preliminary regulatory determination for strontium (see Section V.B.), the agency is delaying the final determination for strontium in order to consider additional scientific data and decide whether there is a meaningful opportunity for health risk reduction by regulating strontium in drinking water.

B. What Comments Did the EPA Receive on Strontium?

Some commenters supported the preliminary determination to regulate strontium. These commenters supported a regulation due to the adverse effect on bone growth and/or the potential for elevated levels of strontium in the environment as a result of spills and disposal of waste products related to gas production.

Many comments called upon the agency to delay the final determination, collect more data and perform additional analyses before making a final determination for strontium. Specifically, the comments were focused on the following areas: the relationship between occurrence and health risk, the RSC of strontium, the costs and benefits of a potential strontium regulation and the feasibility of treating strontium.

Three commenters questioned whether enough water systems show strontium at levels and frequency of concern that a meaningful reduction in health risk can be achieved through a national regulation. Two of these commenters suggested conducting an epidemiology study that evaluates whether adverse human health effects are occurring and at what drinking water concentrations (and frequency of occurrence) to determine whether there is a meaningful opportunity for health risk reduction of a regulation.

Two commenters indicated the agency should quantify the RSC or provide stronger justification for using an RSC of 20%. One commenter stated the RSC has a significant impact on the reference dose. One commenter stated that defaults of 20% and 80% have utility in relatively simple circumstances where it is accepted that the drinking water component is either very small or large. The commenter indicated that it is essential to analyze and quantify the RSC when it is intermediate and there are data to perform a meaningful estimate. The commenter asserted that it is essential because the impact on the MCLG and ultimately the MCL and compliance costs can become significant.

Several commenters indicated concerns with the costs and benefits of a potential strontium regulation. One commenter urged the agency to update the current affordability standard under SDWA before promulgating any new NPDWRs in order to allow rural and small communities to utilize the most economical and safe treatment options. One commenter stated that the agency failed to estimate the social benefits and social costs in its analysis for the strontium determination, specifically the additional energy usage and its externalities. Several commenters compared the cost of a potential strontium regulation to that of the arsenic regulation, based on the percentage and type of systems with strontium occurrence at levels of concern.

Several commenters supported the agency's commitment to conducting more extensive treatment research prior to promulgating a regulation for strontium. Two commenters indicated that the treatment technology to remove strontium may remove beneficial alkaline earth metals, such as calcium, that partially counter the uptake of strontium.

Agency Response: The agency is delaying the final determination for strontium in order to consider additional scientific data and decide whether there is a meaningful opportunity for health risk reduction by regulating strontium in drinking water.

Strontium is known to occur in food, ambient air and soil. While data on levels in those media and estimates of intake from those sources were limited when EPA made the preliminary determination to regulate strontium, the EPA is evaluating recent additions to the exposure database to determine if the agency can develop a data-derived RSC rather than using a default 20% RSC in the calculation of the HRL. In the absence of this type of relevant exposure information, the agency supports the use of the default RSC and may ultimately use the default 20% RSC in the final regulatory determination for strontium and for other compounds in the future. The agency selects the default RSCs for regulatory determinations based on the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (USEPA, 2000).

If the agency makes a final determination to regulate strontium, the EPA will conduct tests on treatment technologies for strontium prior to developing a regulation. The agency understands that strontium may co-occur with beneficial calcium in some drinking water systems and treatment technologies that remove strontium may also remove calcium. The agency is evaluating the effectiveness of treatment technologies under different water conditions, including

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calcium concentrations. The agency will continue to work with stakeholders in evaluating treatment technologies for strontium.

At this time, the agency does not plan to initiate any longer term health effect studies, including human epidemiological studies on the relationship of skeletal effects and strontium exposure levels through consumption of drinking water and foods. The agency will continue to evaluate new health studies related to strontium exposure, including any epidemiology studies. It should be noted that while the agency is not precluded from conducting epidemiological studies, the agency is not required to do so to support the decision to regulate a contaminant.

An evaluation of the costs and benefits of a potential strontium regulation is outside the scope of the regulatory determination process. If the agency decides to regulate strontium, as part of the regulation development process, the agency will conduct a health risk reduction and cost analysis, including an evaluation of the costs and benefits of regulating strontium.

VI. Next Steps

Prior to making a final regulatory determination for strontium, the agency will consider additional data gathered and analyses completed after publication of the preliminary determination (for further information, see discussion in section V.B. of this notice). The agency published the Draft Contaminant Candidate List 4 (CCL 4) on February 4, 2015 (USEPA, 2015a) and will issue a Final CCL 4 after consideration of public comments received. The agency will evaluate and consider contaminants on the Final CCL 4 for the Fourth Regulatory Determination.

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Dated:

Gina McCarthy,
Administrator.