

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 141**

[FRL-7050-8]

RIN 2040-AD06

National Primary Drinking Water Regulations: Minor Revisions to Public Notification Rule and Consumer Confidence Report Rule**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: Today's action proposes to make specific changes to the health effects language for di(2-ethylhexyl) adipate (DEHA) and di(2-ethylhexyl) phthalate (DEHP) in the Public Notification (PN) Rule (May 4, 2000, 65 FR 26020) and the Consumer Confidence Report (CCR) Rule (August 19, 1998, 63 FR 44511). EPA is also clarifying the proper use of the

Integrated Risk Information System (IRIS) database. In addition, today's rule proposes to correct mistakes in Appendix A of the CCR Rule. These minor changes to Appendix A address errors in the list of major sources in drinking water for copper, the placement of regulatory and health effects information for the disinfection byproducts (i.e., bromate, chloramines, chlorite, chlorine, and chlorine dioxide), and reference to chloride dioxide instead of chlorine dioxide. EPA is not reopening its consideration of the health effects statements in the PN and CCR Rules for contaminants other than DEHA and DEHP.

DATES: Written comments on this proposed rule must be received by October 9, 2001.

ADDRESSES: Send written comments to the Comment Clerk, docket number W-01-07, Water Docket (MC 4101), Rm EB 57, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave, NW

Washington, DC 20460. The record for this proposed rule is established under docket number W-01-07. The record is available for inspection from 9 a.m. to 4 p.m. Monday through Friday, excluding legal holidays at the Water Docket, East Tower Basement, Rm EB 57, USEPA, 401 M Street, SW, Washington DC. For access to docket materials, please call 202-260-3027 to schedule an appointment. Comments may be hand-delivered to the Water Docket, U.S. Environmental Protection Agency; 401 M Street SW, East Tower Basement, Rm EB 57, Washington DC, 20460.

FOR FURTHER INFORMATION CONTACT:

Kathleen Williams at (202)-260-2589 or e-mail: williams.kathleena@epa.gov. Contact the Safe Drinking Water Hotline (800-425-4791) for general information about these rules. Hours of operation are 9 am to 5:30 pm (ET), Monday -Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION:**TABLE OF REGULATED ENTITIES**

Category	Examples of regulated entities
State/Local/Tribal governments	Publicly-owned PWSs, such as municipalities; county governments, water districts, water and sewer authorities, state governments, and other publicly-owned entities that deliver drinking water as an adjunct to their primary business (e.g., schools, State parks, roadside rest stops).
Industry	Privately-owned PWSs, such as private utilities, homeowner associations, and other privately-owned entities that deliver drinking water as an adjunct to their primary business (e.g., trailer parks, factories, retirement homes, day-care centers).
Federal government	Federally-owned PWSs, such as water systems on military bases.

In June 2000, the American Chemistry Council (ACC) filed a petition for review of the May 4, 2000 revised Public Notification (PN) Rule in the D.C. Circuit Court of Appeals, alleging that EPA violated Administrative Procedure Act (APA) notice and comment requirements with respect to the health effects language for the contaminants di(2-ethylhexyl)adipate (DEHA) and di(2-ethylhexyl)phthalate (DEHP). ACC contended that the Agency relied solely on the Integrated Risk Information System (IRIS) database to develop health effects language for these two contaminants although other information was available. As part of a settlement agreement with ACC, EPA is proposing minor modifications for the DEHA and DEHP health effects language used in the PN and Consumer Confidence Report (CCR) Rules. EPA is also including a statement in this preamble on the proper use of IRIS.

EPA is also using today's action to propose other minor changes for Appendix A of the CCR Rule. In Appendix A "leaching from wood

preservatives" is incorrectly listed as a major source of copper in drinking water. This rule deletes "leaching from wood preservatives" from the list of major sources for copper. Regulatory and health effects information for the disinfection byproducts bromate, chloramines, chlorite, chlorine, and chlorine dioxide is incorrectly placed in the volatile organic contaminants section of Appendix A. In addition, the entry for chlorine dioxide was inadvertently listed as chloride dioxide. Today's action moves entries for the disinfection byproducts from their existing locations and places them in the inorganic contaminants section of Appendix A. Misspelling of chlorine dioxide is also corrected.

I. Proposed Revisions to the Public Notification Rule

Section 1414(c) of the SDWA required EPA to revise its existing regulations governing the public notification that public water systems must provide to the persons served by the system when the system violates drinking water

standards, or in certain other circumstances. This public notification is an integral part of the public health protection and consumer right-to-know provisions of the SDWA as amended in 1996. EPA's regulations set the requirements that public water systems must follow regarding the form, manner, frequency, and content of a public notice. When there is a violation, public water systems must, among other things, provide information to the public on the potential health effects of exposure to the contaminant in question. The Public Notification (PN) Rule (40 CFR part 141, subpart Q) provides specific health effects statements for each regulated contaminant that a public water system must provide in its public notice.

On May 14, 1999, EPA published proposed revisions to the PN rule for public comment. In that rulemaking EPA proposed to use the same brief health effects language for the PN Rule as EPA had recently required for the CCR Rule, issued in August, 1998. As a result, the PN proposal contained the CCR health effects language for DEHP

and DEHA. During the public comment period, the Chemical Manufacturers Association (now known as the American Chemistry Council) submitted comments questioning several aspects of the health effects language for these two contaminants, including the reference to "general toxic effects" for DEHA and the basis for characterizing DEHP as a human carcinogen. They submitted over 100 pages of comments on these contaminants providing support for their suggested changes to the health effects language. EPA did not change the health effects statements as a result of these comments, but responded to the comments by stating that the current health effects language for DEHA and DEHP is consistent with the most recent Agency IRIS document for those contaminants. EPA published the final public notification rule on May 4, 2000.

On June 30, 2000, the American Chemistry Council filed a petition for review of the final public notification rule in the D.C. Circuit Court of Appeals challenging the health effects language for these two contaminants. ACC specifically challenged EPA's failure to respond to their extensive comments on the health effects language and EPA's apparent reliance solely on the IRIS database.

To resolve the ACC petition, EPA reconsidered comments requesting changes to health effects language and agreed that the response to comments with respect to the issues ACC raised was inadequate. However, any contention that EPA relies solely on IRIS data for health effects language is inaccurate. EPA does not rely solely on IRIS in developing, or considering changes to, the health effects statements for the CCR and PN Rules.

EPA recognizes that IRIS is not a comprehensive toxicological database. There may be more recent relevant information available than is contained in IRIS. IRIS values are not rules adopted after notice and comment rulemaking, although recent IRIS assessments are posted on the Internet and public comments are solicited. IRIS values are not legally binding and are not entitled to conclusive weight in any rulemaking. In addition, EPA or any State agency that uses IRIS should not rely exclusively on IRIS values but should consider all credible and relevant information that is submitted in any particular rulemaking. If an outside party questions IRIS values during the course of an EPA rulemaking (such as a rule to establish health effects language for a contaminant for CCR and PN purposes), EPA considers all credible and relevant information before it in that proceeding.

EPA also believes that some minor changes to the health effects language for these two contaminants is appropriate based on the existing science (which, as noted above, includes but is not limited to the IRIS database.) The specific changes and the rationale for those changes is discussed in detail below.

A. Di(2-ethylhexyl)phthalate

Di(2-ethylhexyl)phthalate (DEHP) was regulated by EPA in 1992 as a B2 Carcinogen (probable human carcinogen) with an MCLG of zero and an MCL of 0.006 mg/L (57 FR 31776). The regulation was based on a 1987 EPA assessment of the data from a study in rats by the National Toxicology Program (NTP, 1982). Nontumor effects of concern included proliferation of peroxisomes, and enlargement of the liver, factors that appear to play a role in tumor development, and effects on reproduction and development (U.S. EPA, 1991). The Consumer Confidence Report/Public Notification language was developed to reflect the potential for these effects to occur when the drinking water exposure exceeds the MCL for a long period of time. The health effects language for DEHP given in Appendix A of the CCR Rule (40 CFR part 141, subpart O) and Appendix B of the PN Rule (40 CFR part 141, subpart Q) states:

"Some people who drink water containing di(2-ethylhexyl)phthalate in excess of the MCL over many years may have problems with their liver, or experience reproductive difficulties, and may have an increased risk of getting cancer."

ACC objected to three components of the Consumer Confidence Report/Public Notification language as follows:

- ACC felt that EPA should not rely on the 1987 cancer classification for DEHP;
- ACC felt that it was very unlikely that DEHP was a cancer hazard in humans and that this should be reflected in the Consumer Confidence Report/Public Notification language; and
- ACC requested that EPA delete the reference to reproductive effects.

In the opinion of EPA, the requested modifications to the Consumer Confidence Report/ Public Notification language are not consistent with the DEHP toxicological data. DEHP does not appear to be a genotoxic carcinogen, but it has not been possible to completely define its mode of tumorigenic action at this time. The data suggest that activation of the Peroxisome Proliferator Activated Receptor, the production of hydrogen peroxide by peroxisomes, enhanced cell proliferation, and

apoptosis may all play a role in tumorigenesis (ATSDR, 2000). However, unless an assessment that incorporates and links the various lines of evidence for a nonlinear mode of action can be completed, carcinogenicity remains as an endpoint of human concern. An Agency assessment is presently underway which may change the classification and quantification of the cancer endpoint, but it is premature to predict the final conclusion of that assessment.

In the time that has elapsed since EPA regulated DEHP, the link between DEHP and effects on reproduction and development has been strengthened (Hileman, 2000). Accordingly, there is no justification for removing the language about the potential for reproductive effects from the Consumer Confidence Report/Public Notification language. Reproductive effects that are associated with exposure to DEHP include abnormalities in testicular maturation in males (Arcadi et al., 1998, Dostal et al., 1988; Gray and Butterworth, 1980), teratogenic effects (Tyl et al., 1988), and effects on fertility (Lamb et al., 1987). The data from the studies by Tyl and Lamb suggest a steep dose-response curve.

On the other hand there are data that indicate that, at least for the biomarkers of liver effects including precancerous changes (i.e. induction of peroxisomal enzymes; liver enlargement), DEHP has a more pronounced effect on rodents than on primates. Accordingly, EPA feels that it is appropriate to qualify the exposures that may lead to adverse health effects from ingestion of water containing DEHP by saying that concentrations would have to be well in excess of the MCL (0.006 mg/L) and occur for a long period of time to be of concern. The testicular effects of DEHP can occur with short duration exposures, particularly if they occur in early development (Arcadi et al., 1998, Dostal et al., 1988). However, they appear to be reversible if exposure ceases before puberty (Dostal et al., 1988) and, thus, generate concern primarily when exposures occur over many years. Accordingly, EPA proposes to modify the Consumer Confidence Report/Public Notification language to state:

"Some people who drink water containing di(2-ethylhexyl)phthalate well in excess of the MCL over many years may have problems with their liver, or experience reproductive difficulties, and may have an increased risk of getting cancer."

—Di(2-ethylhexyl)adipate

Di(2-ethylhexyl)adipate (DEHA) was regulated by EPA in 1992 as a C

Carcinogen (possible human carcinogen) with a MCLG of 0.4 mg/L and an enforceable MCL of 0.4 mg/L (57 FR 31776). The existing health effects statement regarding di(2-ethylhexyl) adipate, found in Appendix A of the CCR Rule (40 CFR part 141, subpart O) and Appendix B of the PN Rule (40 CFR part 141, subpart Q), is as follows:

“Some people who drink water containing di(2-ethylhexyl)adipate well in excess of the MCL over many years could experience general toxic effects or reproductive difficulties.”

ACC raised concerns, and EPA has agreed, that the term “general toxic effects” in the existing health effect statement for di(2-ethylhexyl)adipate may be unnecessarily vague and alarming to the public. The specific toxic effects of DEHA seen in animal toxicological studies are reduction in body weight gain and increase in absolute and relative liver weights. Accordingly, EPA is today proposing to replace the reference to “general toxic effects” with new language that incorporates a more specific description of these “general toxic effects,” namely, weight loss and liver enlargement.

In addition, EPA is proposing to add the qualifier “possible” to the reference to “reproductive difficulties” in the health effects statement for DEHA in the PN and CCR Rules. The MCLG and MCL values for DEHA are derived from the Reference Dose (RfD) of 0.6 mg/kg/day.¹ This RfD is based on two studies in rats: a one-generation reproductive toxicity study which examined effects on fertility, reproductive outcome and gross and histological parameters in parents of both sexes; and a developmental study which assessed the effects of DEHA on gestating females and their developing fetuses (ICI, 1988 a and b). Both studies identified a no-observed-adverse-effect level (NOAEL) of 170 mg/kg/day. The data base for the derivation of the RfD was considered somewhat deficient because of the lack of a multi-generation reproductive study and the lack of relevant data in species other than rats. Accordingly, an uncertainty factor (UF) of 300 was applied to the NOAEL to derive the RfD of 0.6 mg/kg/day. This UF consists of the standard 100 factor for interspecies extrapolation and intraspecies variability, and an additional factor of 3 for database deficiencies.

¹ Using the RfD of 0.6 mg/kg/day and assuming 70 kg body weight, 2 liter/day drinking water consumption, a relative source contribution of 20%, and applying an additional management factor of 10 for possible carcinogenicity of DEHA, the MCLG is 0.4 mg/liter. The MCL was also established at 0.4 mg/liter.

In deriving the RfD for DEHA, it was therefore implicitly recognized that the data base for reproductive and developmental effects was not entirely satisfactory. To reflect this uncertainty in the data base, EPA believes it is appropriate to include in the new health effects statement the wording “possible” before “reproductive difficulties.”

Today, EPA is proposing to modify the existing health effects statement regarding di(2-ethylhexyl)adipate in the PN and CCR Rules to state as follows:

“Some people who drink water containing di(2-ethylhexyl)adipate well in excess of the MCL over many years could experience toxic effects such as weight loss, liver enlargement or possible reproductive difficulties.”

EPA believes that this change is appropriate. It is critical that standard health effects language for public notification conveys to the public clear descriptions, in easy-to-understand language, of the potential adverse health effects of a drinking water contaminant when such a contaminant is found at concentrations above the Federal standard.

II. Proposed Revisions to the Consumer Confidence Report Rule

The Consumer Confidence Report (CCR) Rule (40 CFR part 141, subpart O) requires community water systems to issue an annual water quality report to their customers. The report provides a snapshot of local drinking water quality, including information on the source of the water, the contaminants found in the water, the potential health effects of any contaminants found above Federal health standards, the ways the water system protects its water supply, and how consumers can get involved in protection of source water. As part of that rule, CWSs must provide a statement concerning the health effects of contaminants when those contaminants are found at levels that violate the regulatory standard. Because the PN and CCR rules are closely related, EPA has required that systems use the same health effects language for CCR purposes as for PN purposes. For this reason, EPA is proposing to make the same changes to the CCR health effects language for DEHP and DEHA as is proposed today for the PN Rule.

EPA is also proposing to make the following minor corrections to Appendix A of the CCR Rule (40 CFR part 141, subpart O):

A. For the entry on Copper: “Leaching from wood preservatives” is listed as a major source of copper in drinking water. EPA mistakenly included that listing although leaching from wood preservatives is not a major source of

copper in drinking water. This rule proposes to delete that part of the entry so the amended appendix lists only “corrosion of household plumbing systems; erosion of natural deposits” as major sources for copper in drinking water.

B. For the disinfection byproducts entries: Bromate, Chloramines, Chlorite, Chlorine, and Chlorine Dioxide. EPA mistakenly placed information for these contaminants in the volatile organic contaminants section of Appendix A instead of the inorganic contaminants section. This rule proposes to correct that mistake by placing information for these contaminants in the inorganic contaminants section of Appendix A. Also, the entry for chlorine dioxide was misspelled. This rule also proposes to correct that mistake by replacing “chloride dioxide” with “chlorine dioxide” in the appendix.

EPA does not solicit, and will not respond to, comments on the text of the health effects statements for these or any contaminants other than DEHA and DEHP.

III. Administrative Requirements

A. Executive Order 12866—Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51735, October 4, 1993) the Agency must determine whether the regulatory action is “significant” and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines “significant regulatory action” as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a “significant regulatory action” under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be “economically significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This proposed rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866. This rule makes minor changes to the Public Notification Rule and Consumer Confidence Report Rule which do not change the regulatory burden.

C. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with “Federal mandates” that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying

potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today’s rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or Tribal governments or the private sector. The rule imposes no enforceable duty on any State, local or Tribal governments or the private sector. This rule does not change the costs to State, local, or Tribal governments as estimated in the final Public Notification Rule (65 FR 26020, May 4, 2000) and the final Consumer Confidence Report Rule (August 19, 1998, 63 FR 44511), and does not change either the frequency of reports or the regulatory burden of public notification. Thus, today’s rule is not subject to the requirements of sections 202 and 205 of the UMRA.

For the same reason, EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus today’s rule is not subject to the requirements of section 203 of UMRA.

D. Paperwork Reduction Act

This action does not impose any new information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* This rule makes minor changes to the Public Notification Rule and the Consumer Confidence Report Rule, and does not change the frequency of reporting or the regulatory burden. The rule imposes no additional enforceable duty on any State, local or tribal governments or the private sector.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

E. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice-and-comment rulemaking requirement under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small government jurisdictions.

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, “which are appropriate to the activities for the agency” after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 U.S.C. 601(30)–(5). In addition to the above, to establish an alternative small business definition, agencies must consult with SBA’s Chief Counsel for Advocacy.

For purposes of assessing the impacts of today’s rule on small entities, EPA considered small entities to be public water systems serving 10,000 or fewer persons. This is the cut-off level specified by Congress in the Safe Drinking Water Act Amendments of 1996 for small system flexibility provisions. In accordance with the RFA requirements, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration, finalized this definition for the final CCR regulation, and expressed its intention to use the alternative definition for all future drinking water regulations (63 FR 44511, August 19, 1998).

After considering the economic impacts of today’s proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This rule makes minor changes to the Public Notification Rule and the Consumer Confidence Report Rule and imposes no additional enforceable duty on any State, local or tribal governments or the private sector. It does not change

either the frequency of reports or the regulatory burden of public notification.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

F. National Technology Transfer and Advancement Act

Section 12 (d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., material specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

G. Executive Order 12898—Environmental Justice Strategy

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. Today's proposed rule makes minor changes to the Consumer Confidence Report Regulation and Public Notification Regulation, and does not alter the regulatory requirements of those regulations. The Agency considered environmental justice related issues concerning the potential impacts of public notification during development of the Public Notification Regulation and Consumer Confidence Report Regulation. In the May 4, 2000, PN Rule (65 FR 2620), EPA concluded that the PN requirements would be beneficial to low-income and minority communities. In the August 19, 1998 Consumer Confidence Report Regulation (August

19, 1998, 63 FR 44511), EPA determined that provisions in that regulation would be beneficial to low-income and minority communities, particularly the provision requiring a good faith effort to reach non bill-paying customers.

H. Executive Order 13132—Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Today's rule proposes minor changes to the Consumer Confidence Report Regulation and Public Notification Rule. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

I. Executive Order 13175—Consultation and Coordination with Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

This proposed rule does not have tribal implications. It will not have

substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Today's rule makes minor changes to the Consumer Confidence Report Rule and Public Notification Rule. It imposes no additional enforceable duty on any tribal governments or the private sector, and does not change either the frequency of reports or the regulatory burden of public notification. Thus, Executive Order 13175 does not apply to this rule.

In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and tribal governments, EPA specifically solicits additional comment on this proposed rule from tribal officials.

J. Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)), provides that agencies shall prepare and submit to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, a Statement of Energy Effects for certain actions identified as "significant energy actions." Section 4(b) of Executive Order 13211 defines "significant energy actions" as "any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) that is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action." This rule is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

IV. References

Agency for Toxic Substances and Disease Registry (ATSDR) 1999. Toxicological profile for di(2-ethylhexyl)phthalate. December. U.S.

Department of Health and Human Services. Public Health Service.

Agency for Toxic Substances and Disease Registry (ATSDR) 2000. Toxicological profile for di(2-ethylhexyl)phthalate (update) September U.S. Department of Health and Human Services. Public Health Service.

Arcadi, F.A., C. Costa, C. Imperatore, A. Marchese, A. Rapisarda, M. Salemi, G.R. Trimarchi, and G. Costa, 1998. Oral toxicity of bis(2-ethylhexyl)phthalate during pregnancy and suckling in Long-Evans rat. *Food Chem Toxicol* 36:963–970 (as cited in ATSDR, 2000).

Dostal, L.A., R.E. Chapin, S.A. Stephanski, M.W. Harris, and B.A. Schwetz, 1988. Testicular toxicity and reduced Sertoli cell numbers in neonatal rats by di(2-ethylhexyl)phthalate and the recovery of fertility as adults. *Toxicol. Appl. Pharmacol.* 95:104–121.

Gray, T.J. and K.R. Butterworth. 1980. Testicular atrophy produced by phthalate esters. *Arch. Toxicol.* 1980 (Supp. 4):452–455.

Hileman, B. 2000. Alert on phthalates. *Chem. and Eng. News.* 78 (32):52–54.

ICI Central Toxicology Laboratory (1988a). “Di(2-ethylhexyl)adipate (DEHA): Fertility study in rats.” Study No. RR0374. Alderly Park, Cheshire, UK. Tinston DJ.

ICI Central Toxicology Laboratory (1988b). “Di(2-ethylhexyl)adipate: Teratogenicity study in the rat”. Study No. RR0372. Alderly Park, Cheshire, UK. Hodge MCE.

Lamb, J.C., R.E. Chapin, J. Teague, A.D. Lawton, J.R. Reel, 1987. Reproductive effects of four phthalic acid esters in the mouse. *Toxicol. Appl. Pharmacol.* 88:255–269.

NTP 1982. Carcinogenesis bioassay of di(2-ethylhexyl)phthalate (CAS No 117–81–7) in F344 rats and B6C3F₁ mice. Department of Health and Human Services. Public Health Services. National Institute of Health. NTP Publication No. 217.

Tyl, R.W. 1988. Developmental toxicity evaluation of dietary di(2-ethylhexyl) phthalate in Fischer 344-rats and CD–1 mice. 10:395–412.

U.S. EPA. 1991. Drinking Water Criteria Document for Phthalic Acid Esters (PAES). Environmental Criteria and Assessment Office. Office of Health and Environmental Assessment.

Cincinnati, OH 45268. ECAO–CIN–D009. August 1988, Revised August 1991.

List of Subjects in 40 CFR Part 141

Environmental protection, Chemicals, Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

Dated: August 30, 2001.

Christine Todd Whitman,
Administrator.

For the reasons set out in the preamble, 40 CFR part 141 is proposed to be amended as follows:

PART 141—[AMENDED]

1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

Subpart Q—[AMENDED]

2. Appendix B to Subpart Q is amended by revising entries 33. for “Di(2-ethylhexyl) adipate” and 34. for “Di(2-ethylhexyl) phthalate” to read as follows:

APPENDIX B TO SUBPART Q OF PART 141—STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant (units)	MCLG (mg/l) b)	MCL (mg/l)	Standard health effects language for public notification
*	*	*	*
E. Synthetic Organic Chemicals (SOCs).			
*	*	*	*
33. Di(2-ethylhexyl) adipate	0.4	0.4	Some people who drink water containing di(2-ethylhexyl)adipate well in excess of the MCL over many years could experience toxic effects such as weight loss, liver enlargement or possible reproductive difficulties.
34. Di(2-ethylhexyl) phthalate	0	0.006	Some people who drink water containing di(2-ethylhexyl)adipate well in excess of the MCL over many years may have problems with their liver, or experience reproductive difficulties, and may have an increased risk of getting cancer.
*	*	*	*

Subpart O—[AMENDED]

3. Appendix A to Subpart O is amended:

a. under the heading “Volatile organic contaminants” by removing entries for: “Bromate (ppb)”, “Chloramines (ppm)”, “Chlorite (ppm)”, “Chlorine (ppm)”, and “Chloride dioxide (ppm)”.

b. under the heading “Inorganic contaminants” by adding in alphabetical order entries for: “Bromate (ppb)”, “Chloramines (ppm)”, “Chlorine (ppm)”, “Chlorine dioxide (ppm)”, and “Chlorite (ppm)”.

c. under the heading “Inorganic contaminants” by revising the entry for “copper (ppm)”.

d. under the heading “Synthetic organic contaminants including pesticides and herbicides” by revising entries for “Di(2-ethylhexyl) adipate (ppb)” and “Di(2-ethylhexyl) phthalate (ppb)”.

APPENDIX A TO SUBPART O—REGULATED CONTAMINANTS

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
*	*	*		*	*	*
Inorganic contaminants:						
*	*	*		*	*	*
Bromate (ppb)	0.010	1000	10	0	By-product of drinking water chlorination.	Some people who drink water containing bromate in excess of the MCL over many years may have an increased risk of getting cancer.
*	*	*		*	*	*
Chloramines (ppm)	MRDL = 4		MRDL = 4	MRDLG = 4	Water additive used to control microbes.	Some people who use water containing chloramines well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chloramines well in excess of the MRDL could experience stomach discomfort or anemia.
Chlorine (ppm)	MRDL = 4		MRDL = 4	MRDL = 4	Water additive used to control microbes.	Some people who use water containing chlorine well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chlorine well in excess of the MRDL could experience stomach discomfort.
Chlorine dioxide (ppm)	MRDL = .8	1000	MRDL = 800	MRDLG = 800	Water additive used to control microbes.	Some infants and young children who drink water containing chlorine dioxide in excess of the MRDL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorine dioxide in excess of the MRDL. Some people may experience anemia.
Chlorite (ppm)	1		1	0.8	By-product of drinking water chlorination.	Some infants and young children who drink water containing chlorite in excess of the MCL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorite in excess of the MCL. Some people may experience anemia.
*	*	*		*	*	*
Copper (ppm)	AL=1.3		AL=1.3	1.3	Corrosion of household plumbing systems; Erosion of natural deposits.	Copper is an essential nutrient, but some people who drink water containing copper in excess of the action level over a relatively short amount of time could experience gastrointestinal distress. Some people who drink water containing copper in excess of the action level over many years could suffer liver or kidney damage. People with Wilson's disease should consult their personal doctor.
*	*	*		*	*	*
Synthetic organic contaminants including pesticides and herbicides:						

APPENDIX A TO SUBPART O—REGULATED CONTAMINANTS—Continued

Contaminant (units)	Traditional MCL in mg/ L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
Di(2-ethylhexyl) adipate (ppb).	.4	1000	400	400	Discharge from chemical factories.	Some people who drink water containing di(2-ethylhexyl) adipate well in excess of the MCL over many years could experience toxic effects such as weight loss, liver enlargement or possible reproductive difficulties.
Di(2-ethylhexyl) phthalate (ppb).	.006	1000	6	0	Discharge from rubber and chemical factories.	Some people who drink water containing di(2-ethylhexyl) phthalate well in excess of the MCL over many years may have problems with their liver, or experience reproductive difficulties, and may have an increased risk of getting cancer.
*	*	*		*	*	*

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