COTTONWOOD
ENVIRONMENTAL LAW CENTER

12/23/2022

Custer Gallatin National Forest
Attn: Forest Supervisor, Mary Erickson P.O. Box 130
Bozeman, MT 59771

RE: Preliminary Environmental Assessment for the East Crazy Inspiration Divide Land Exchange

Dear Ms. Erickson,

I am writing on behalf of Cottonwood Environmental Law Center ("CELC"), a Bozeman-based conservation organization. Thank you for the opportunity to provide public comment to the Custer Gallatin National Forest ("Forest Service") on the Preliminary Environmental Assessment for the East Crazy Inspiration Divide Land Exchange ("EA").

I. Cottonwood comments on the East Crazy Inspiration Divide Land Exchange

This proposal is not necessary. Cottonwood has members that are also members of the Crow Tribe that have Treaty Rights that allow them to access public land behind corners in the Crazy Mountains. The Fort Laramie Treaties of 1851 and 1868 allow Cottonwood members that are also Crow members to access federal land that might otherwise be unavailable for hunting and spiritual ceremonies.

a. By ignoring corner crossing as a legitimate public access option, the Forest Service has not adequately analyzed a reasonable range of alternatives to the land exchange.

The EA states that the land swap is needed to enhance public access and improve recreational opportunities in the Crazy Mountains.[1] These goals could be accomplished by using corner crossing opportunities to adjust existing trail systems so that they travel through public land. The Forest Service failed to analyze this alternative option in its EA.

[1] EA, pg 7

The National Environmental Policy Act ("NEPA")[2] requires the Forest Service to "evaluate reasonable alternatives to the proposed action, and, for alternatives that the agency eliminated from detailed study, briefly discuss the reasons for their elimination." [3] Reasonable alternative is defined as "a reasonable range of alternatives that are technically and economically feasible, and meet the purpose and need for the proposed action." [4] Corner crossing is a reasonable alternative to the proposed action, and it should have been analyzed in the EA.

The Pacific Railway Act of 1862 created the private-public checkerboard structure that now exists in the Crazies. The Homestead Act of 1862 gave U.S. citizens the right to claim ownership and access those public land parcels. The Railway Act allows homesteaders to access federal land. When these two acts are coupled, the right for citizens to use corner crossing to access public land becomes clear. Why? Because there were no other legal means of accessing the landlocked public parcels that were promised to homesteaders.

The Federal Land Policy and Management Act of 1976 ("FLPMA") ended the Homestead Act and phased out the practice of homesteading, but it explicitly reserved previously-established land use rights:

> *"Nothing in this Act, or in any amendment made by this Act, shall be construed as terminating any valid lease, permit, patient, right-of-way, or other land use right or authorization existing on the date of approval of this Act"* [5]

Because settlers had a right to cross corners to access federal land they were homesteading under the Homestead Act, the provision of FLPMA cited above retained the federal government and public's right to access public land behind corners of private property. This right is also retained by the public under the Ninth Amendment of the U.S. Constitution.

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[2] 42 U.S.C. § 4321 et seq.
[3] § 1502.14 National Environmental Policy Act NEPA Implementing Regulations, May 20, 2022
[4] National Environmental Policy Act NEPA Implementing Regulations, May 20, 2022 pg 48
[5] FLPMA, Title VII, Sec. 701.

Linn County Bank v. Hopkins (1892) established that "two tracts of land touching only at one point are not contiguous," confirming that two parcels of private land touching at one point are *not* an impassable barrier to homesteaders who were seeking to cross from one parcel of public land to another. Therefore, the right to access public land via corner crossing still stands.

While corner crossing may not be the final solution to land access/management issues in the Crazies, it is a reasonable alternative that was never included or analyzed in the Forest Service's reasonable range of alternatives. An alternative that rerouted existing trails so that they cross publicly-accessible corners could negate the need to swap entire land parcels.

The Forest Service should complete a supplementary EA or full Environmental Impact Statement that considers corner crossing as an alternative to the proposed land parcel swaps. At the very least, the Forest Service is required to discuss why the corner crossing option was not included in the current EA.

b. The Forest Service did not analyze the indirect and cumulative impacts of increasing the Yellowstone Club's ski terrain, and therefore it did not meet NEPA process obligations.

The Montana DEQ has issued the Yellowstone Club a permit to make snow using treated wastewater near Eglise Mountain. The Forest Service violated NEPA by failing to analyze the Yellowstone Club applying for (and receiving) an additional permit to blow snow pollution on the newly acquired and adjacent land. This is a reasonably foreseeable action. Cottonwood has challenged the snow-making permit for violations of the Montana Environmental Policy Act and Montana Constitution. In particular, the Montana DEQ failed to address the impacts of the snow melting, and pharmaceutical pollution reaching the tributaries and main stem of the Gallatin River. The U.S. EPA and Montana DEQ have generated science that raises significant questions about the effects of pharmaceuticals on fish, amphibians, and humans. Cite.

The EA fails to account for the indirect and cumulative impacts of this land transfer by failing to analyze the environmental impacts of snowmaking using treated wastewater on the YC's newly acquired land. The indirect impacts are pharmaceuticals polluting the Gallatin River and its tributaries. The cumulative impacts include the impacts of the reasonably foreseeable snowmaking combined with the impacts of the already permitted snowmaking.

Given the fact that the DEQ has already granted the YC a permit[6] to make snow using treated wastewater, it is a reasonably foreseeable action that the YC would spray snow made from treated wastewater on the new ski terrain it would acquire during the land swap. The impacts of spraying treated wastewater on this newly acquired land were not analyzed in the EA. Therefore, no analyses have been performed to determine how the treated wastewater would impact the Inspiration Divide area of the land swap. The Inspiration Divide area includes numerous Gallatin River tributary streams, including Third Yellow Mule Creek and Muddy Creek.

The EA failed to analyze the indirect and cumulative impacts of YC snowmaking in this area, including, but not limited to: pharmaceutical pollution, nutrient loading, human health impacts, and wildlife impacts.

/s/ John Meyer
JOHN MEYER

[6] https://deq.mt.gov/News/pressrelease-folder/news-article5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

December 18, 2008

EPA-SAB-09-007

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: SAB Advisory on Aquatic Life Water Quality Criteria for Contaminants of Emerging Concern

Dear Administrator Johnson:

The Science Advisory Board (SAB) Ecological Processes and Effects Committee, augmented with additional experts, reviewed the EPA White Paper titled *Aquatic Life Criteria for Contaminants of Emerging Concern* ("White Paper"). EPA's 1985 *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* ("Guidelines") specify procedural and data requirements for deriving ambient water quality criteria for the protection of aquatic life (aquatic life criteria). The Agency is faced with a number of technical issues and challenges in deriving aquatic life criteria for contaminants of emerging concern (CECs). To address these technical issues, the Office of Water and Office of Research and Development have proposed recommendations for interpreting and/or adapting principles in the 1985 Guidelines. EPA's White Paper describes the proposed recommendations, focusing in particular on CECs that disrupt endocrine function in animals. The White Paper also explores these recommendations in the context of a case example CEC, ethynylestradiol, a synthetic pharmaceutical estrogen.

EPA's Office of Water (OW) requested that the SAB: 1) comment on the technical merit, practicality, and implementability of recommendations in the White Paper; 2) comment on whether the White Paper identifies the appropriate issues to be addressed in deriving aquatic life criteria for CECs; 3) suggest ways to improve the utility of the ethynylestradiol case example; and 4) offer other suggestions to assist the Agency in implementing recommendations in the White Paper. The enclosed advisory report provides the advice and recommendations of the SAB.

Overall, the SAB finds that, in the White Paper, EPA has identified appropriate technical issues to be considered in deriving aquatic life criteria for CECs. However, EPA was constrained by the 1985 Guidelines which, although excellent when developed, were never envisioned for use with the current CECs. The 1985 Guidelines established a complex process to evaluate risk by using information from many areas of aquatic toxicology. The SAB finds that the derivation of aquatic life criteria needs to be more broadly risk-based, using a transparent and consistent framework that provides necessary flexibility not presently possible within the algorithm approach of the 1985 Guidelines. Hence, the SAB recommends that, to the extent practicable, the derivation of aquatic life criteria be risk-based using the principles defined in EPA's 1998 *Guidelines for Ecological Risk Assessment* and the more recent *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment: A Report of the U.S. EPA Science Advisory Board* (U.S. EPA Science Advisory Board, 2007).

Within the context of risk-based aquatic life criteria, the SAB recommends that EPA consider issues in addition to those identified in the White Paper, and that the Agency customize and update the 1985 Guidelines to address these issues. In particular, we urge EPA to include consideration of probable direct and/or indirect impacts on food webs, ecological processes and services, and endangered or unique species of special value or concern. These issues could be incorporated through development of a conceptual model as exemplified in Figure 1 of the enclosed report. We also recommend that EPA develop multiple lines of evidence, consider uncertainty, and bolster consideration of mode of action in the criteria development process. We suggest that mammalian pharmacology data available from the drug discovery process, genomics/proteomics/metabolomics, and quantitative structure activity relationships (QSARs) be used to screen CECs for modes of action and assess potential multiple modes of action for individual CECs. To increase efficiency, parallel processes could then be considered when developing aquatic life criteria for compounds with similar modes of action.

The SAB generally supports EPA's proposed approaches for interpreting and/or adapting principles in the Guidelines to address technical issues discussed in the White Paper. However, we have noted specific concerns about these approaches and provide recommendations to improve the White Paper. We emphasize that many CECs will require special consideration because they do not fit the effect model discussed in the White Paper (i.e., disruption of endocrine function), or may be not be well enough understood to allow appropriate judgment of their mode of action. In addition, we note that specific issues such as the potential for joint interactions affecting toxicity exist for many CECs that may occur in mixtures in the environment and which may also interact with environmental variables such as temperature. Such possible interactions should be considered. As more information is developed to account for the interactive effects of CECs, it is possible that water quality criteria may be revised up or down for individual CECs based upon data on joint interactions; use of such data would produce more risk-based criteria.

The SAB finds that the ethynylestradiol illustrative example in the White Paper is a well-written and thorough review of the existing literature. It illustrates the complexities inherent in generating aquatic life criteria for CECs. However, we do provide recommendations to clarify the example and make it more useful.

The SAB also provides other suggestions to assist EPA in implementing the proposed recommendations in the White Paper. These suggestions focus on: data collection and research activities; developing tissue residue-based criteria; developing exposure and effect indicators that could be used in future derivation of criteria; special considerations for sensitive or commercially/recreationally important species; and obtaining input from private industry and state governments.

Thank you for the opportunity to provide advice on this important topic. The SAB looks forward to receiving the Agency's response to this advisory and to updates on any additional follow-up activities.

Sincerely,

/Signed/ ***/Signed/***

Dr. Deborah L. Swackhamer, Chair
Science Advisory Board

Dr. Judith L. Meyer, Chair
Ecological Processes and Effects Committee

U.S. Environmental Protection Agency
Science Advisory Board
Ecological Processes and Effects Committee

Augmented for the Advisory on the EPA's Aquatic Life Water Quality Criteria

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List of Acronyms

ACR - Acute to Chronic Ratio
AhR - Aryl Hydrocarbon Receptor
ALC - Aquatic Life Criteria
AV - Acute Value
CCC - Criterion Continuous Concentration
CEC - Contaminant of Emerging Concern
CMC - Criterion Maximum Concentration
CV - Chronic Value
CYP3A - Cytochrome P450 3A
EC_{10} - Concentration causing an effect in 10 percent of the test organisms
EC_{20} - Concentration causing an effect in 20 percent of the test organisms
EC_x - Concentration causing an effect in x percent of the test organisms
EDC - Endocrine Disrupting Compound
EE2 - Ethynylestradiol
ELS - Early Life Stage Test
EPA - U.S. Environmental Protection Agency
ER - Estrogen Receptor
F_0 - The initial parent generation in a multigeneration reproduction study
F_1 - The first offspring generation in a multigeneration reproduction study
FDA - U.S. Food and Drug Administration
FFLC - Fish Full Life Cycle
FIFRA - Federal Insecticide Fungicide and Rodenticide Act
LC50 - Test concentration causing in mortality to 50% of the test population
LOEC - Lowest Observed Effect Concentration
LOEL - Lowest Observed Effect Level
NOAA - National Oceanic and Atmospheric Administration
NOEC - No Observed Effect Concentration
NOEL - No Observed Effect Level
OECD - Organization for Economic Cooperation and Development
ORD - U.S. Environmental Protection Agency Office of Research and Development
OSWER - U.S Environmental Protection Agency Office of Solid Waste and Emergency Response
OW - U.S. Environmental Protection Agency Office of Water
PBPK - Physiologically Based Pharmacokinetic Model
PDBE - Polybrominated diphenyl ether
PFOS - Perfluorinated octynyl sulfonate
PLC - Partial Life Cycle
QSAR - Quantitative Structure Activity Relationship
ROPC - Receptor of Potential Concern
SAB - U.S. Environmental Protection Agency Science Advisory Board
SETAC - Society of Environmental Toxicology and Chemistry
SSD - Species Sensitivity Distribution
SSRI - Selective Serotonin Reuptake Inhibitor
TSCA - Toxic Substances Control Act
USDA - U.S. Department of Agriculture

1. EXECUTIVE SUMMARY

EPA's Office of Water (OW) requested that the Science Advisory Board (SAB) provide advice on the Agency's proposed recommendations pertaining to derivation of water quality criteria for the protection of aquatic life (aquatic life criteria) for contaminants of emerging concern (CECs). The Agency's proposed recommendations are provided in a white paper titled *Aquatic Life Criteria for Contaminants of Emerging Concern* (White Paper). The White Paper, prepared by the EPA Office of Water/Office of Research and Development Emerging Contaminants Workgroup, was reviewed by the SAB Ecological Processes and Effects Committee (Committee). To augment the expertise on the Committee for this advisory activity, several environmental toxicologists with specific knowledge of the effects of endocrine disrupting chemicals also participated in the review.

EPA's Office of Water develops ambient water quality criteria that provide guidance to states and tribes for adoption of water quality standards. The EPA document, *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (hereafter referred to as the "Guidelines") (Stephan et al., 1985), sets forth a methodology for deriving ambient water quality criteria for the protection of aquatic life. The Guidelines specify various data and procedural recommendations for evaluating risk and deriving criteria and also define general risk management goals for the criteria. Most of EPA's aquatic life criteria have been derived using methods in the Guidelines, and EPA has stated that the Agency intends to continue using the Guidelines to derive aquatic life criteria. However, EPA has also indicated that it faces a number of technical challenges in deriving aquatic life criteria for CECs. In its White Paper, the Agency described these technical challenges and proposed recommendations to interpret and/or adapt Guidelines principles to address the challenges. One of the Committee's key recommendations is that EPA incorporate risk assessment principles, as defined by the 1998 *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998), within the framework of the 1985 aquatic life criteria Guidelines. Criteria derived within the risk assessment framework will provide additional consistency with other ongoing work at EPA and will provide necessary flexibility not presently possible within the algorithm approach of the 1985 Guidelines. In this regard, it is suggested that EPA also consider recommendations and findings in the recent SAB report, *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment: A Report of the U.S. EPA Science Advisory Board* (U.S. EPA Science Advisory Board, 2007).

The term "contaminant of emerging concern" or CEC has been used by EPA to identify a variety of chemical compounds that have no regulatory standard, have been recently discovered in the natural environment because of improved analytical chemistry detection levels, and potentially cause deleterious effects to aquatic life at environmentally relevant concentrations. The Agency is particularly concerned about pharmacologically active chemical compounds and personal care products because: 1) they are commonly discharged at wastewater treatment plants, and 2) some of these compounds are designed to stimulate a physiological response in humans, plants, and animals.

The first part of EPA's White Paper (Part I), *General Challenges and Recommendations*, describes: 1) the technical challenges EPA faces in deriving aquatic life criteria for CECs; and 2) the proposed recommendations to address those challenges. The second part of the White Paper

(Part II), *Illustration of Recommendations Using Data for 17α – Ethynylestradiol (EE2)*, explores EPA's recommendations in the context of an example CEC, ethynylestradiol (EE2), which is a synthetic pharmaceutical estrogen. In its charge to the SAB, EPA requested comments on the technical merit, practicality, and implementability of recommendations in the White Paper to address: a) relevance of acute toxicity effect concentrations in setting aquatic life criteria for CECs; b) defining minimum data requirements regarding taxonomic coverage in toxicity testing; c) use of non-resident species in criteria development; d) defining appropriate chronic toxicity data; e) selection of effect endpoints upon which to base criteria; and f) involvement of an expert panel in the criteria development process. In addition, EPA asked the SAB to: comment on whether the Agency has identified the appropriate issues to be addressed in deriving aquatic life criteria for CECs; offer suggestions that may improve the utility of Part II of the White Paper; and offer suggestions that would assist the Agency in implementing proposed recommendations in the White Paper. In response to the charge questions, the Committee has provided comments and recommendations to improve the White Paper and assist EPA in deriving aquatic life criteria for contaminants of emerging concern.

Relevance of acute toxicity effect concentrations in deriving aquatic life criteria for CECs

Many CECs are physiologically active at concentrations orders of magnitude lower than those causing acute lethality, and concentrations sufficient to cause lethality may never occur in the environment. Therefore, in the White Paper the Agency recommends that, when sufficient information demonstrates a negligible risk of acute lethality for a CEC, the "criterion continuous concentration" (i.e., the concentration intended to protect against the longer term effects of exposure on survival, growth, and reproduction) be used to derive aquatic life criteria. In principle, the Committee supports EPA's suggestion to derive aquatic life criteria solely from criteria continuous concentrations (CCCs) for CECs when available information indicates that this is appropriate. However, we have recommended the following amendments in the White Paper:

- Not enough is known about some classes of CECs (e.g., nanoparticles) to determine whether acute toxicity needs to be taken into account in deriving aquatic life criteria. Therefore, all available data on any new class of CECs should be used in determining whether acute toxicity is likely to occur in environmentally relevant settings.

- Some CECs appear to have differing modes of action for acute toxicity vs. chronic toxicity. Lowest Observed Effect Concentrations (LOECs) and LC50s (test concentrations that result in mortality to 50% of the test population) are within one order of magnitude for some CECs, making acute toxicity relevant in deriving aquatic life criteria. Therefore, "criteria maximum concentrations" (CMCs) to protect against acute effects should be derived for compounds where LOECs are found to be within 1-2 orders of magnitude of LC50s.

- Pulsed discharges of CECs may occur during natural disasters and spills and result in atypically high concentrations in the environment. Therefore, criteria documents for CECs should always identify the CMC as a data gap when it is not used to derive criteria. Furthermore, as discussed in Section 4.1.1 of this report, aquatic life criteria derivations should consider whether concentrations capable of causing acute toxicity may occur during

these pulsed discharges. Under this scenario, it may be important to use CMCs in addition to CCCs in the aquatic life criteria derivation process.

- Mixtures of CECs with comparable modes of action may result in higher effective concentrations than would be expected based on the concentrations of any single compound. Therefore, research is needed to determine how aquatic life criteria for CECs can take into account the fact that aquatic organisms are exposed to mixtures of chemicals with similar modes of action.

- To maintain transparency in cases when CMCs are not used in criteria development, a summary of all available data that provide information on the relevance of acute toxicity should be included in any aquatic life criteria document.

Defining minimum data requirements regarding taxonomic coverage in toxicity testing

In the White Paper, EPA has recommended that, for CECs without complete chronic toxicity data sets to fulfill minimum data requirements, there be an evaluation of whether sufficient information exists to conclude that certain taxa would not be sensitive to a particular chemical. Thus, EPA recommends that the minimum data requirements for taxonomic coverage (specified in the Guidelines) be viewed as information requirements instead of toxicity test requirements. The Committee understands and appreciates the desirability of avoiding the extra work required to develop chronic data on species that are unlikely to be sensitive to certain CECs. However, we emphasize that it is equally important to perform adequate testing to ensure protection of aquatic life. We generally support the broad taxonomic coverage requirements in the Guidelines but agree that these could be viewed as information requirements instead of test requirements. We find that, if sufficient information exists on the insensitivity of certain taxa to particular chemicals, expert judgment concerning data development should prevail. This would result in a more focused approach to data development, keeping in mind weight of evidence rather than a requirement for testing all taxa specified in the Guidelines. As indicated below, we have provided specific recommendations to improve the process of determining appropriate taxonomic coverage to develop aquatic life criteria for CECs:

- EPA needs to define what constitutes a sufficiently robust set of chronic data for criteria development. Although the example used in the White Paper generally illustrates EPA's proposed process for making decisions concerning taxonomic coverage, it would be helpful if EPA were more explicit in identifying what constitutes a "sufficiently robust set of chronic data" and "a reasonable understanding of the mode of action for the chemical that may allow inferences."

- The White Paper should place greater emphasis on information useful for development of aquatic life criteria, rather than just toxicity test requirements. Incorporating effects on ecological processes (e.g., food webs, nutrient cycling, primary production) rather than only target species would be valuable in criteria development, and would follow more recent scientific thinking.

- As further discussed in Section 4.1.2 of this advisory report, EPA should consider shifting from an approach requiring a minimum level of taxonomic coverage to the approach of determining receptors of potential concern (ROPCs).

- Examples showing the unanticipated effects of CECs on non-target organisms (e.g., the impact of antibiotics on plants and effect of atrazine on the quality of algae available as food for other species) should be used in Part I of the White Paper to help describe how the aquatic life criteria development process needs to be more flexible depending on the compounds under evaluation.

Use of non-resident species in criteria development

Historically, EPA has not included data from toxicity testing with non-resident species in the actual criteria derivation process. In the White Paper, EPA recommends that "non-resident" species data be used in the aquatic life criteria derivation process if such data would enable a better estimation of species sensitivity distributions. The Committee agrees; we find that the exclusion of non-resident species data from criteria derivation is biologically and practically inconsistent with the intent of the Guidelines (i.e., providing an objective, internally consistent, appropriate, and feasible way of deriving national criteria). We have provided a number of specific recommendations concerning the use of non-resident species data:

- Because of the frequent use of non-resident species in toxicity testing, such species could potentially be over-represented in aquatic life criteria databases. Therefore, the proportion of the data set that should include resident species should be carefully evaluated by an expert advisory panel assembled to review each criterion.

- Although non-resident species can be used for criteria development, in no case should a criterion be developed on the basis of non-resident species data alone. Although the Guidelines have been designed to protect aquatic communities (including endangered species), EPA should support research that addresses the suitability of the use of surrogate species in assessing the responses of various resident aquatic species (e.g., endangered or long-lived species and species with varying life history strategies) to endocrine disrupting and other CECs.

- Differences in strains, husbandry, health, and parasite and pathogen load (i.e., other stressors) contribute to variations in toxicity test response and thus should be considered in the criteria development process.

- Issues to be considered in prioritizing species responses should include their vulnerability, endangerment status, and recreational, commercial and ecological value.

- Non-resident and resident species data must meet test guidelines for data and method validity.

Defining appropriate chronic toxicity data

In the White Paper, EPA recommends that the Guidelines requirements for chronic toxicity test data be tightened by requiring at least one full life-cycle test for a fish (life-cycle tests are already required for invertebrates) unless there is a compelling body of information indicating that life processes outside the early life stage or partial life-cycle exposure/observation window are not critical to capturing the biologically important effects of chronic exposure to the chemical. As further discussed in Section 4.1.4 of this report, the Committee strongly supports the use of fish full life-cycle test data in appropriate cases to develop aquatic life criteria. We find that it would be useful to develop a tiered testing approach to determine an appropriate rationale for use of data from fish full life-cycle, partial life-cycle, and possibly multigenerational testing to derive aquatic life criteria for CECs with parallel modes of action. We have provided additional recommendations concerning the requirement for chronic toxicity data.

- EPA should critically review data dealing with transgenerational responses of aquatic species and evaluate whether this additional testing would provide significant new information to inform the criteria development process.

- Test guidelines should include flexibility to include assessment of key developmental events, and professional judgment from an expert panel should be used to evaluate the relevance of non-traditional endpoints such as immune function and organism behavior. Behavioral endpoints (e.g., predator-prey interactions) may hold some promise for criteria development if the assays can be related to population-level responses and variability can be understood.

Selection of effect endpoints upon which to base criteria

In the White Paper, EPA has identified a number of endpoints that could be considered (in addition to the "traditional" endpoints of survival, growth, and reproduction) in developing aquatic life criteria for CECs. Moreover, the Agency has recommended more thorough exploration of the use of such endpoints in criteria development. Generally, the Committee agrees that EPA should continue to explore the possibility of using sublethal endpoints in helping to set aquatic life criteria. However, we caution EPA that such "non-traditional" endpoints must ultimately be linked to population endpoints (i.e., potential impacts to populations must be considered, not solely effects on individual organisms). We have provided a number of recommendations concerning use of these endpoints:

- EPA should use "non-traditional measures" to develop an understanding of and confirm mode of action of CECs.

- As further discussed in Section 4.1.5 of this advisory report, EPA should use human health information and toxicology tools (genomics/physiologically-based pharmacokinetic models [PBPKs]) to reduce the uncertainty of aquatic life criteria for CECs.

- EPA should consider the following key points concerning use of the non-traditional endpoints discussed in the White Paper: 1) vitellogenin in males and juveniles is an indicator

Involvement of an Expert Panel

Because the development of aquatic life criteria for CECs may be dependent on technical interpretations of a wide range of toxicological information, EPA has proposed that expert panels be used to provide professional judgment during criteria development. The Committee strongly supports the use of panels comprised of experts with a balanced range of perspectives to provide professional judgment during the process of developing aquatic life criteria. However, we note that the use of expert panels could lead to less consistency in how aquatic life criteria are determined if the panels are not selected carefully. To help alleviate this potential problem, we recommend that EPA develop specific guidance on the role of expert panels in problem formulation, data evaluation, and generation of advice to support criteria development. Specifically, we recommend that:

- The process for the use and selection of expert panels be described in detail and that it be transparent.

- The panels be given clear charges and understanding of their roles in the process.

- EPA take advantage of similar expert panel processes occurring in Europe and Asia to the extent possible.

Technical issues addressed in the White Paper

The Committee was asked to comment on whether EPA has identified the appropriate technical issues in the White Paper, and whether there are additional important issues that the Agency has not identified. We find that EPA has identified appropriate technical issues in the White Paper. However, as further discussed in Section 4.1.6 of this advisory report, we recommend that the Agency address additional issues to customize and update the 1985 Guidelines and thereby increase the flexibility and specificity of the aquatic life criteria derivation process. The following additional issues are of particular importance:

- In the White Paper, EPA should articulate principles that can be applied when modifying the 1985 Guidelines to develop water quality criteria for CECs. In particular, as further discussed in Section 4.2 of this advisory report, these principles should address: 1) obtaining a wide range of inputs from diverse perspectives; 2) developing a conceptual model as exemplified in Figure 1 of this report; 3) developing criteria for using multiple lines of evidence; and 4) identifying/including uncertainties (quantitative and qualitative) associated with criteria development.

- It is particularly important that understanding and presenting uncertainty become an intrinsic part of the aquatic life criteria development process. For example, the uncertainties inherent in understanding modes of action, concentration-response relationships, extrapolation of sensitivities, and derivation of ecological effects should be quantified and/or described in a narrative sense.

- EPA should bolster the consideration of mode of action in the aquatic life criteria derivation process. It is important that aquatic life criteria for CECs take into account the fact that aquatic organisms are exposed to mixtures of these chemicals. As more information becomes available to account for the interactive effects of CECs, it is possible that water quality criteria may be revised up or down for individual CECs based upon data on joint interactions. Use of such data would produce more risk-based criteria. Understanding the mode of action of a compound is very important in estimating mixture interactions. In fact, pharmacological mode of action is the basis for evaluating multiple drug prescriptions in humans by pharmacists. EPA should use mammalian pharmacology data available from the drug discovery process, genomics/proteomics/metabolomics and quantitative structure activity relationships (QSARs) to screen CECs for modes of action, identify CECs that may act in an additive manner as mixtures, and assess potential multiple modes of action for individual CECs. The Committee strongly recommends enhancing the communication and data transfer capabilities between agencies such as the U.S. Food and Drug Administration (FDA) and EPA to provide mode of action information.

- In deriving aquatic life criteria for CECs, EPA should bolster consideration of ecology and indirect ecological effects and also give special consideration to the protection of threatened and endangered species.

Part II of the White Paper

Part II of the White Paper uses ethynylestradiol (EE2) as a model chemical to illustrate the technical issues presented and provide a basis for understanding the recommendations in Part I. The Committee was asked to offer suggestions to improve the utility of Part II. The Committee finds that Part II is a well-written and thorough review of the existing literature on EE2. We agree that EE2 is an appropriate initial focal CEC given the extensive data available relative to other CECs and the ease with which it illustrates the complexities inherent in generating CEC-specific water quality criteria. We have provided a number of specific recommendations to improve Part II:

- EPA should explicitly recognize that EE2 is unique in being a data-rich CEC. The White Paper should highlight the fact that the Agency's interest in CECs goes beyond endocrine-active substances, and discuss how the process outlined for EE2 might be applied to other substances, particularly those for which less data are available and which have different modes of action.

- The Committee suggests that some of the illustrative pieces of Part II could also be presented in Part I in the form of succinct text boxes illustrating key concepts derived from the various

recommendations, and that the recommendations could be best illustrated if the text boxes were not restricted to EE2 but rather included other CECs.

- Part II should discuss how the individual effects of EE2 on biota might be changed by mixtures of compounds, especially those with similar modes of action.

- As stated previously, a criterion should not be developed on the basis of non-resident species data alone. Therefore, Part II should indicate that resident species data, especially data from life-cycle tests using resident species, remain extremely valuable and that results from non-resident species tests may not be generalized to resident species without comparative sensitivity studies.

- The possibility of transgenerational effects should be explicitly addressed in Part II.

- A broader array of endpoints should be included in Part II. For example, although EE2 is a potent estrogen receptor agonist, it can also affect the central nervous system (through steroid biotransformation), and an endpoint should be considered to reflect this. Part II should also note that relevant and reproducible endpoints indicative of adverse population level effects need to be used.

- As further discussed in Section 4.3 of this advisory report, the use of weight of evidence is implicit in the evaluation done in Part II, and should be explicitly discussed. Furthermore, when appropriate data are available, EC_x values (i.e., concentration causing an effect in x percent of the test organisms) should be used in Part II instead of NOECs/LOECs (i.e., no observed effects concentrations/lowest observed effects concentrations). The use of the EC_x values takes advantage of more of the information from a toxicity test, and confidence intervals can be generated. The raw data from most toxicity tests can be used to calculate an EC_x value. The selection of a specific EC_x value for derivation of an aquatic life criterion depends upon the level of protection or effect that decision makers are willing to accept or detect in the field. However, an EC_{20} has been used for most species and an EC_{10} has been used for threatened and endangered species. The Committee notes that if data are not available to calculate an EC value, EPA should recommend in Part II that such values be developed and used in future criteria derivation. Published data sets are available for much of the fathead minnow and other species toxicity tests conducted at EPA's Duluth Laboratory and other laboratories. If the data are available then the regression should be calculated. The Committee also notes that if the data are not available then the value of the NOEL/LOEL (no observed effect level/lowest observed effect level) should be carefully evaluated. Without information on the variability of the test results, and consequently the statistical power, it is not clear what the values represent.

- As further discussed in Section 4.3 of this report, the clarity and transparency of Part II could be improved in a number of areas.

Suggestions to assist EPA in implementing recommendations discussed in the White Paper

In Section 4.4 of this advisory report, the Committee has provided comments and recommendations to assist EPA in implementing the approaches discussed in the White Paper. The following key recommendations are provided:

- As noted at the beginning of this Executive Summary, the principles for conducting Ecological Risk Assessment should be incorporated into the process of deriving aquatic life criteria for CECs. The Committee recommends that, pending revision of the 1985 Guidelines, EPA develop a separate process document that discusses the intended application of aquatic life criteria for CECs. This process document should establish linkages between the Guidelines, EPA's Ecological Risk Assessment Principles (U.S. EPA, 1992, 1998), the recent SAB report, *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment: A Report of the U.S. EPA Science Advisory Board* (U.S. EPA Science Advisory Board, 2007), and the White Paper.

- EPA should prioritize the list of CECs for which aquatic life criteria will be developed. Data needs for these chemicals should be identified, and EPA should fund the research and data collection activities necessary to support aquatic life criteria development for CECs. In this regard, the Committee recommends that EPA's Office of Water and Office of Research and Development look for opportunities to leverage EPA research with ongoing research in other federal agencies, international agencies, and industry groups.

- EPA should incorporate use of conceptual models and ecosystem-based criteria into the process of deriving aquatic life criteria for CECs. The Committee notes that EPA programs are moving toward developing more comprehensive ecosystem-relevant criteria that take into consideration population-community structure, ecosystem functions and processes, and ecosystem services. Accordingly, the Committee notes that it is important to develop the link between the protected resource, the assessment endpoint, and the measurement endpoint, and a conceptual model would clarify those linkages.

- For bioaccumulative CECs where food chain transfer is a concern, EPA should consider developing tissue-based criteria (i.e., expressing the criterion as a concentration of the pollutant in fish tissue rather than a concentration in the water).

- EPA should also consider expanding the definition of CECs to include chemicals and other substances of increasing environmental concern due to anthropogenic activities and inadequate regulatory approaches. The White Paper focuses on endocrine disrupting chemicals. However, the Committee notes that some CECs do not fit the effect model of endocrine disrupting chemicals, or are not well enough understood at this time to allow a judgment of their mode of action. Nanoparticles are an example of such a class of compounds. Additional work is needed to further develop recommendations for deriving aquatic life water quality criteria for these other kinds of chemicals.

- In Section 4.4 of this advisory report the Committee recommends additional research to address important issues such as: the effects of mixtures of CECs, interactions between CEC

and other stressors, modes of action of CECs, comparative sensitivities of resident and non-resident species, and use of field study results to inform the derivation of aquatic life criteria. The Committee also recommends that the discussion of taxonomic coverage in the White Paper be expanded to include specific recommendations concerning derivation of criteria to protect marine organisms. EPA's 1985 Guidelines call for assessment of marine organisms in the same manner as freshwater organisms. However, due to specific issues unique to marine organisms, such as physiological requirements (e.g., maintenance of salt balance) and life-history strategies (e.g., reproduction tied to tidal cycles), more specific guidance for CECs is likely needed. We suggest that such guidance may be best addressed by convening a "Pellston" type workshop (Society of Environmental Toxicology and Chemistry, 2008) that is comprised of experts from multiple disciplines and types of organizations.

2. INTRODUCTION

EPA's Office of Water (OW) requested that the Science Advisory Board (SAB) provide advice on the Agency's proposed recommendations pertaining to derivation of water quality criteria for the protection of aquatic life (aquatic life criteria) for contaminants of emerging concern (CECs) such as pharmaceuticals and personal care products that are commonly discharged in municipal wastewaters. EPA's proposed recommendations are provided in a white paper titled *Aquatic Life Criteria for Contaminants of Emerging Concern* (White Paper). The White Paper, prepared by the EPA Office of Water and Office of Research and Development Emerging Contaminants Workgroup, was reviewed by the SAB Ecological Processes and Effects Committee (Committee). To augment the expertise on the Committee for this advisory activity, several environmental toxicologists with specific knowledge of the effects of endocrine disrupting chemicals also participated in the review. The Committee held a public teleconference on June 23, 2008 to discuss its charge and receive a briefing from EPA, met on June 30th – July 1, 2008, and held a follow-up discussion in a public teleconference on September 16, 2008.

EPA's Office of Water is charged with protecting aquatic life, wildlife, and human health from the adverse water-mediated effects of anthropogenic pollutants. In support of this mission, OW develops ambient water quality criteria that serve as guidance to states and tribes for adoption of water quality standards. The EPA guidance document, *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (Guidelines) (Stephan et al., 1985), sets forth a methodology for deriving ambient water quality criteria for the protection of aquatic life. The Guidelines specify various data and procedural recommendations for criteria derivation and also define general risk management goals for the criteria. Most of EPA's aquatic life criteria have been derived using methods in the Guidelines. EPA has informed the Committee that the Agency intends to continue using the Guidelines to derive aquatic life criteria. However, EPA has also stated that it faces a number of technical challenges in deriving aquatic life criteria for CECs. The white paper describes these technical challenges and proposes recommendations to interpret and/or adapt Guidelines principles to address the challenges.

The term CEC has been used by EPA to identify a variety of chemical compounds that have no regulatory standard, have been recently discovered in the natural environment because of improved analytical chemistry detection levels, and potentially cause deleterious effects to aquatic life at environmentally relevant concentrations. The Agency has indicated that it is particularly concerned about pharmacologically active chemical compounds and personal care products that are commonly discharged at wastewater treatment plants and may stimulate physiological responses in humans, plants, and animals. Many of these compounds are known to disrupt endocrine function in animals, and are thus referred to as endocrine disrupting chemicals. These chemicals may demonstrate low acute toxicity but cause significant reproductive effects at very low levels of exposure. In addition, the effects of exposure of aquatic organisms to CECs during the early stages of life may not be observed until adulthood. These chemicals may also have very specific modes of action that affect only certain types of aquatic animals (e.g., vertebrates such as fish). Therefore, EPA has suggested that traditional chronic toxicity test

endpoints specified in the Guidelines may not be sufficiently comprehensive, and Guidelines requirements for taxonomic coverage in toxicity testing may not be appropriate to derive aquatic life criteria for these chemicals. The White Paper focuses on recommendations to derive aquatic life criteria for endocrine disrupting chemicals.

The first part of EPA's White Paper (Part I), *General Challenges and Recommendations*, describes: 1) the technical challenges facing EPA in deriving aquatic life criteria for CECs; and 2) the recommendations to address those challenges. The second part of the White Paper (Part II), *Illustration of Recommendations Using Data for 17α – Ethynylestradiol (EE2)*, explores EPA's recommendations in the context of an example CEC, ethynylestradiol (EE2), which is a synthetic pharmaceutical estrogen. In its charge to the SAB, OW requested comments on the technical merit, practicality, and implementability of recommendations in the White Paper to address: a) relevance of acute toxicity effect concentrations in setting aquatic life criteria for CECs; b) defining minimum data requirements regarding taxonomic coverage in toxicity tests; c) use of non-resident species in criteria development; d) defining appropriate chronic toxicity data; e) selection of effect endpoints upon which to base criteria; and f) involvement of an expert panel in the criteria development process. In addition, OW asked the SAB for: comments on whether the Agency has identified the appropriate issues to be addressed in deriving aquatic life criteria for CECs; suggestions to improve the utility of Part II of the White Paper; and suggestions to assist the Agency in implementing proposed recommendations in the White Paper.

The Committee generally supports EPA's proposed approaches for interpreting and/or adapting Guidelines principles to address the technical challenges discussed in the White Paper. However in this advisory report we have recommended improvements to the approaches proposed in the White Paper. In addition, we have noted a number of specific technical and practical issues and caveats that should be considered by EPA when implementing the proposed approaches.

The Committee finds that, in the White Paper, EPA has identified appropriate technical issues and challenges to developing aquatic life criteria for CECs. However, we recommend that the Agency address additional issues to customize and update the Guidelines and thereby increase the flexibility and specificity of the aquatic life criteria derivation process. We find that EPA could clarify the process of developing aquatic life criteria for CECs by articulating a clear set of principles that could be applied when modifying the Guidelines. We also emphasize the importance of developing a conceptual model, as exemplified in Figure 1 of this advisory report, to guide the process of developing aquatic life criteria for CECs. The Committee finds that Part II of the White Paper is a well-written and thorough review of the existing literature on EE2 that illustrates the complexities inherent in generating aquatic life criteria for CECs. However, we have provided recommendations to improve the usefulness of this case example. In particular we suggest that EPA more explicitly describe how the illustration in Part II was developed from the recommendations in Part I of the White Paper.

The Committee has also provided other suggestions to assist EPA in implementing the proposed recommendations in the White Paper. These suggestions focus on: improved data collection and research activities; development of tissue residue-based criteria (i.e., expressing the criterion as a concentration of the pollutant in fish tissue rather than a concentration in the water) for bioaccumulative CECs where food chain transfer is a concern; use of indicators for

future development of criteria; special considerations for endangered or commercially/recreationally important species; obtaining input from private industry and state governments; and consideration of a mixture strategy for CECs.

3. CHARGE TO THE COMMITTEE

EPA's Offices of Water (OW) and Research and Development (ORD) sought advice from the Science Advisory Board on the scientific and technical merit of a draft white paper on aquatic life water quality criteria (ALC) for contaminants of emerging concern (CEC). The white paper developed by the EPA Emerging Contaminants Workgroup describes how the Agency intends to address the challenges it faces in developing ALC for CECs. The specific charge questions below were provided to the Committee:

1. The following recommendations have been developed to address important technical challenges and issues in deriving water quality criteria for CECs. Please comment on the technical merit, practicality, and implementability of the recommendations addressing the following issues as described in Part I of the white paper and the ethynylestradiol (EE2) case study in Part II.

   a. Relevance of Acute Toxicity Effect Concentrations in Setting ALC for CECs:

   Criteria consist of a Criterion Maximum Concentration (CMC), intended to address acute lethality and a Criterion Continuous Concentration (CCC), intended to address effects of chronic exposures on survival, growth, and reproduction. Many CECs are physiologically active at concentrations orders of magnitude lower than those causing acute lethality, and the high concentrations sufficient to cause lethality may never occur in the environment. Rather than rotely requiring a robust acute toxicity data set for such chemicals, the workgroup recommends that aquatic life criteria consist of only a CCC and that no CMC be derived, when sufficient information demonstrates risks of acute lethality are negligible.

   b. Defining Minimum Data Requirements Regarding Taxonomic Coverage:

   If an acute criterion is not calculated, then the CCC cannot be calculated using the acute to chronic ratio (ACR) approach and must be instead calculated directly from chronic toxicity data. Procedures for this are included in the Guidelines (pages 40-42), but they require that acceptable chronic toxicity tests be conducted for a broad range of taxonomic groups. In the case of many CECs, toxicological research tends to focus on organisms for which the mode of action is most relevant (e.g., vertebrates for estrogen mimics) and may have limited data coverage for other taxonomic groups that will likely be less sensitive. To avoid generation of resource-intensive chronic toxicity data for insensitive species that will have little impact on the final criterion, the workgroup recommends interpreting the minimum data requirements for taxonomic coverage as <u>information</u> requirements instead of <u>toxicity test</u> requirements. By this we mean that, rather than requiring a specific chronic toxicity test, the data requirement for certain taxonomic group expected to be insensitive might be met by a body of information demonstrating insensitivity of the taxon to the CEC.

c. Use of Non-Resident Species in Criteria Development:

Historically, EPA has not used data derived from toxicity testing with non-resident species in the actual criteria derivation process. Excluding species simply because they are not resident may be unnecessarily restrictive for the purposes of deriving national criteria, and may actually increase rather than decrease uncertainty. The workgroup recommends that non-resident species be considered for use in criteria derivation calculations, focusing on those species with widely used and standardized test methods and for which there is reason to believe that they would represent the sensitivity of comparable resident species. Furthermore, the workgroup specifically suggest accepting data for zebrafish (*Danio rerio*) and Japanese medaka (*Oryzias latipes*), to reflect international efforts toward data equivalency.

d. Defining Appropriate Chronic Toxicity Data:

For fish, the Guidelines allow the use of early life stage (ELS; egg to juvenile) exposures in lieu of full life-cycle (F_0 egg to F_1 offspring) or partial life-cycle (F_0 adult to F_1 juvenile) exposures for determining chronic toxicity of chemicals, unless there is reason to believe this is inappropriate. Current understanding of many CECs, particularly endocrine disrupting compounds (EDCs), is that important effects of these chemicals may not occur, or at least not be expressed, until after the ELS exposure window; in fact, partial life-cycle exposures may also miss important effects, such as those on sexual development. For such chemicals, it is clear that the definition of an acceptable chronic test must include consideration of key windows of exposure and effect (e.g., to include sexual development and reproduction in assessments of steroid hormone agonists/antagonists). However, even more broadly, the workgroup recommends that the Office of Water consider amending the chronic data acceptability requirements in the Guidelines to require at least one full life-cycle test for a fish (for invertebrates, life-cycle tests are already required) unless there is a compelling body of information indicating that life processes outside the early life stage or partial life-cycle exposure/observation window are not critical to capturing the biologically important effects of chronic exposure to the chemical. This amended requirement would include all chemicals, not just EDCs/CECs.

e. Selection of Effect Endpoints upon Which to Base Criteria

Aquatic life criteria typically are based on direct measures of survival, growth, and reproduction; other measures of response are generally not included unless they can be shown to be closely linked to expected changes in population dynamics. The workgroup supports this existing guidance, but recognizes that many CECs, particularly those with very specific modes of action like steroid hormone agonists/antagonists, will have data for a wide variety of histological, biochemical, physiological, or behavioral endpoints that may warrant consideration as measures of biologically important effects. The degree to which such measures can be used to infer population level effects is likely endpoint-, chemical-, and/or organism-specific, and developing a universal list of recommended endpoints is therefore beyond the scope of the workgroup's activities. Rather, the recommendation here is simply that criteria development more thoroughly explores such possibilities.

f. Involvement of an Expert Panel:

While not addressed explicitly in the Guidelines, the complexities involved in the assessment of many CECs, and the reliance on professional judgment in making some of the determinations required under the workgroup's recommendations, make clear the need to bring the best scientific knowledge to bear in the development of criteria for CECs, as well as other chemicals. The workgroup supports the recommendation from a Society of Environmental Toxicology and Chemistry (SETAC) Pellston workshop held in 2003 (Mount et al., 2003) indicating that criteria development should involve recruitment of an expert panel early in the process to insure that all relevant issues are considered during initial development of the criterion and to provide scientific perspective on decisions that are made as part of the process. Such a panel would not undermine the authority of the Agency to make policy decisions regarding criteria, but would ensure that such policy decisions are made from the best possible technical foundation. It is envisioned that expert panels would be formed around specific chemicals, or perhaps groups of chemicals with chemical or toxicological similarities (e.g., same mode of action).

2. Please comment on whether EPA has identified the appropriate issues to be addressed in deriving ALC for CECs. Are there additional important issues that EPA has not identified?

3. Part II of this white paper was specifically developed as a companion to Part I and focuses on the use of ethynylestradiol as a model chemical to illustrate the technical issues presented by the workgroup, as well as providing a basis for understanding the recommendations. Does the Committee have suggestions that may improve the utility of Part II of this white paper for the purposes stated above?

4. Does the Committee have suggestions that would assist EPA in implementing the proposed recommendations discussed in the white paper, particularly with respect to developing the necessary scientific data and information and/or providing expert scientific input at the appropriate stages of the risk assessment process?

4. RESPONSE TO CHARGE QUESTIONS

In the responses to each of the charge questions, the Committee has listed the key findings and comments as bullets. These comments are followed by numbered lists of the key recommendations.

4.1 Charge Question 1. Please comment on the technical merit, practicality, and implementability of recommendations addressing the following issues as described in Parts I and II of EPA's white paper on Aquatic Life Criteria for Contaminants of Emerging Concern: a) relevance of acute toxicity effect concentrations in setting aquatic life criteria for contaminants of emerging concern; b) defining minimum data requirements regarding taxonomic coverage; c) use of non-resident species in criteria development; d) defining appropriate chronic

toxicity data; e) selection of effect endpoints upon which to base criteria; and f) involvement of an expert panel.

4.1.1 Relevance of Acute Toxicity Effect Concentrations

As discussed in EPA's White Paper, aquatic life water quality criteria consist of a Criterion Maximum Concentration (CMC) intended to protect against severe acute effects of exposure to contaminants, and a Criterion Continuous Concentration (CCC) intended to protect against the longer term effects of exposure on survival, growth, and reproduction. EPA's Guidelines (Stephan et al., 1985) specify various data and procedural recommendations for criteria derivation. The CMC is determined based on available acute values (AVs). Acute values are median lethal concentrations or median effect concentrations from aquatic animal acute toxicity tests (48 to 96 hours long) meeting certain data quality requirements. The CCC is generally determined based on available chronic values (CVs), which are either: a) the geometric mean of the highest no observed effect concentration (NOEC) and the lowest observed effect concentration (LOEC) for effects on survival, growth, or reproduction in aquatic animal chronic tests; or b) in some recent criteria the EC_{20} (the test concentration that would cause a reduction in survival, growth, or reproduction in 20% of the test population) based on concentration-effect regression analyses of the toxicity test data. If chronic toxicity test data are not available for at least eight genera of aquatic organisms with a specified taxonomic diversity, the CCC is derived on the basis of an acute to chronic ratio (ACR) (i.e., the ratio of the AV to CV from parallel acute and chronic tests for at least three species with a specified taxonomic diversity). EPA's White Paper states that many CECs are physiologically active at concentrations orders of magnitude lower than those causing acute lethality, and that concentrations high enough to cause acute lethality may never occur in the environment. Therefore, in the White Paper the Agency recommends that, when sufficient information demonstrates a negligible risk of acute lethality for a CEC, the ALC for that contaminant could consist of only a CCC.

In principle, the Committee supports EPA's recommendation to derive aquatic life criteria directly from CCCs thus forgoing CMCs and ACRs. The Committee recognizes that, for many CECs, acute toxicity may only occur at concentrations several orders of magnitude greater than those likely to occur in the aquatic environment. The Committee also recognizes that the suggestion to forgo derivation of CMCs is not designed to truncate the aquatic life criteria development process, but rather is designed to allocate resources to areas most likely to affect the final aquatic life criteria and to avoid delaying implementation of aquatic life criteria due to a lack of data for species that are not likely to be sensitive. It is noted, however, that in cases of emergency releases of CECs (e.g., during floods or equipment failure), the potential for acute toxicity would need to be considered. Therefore, criteria documents for CECs should always identify the CMC as a data gap when it is not used to derive criteria.

Caveats concerning use of the Criterion Continuous Concentration for aquatic life water quality criteria

Although the Committee generally supports EPA's recommendation to derive aquatic life criteria for CECs directly from CCCs, we note that the following points should be considered by the Agency when implementing this recommendation:

- Some CECs do not fit the effect model of endocrine disrupting chemicals. Foremost on the Committee's list of concerns is that some CECs do not fit the effect model of endocrine disrupting chemicals (EDCs), or are not well enough understood at this time to allow a judgment of their mode of action. Nanoparticles are an example of such a class of compounds. Additional work is needed to further develop recommendations for deriving aquatic life water quality criteria for these other kinds of chemicals. EPA's White Paper focuses in particular on CECs that disrupt endocrine function in animals. Thus, many of the Committee's comments address deriving ALCs for CECs with modes of action similar to those of EDCs.

- For some CECs, acute toxicity may occur in environmental settings. The Committee notes that for some CECs, the LOECs and LC50s (test concentrations that result in mortality to 50% of the test population) are within one order of magnitude of each other, indicating that acute toxicity may occur in environmental settings. For these chemicals derivation of a CMC may be appropriate. Examples of such chemicals include fluoxetine (a selective serotonin reuptake inhibitor or SSRI) and gemfibrozil (a blood cholesterol regulator).

- Some compounds have differing modes of action for acute and chronic toxicity. The Committee is particularly concerned that some compounds may have differing modes of action for acute and chronic toxicity. In these cases, acute toxicity may be of concern in environmental settings and it may be appropriate to derive both a CMC and CCC.

- Pulsed discharge may result in high ambient concentrations of CECs. The Committee is concerned that the pulsed nature of some CEC releases (for example: pulsed industrial discharge; tidal action in the marine environment; and recurring natural events such as fluctuations in environmental concentrations of contaminants in ephemeral waterbodies due to evaporation and hurricanes that can cause flooding and release of untreated sewage) may result in short-term concentrations of CECs that could exceed what would generally be considered environmentally relevant concentrations. Although CCCs may be applicable in these situations, the Committee finds that acute toxicity should be considered to account for the effects of compounds where extreme pulses may occur more frequently than the three-year benchmark set by the Guidelines.

- Consideration of mixture effects is important. An additional concern of the Committee is the need for the consideration of mixture effects in determining whether acute toxicity could occur in natural settings. The White Paper explicitly references common modes of action for multiple compounds (as in the examples of EE2, estrone, and estradiol). The Committee feels strongly that mixture effects of compounds with similar modes of action should be taken into account in determining whether acute toxicity may occur in environmental situations. Thus a mixtures strategy is needed to guide development and interpretation of aquatic life criteria for CECs.

Committee recommendations concerning the relevance of acute toxicity effect concentrations

As a consequence of the Committee's discussion and concerns listed above, we provide the following recommendations to amend the White Paper text concerning derivation of aquatic life criteria on the basis of the Criterion Continuous Concentration:

1. Part 1 of EPA's White Paper contains a bulleted list (on page 28) identifying the kinds of information that should be reviewed in order to determine whether the differences between the CMCs and CCCs would be great enough to conclude that the CMC is not needed to develop ALC. The Committee finds that this list is very helpful. It addresses some of the concerns raised during the Committee's deliberation and it may be particularly useful in providing lines of evidence to determine whether acute toxicity data are needed. Therefore, we encourage expansion of this list in the final White Paper to include additional information addressing the points mentioned above.

2. The Committee suggests that all available data on any new class of CECs should be used in determining whether acute toxicity is likely to occur in environmentally relevant settings. These data should be summarized to document when additional data are needed, or when it is justifiable to move aquatic life criteria development forward without the derivation of CMCs.

3. The Committee recommends that CMCs be derived for compounds where LOECs are found to be within 1-2 orders of magnitude of LC50s.

4. The Committee recommends that the likelihood of pulses of exposure to contaminants be considered in determining the range of environmentally relevant concentrations for criteria development.

5. The Committee suggests that EPA consider the mixture effects of compounds with similar modes of action when determining the range of environmentally relevant concentrations for criteria development.

The Committee finds that, together with those in the White Paper, these considerations should allow a robust determination of whether CMCs are necessary for derivation of ALC for CECs.

4.1.2 Defining Minimum Data Requirements Regarding Taxonomic Coverage

EPA's draft White Paper states that a consequence of dropping acute toxicity testing requirements for deriving aquatic life criteria for CECs is the inability to calculate a CCC using the ACR approach. The Committee notes that CCCs could, however, be developed directly from sufficiently robust sets of chronic data using procedures in the Agency's Guidelines (Stephan et al., 1985, pages 40-42). These procedures require that acceptable chronic toxicity tests be conducted for a broad range of taxonomic groups. EPA has suggested that, if insufficient data from actual toxicity tests are available to fulfill the minimum data requirements for CECs, a reasonable understanding of the toxicological mode of action for a chemical may allow inferences as to what taxa (and endpoints) are most likely to be insensitive, and measured chronic values for those taxa might not be needed. Thus, in the White Paper, EPA has

recommended that, for CECs without complete chronic toxicity data sets to fulfill minimum data requirements, there be an evaluation of whether sufficient information exists to conclude that certain taxa would not be sensitive to the chemical. To accomplish this, EPA recommends interpreting the minimum data requirements for taxonomic coverage as "information requirements" instead of "toxicity test requirements." EPA notes that this would avoid generation of resource-intensive chronic toxicity data for insensitive species that would have little impact on the final criterion. The Committee agrees with EPA's recommendation. However, as further discussed below, the Agency needs to define: 1) what constitutes a sufficiently robust set of chronic data for criteria derivation, and 2) what constitutes a reasonable understanding of the mode of action for the chemical that may allow inferences concerning the insensitivity of particular taxa. In addition, the Committee has noted a number of concerns that should be addressed by EPA as it implements the proposed approach.

The Committee finds that the White Paper contains a comprehensive discussion of the issue of taxonomic coverage for developing aquatic life criteria. EPA's 1985 Guidelines require that data be available for the following organisms: a salmonid in the class Osteichthyes, a second family in the class Osteichthyes, a third family in the phylum Chordata, a planktonic crustacean, a benthic crustacean, an insect, a family in a phylum other than Arthropoda or Chordata, and a family in any order of insect or other phylum not already represented. This requirement is the same for freshwater as well as marine organisms. In the White Paper, EPA notes these taxonomic coverage requirements but recommends movement to a more "expert judgment" approach that is logical and should address some of the unique properties of CECs. The Committee understands and appreciates the desirability of avoiding the extra work required to develop chronic data for species that are unlikely to be sensitive to certain CECs. On the other hand, we emphasize that it is equally important to perform adequate testing to ensure protection of aquatic life. Therefore it is important to define what constitutes a sufficiently robust set of chronic data for criteria derivation and also to provide additional guidance concerning the data needed to infer that various taxa are insensitive to chemicals with specific modes of action.

As further discussed in Section 4.2 of this report, the derivation of aquatic life criteria should be risk-based and include consideration of probable direct and/or indirect impacts on food webs; ecological processes and services; and unique, endangered, and sensitive species. Thus, a major factor in determining that toxicity test data are not needed for particular taxa should be an assessment of the potential consequences of incorrectly concluding that a contaminant would have no effect. The ecological data requirements for supporting a conclusion of no effect (i.e., the level of "power" deemed sufficient for detecting a specified consequential effect) depend at least in part on an assessment of the social and biological values at risk and the potential for consequential losses. Moreover, because goals for aquatic life criteria should extend to the protection of ecosystems and their services rather than individual targeted organisms or specific subsystems, there is a need to assure that biological assessments adequately address a broad range of taxa and environmental contexts.

Concerns regarding taxonomic coverage for testing CECs

The Committee emphasizes that there are instances in which CECs have been shown to have unanticipated effects on non-target organisms. Examples include the impact of antibiotics on

plants (Brain et al., 2008) and atrazine effects on the quality of algae (Pennington and Scott, 2001). These types of examples should be used in Part I of the White Paper to help describe how the aquatic life criteria development process might need to be more flexible depending on the compounds under evaluation. In addition, we note the following important points to be considered concerning appropriate taxonomic coverage for deriving aquatic life criteria for CECs:

- There is a need to maintain broad taxonomic coverage for development of aquatic life criteria. The White Paper suggests that knowing certain modes of action could potentially focus testing on a particular type of organisms (e.g., vertebrates for "estrogenic" compounds). This suggestion is not wholly supported by the Committee. As stated in the 1985 Guidelines, the procedure for estimating the 5th percentile final chronic value is to use the four lowest values in the data set. This approach considers primarily vertebrates, and it is appropriate for EE2. However, it is not always appropriate (e.g., in the case of the weak estrogenic compound bisphenol A) to give primary consideration to vertebrates. Staples et al. (2008) compared four species sensitivity distribution methods to develop a predicted no-effect concentration for the aquatic environment for bisphenol A. Their study indicated that when using the Guidelines approach, the four lowest predicted values belonged to three invertebrates and one vertebrate. Clearly, this finding suggests that there is a need to maintain a broad taxonomic coverage in the development of aquatic life criteria.

- Little is known of chronic effects of CECs on "wild type" species. The Committee is concerned that much of the toxicity testing for CECs has been done on animals that are highly amenable to laboratory conditions and little is known of chronic effects of chemicals on "wild types." There is also some probability that criteria protecting "lab species" might not protect species of special concern like the endangered short-nosed sturgeon, several species of Pacific salmon, or the bull trout. Research is needed to evaluate the differences and similarities between life-histories and sensitivities of endangered/threatened and standard laboratory animals used for toxicity testing in order to have more confidence that surrogate species will provide sufficient information to develop protective criteria.

- Modes of action are not known for some CECs. The Committee notes that it is not safe to assume that a known mode of action is the only mode of action for a CEC. Different organisms may be affected in different ways by the same compound both as adults and at earlier stages of development. There is also the potential for synergism among CECs in mixtures and in interactions with environmental variables. It is the exception rather than the rule that modes of action are known for CECs.

Committee recommendations to improve the process of determining appropriate taxonomic coverage

Although the example used in Part II of EPA's White Paper to illustrate derivation of aquatic life criterion for an endocrine disrupting chemical is data-rich, the Committee notes that the same cannot be said for all or even most CECs. As EPA correctly states in the White Paper, in many cases non-traditional endpoints (i.e., endpoints not traditionally measured in toxicity testing) will almost certainly need to be considered for CECs. However, the use of non-traditional endpoints

requires an understanding of their relevance to the health of the organism, and ultimately the population, and also an understanding of the variability inherent in the measure. The key to determining appropriate taxonomic coverage and endpoints is ecological relevance. These considerations call for keeping the taxonomic coverage as broad as possible, considering the trophic position of the test organisms, and establishing a clear process or set of guidelines to determine the "insensitivity" of taxa. The Committee provides the following recommendations to improve the process of determining appropriate taxonomic coverage for criteria development:

1. EPA needs to define what constitutes a sufficiently robust set of chronic data. Although the example used in the White Paper generally illustrates EPA's proposed process for making decisions concerning taxonomic coverage, it would be helpful to be more explicit in identifying what constitutes a "sufficiently robust set of chronic data" and "a reasonable understanding of the mode of action for the chemical that may allow inferences." The language in the White Paper introduces uncertainty in both the general approach and in setting up specific test conditions.

2. EPA should consider emphasizing in the White Paper information necessary for development of aquatic life criteria rather than just toxicity test requirements. To that end, guidance on information needed to determine effects on ecological processes (e.g., food webs, nutrient cycling, and primary production) rather than only target species would be valuable in criteria development, and would follow more recent scientific thinking. In addition, there is a need for consideration of appropriate conceptual models that include fate pathways and exposure to the CECs. An understanding of exposure pathways could help direct testing toward more relevant species.

3. An approach that might be considered by EPA would be to shift from a minimum level of required taxonomic coverage toward determining receptors of potential concern (ROPCs). EPA acknowledges in the White Paper example illustrating development of an aquatic life criterion for EE2 that certain types of organisms might be differentially sensitive or impacted by a compound. The Committee notes that, if sufficient information exists on sensitivity, then expert judgment concerning data development should prevail. This would result in a more focused approach to data development keeping in mind a weight of evidence rather than a broad requirement for testing all eight taxa specified in the Guidelines. This would be a more flexible risk-based rather than set approach and would be consistent with the risk-assessment terminology used throughout Part I of the White Paper.

4. Examples showing the unanticipated effects of CECs on non-target organisms (e.g., the impact of antibiotics on plants and atrazine effects on the quality of algae) should be used in Part I of the White Paper to help describe how the aquatic life criteria development process might need to be more flexible depending on the compounds under evaluation.

5. The Committee recommends that the discussion of taxonomic coverage in the White Paper be expanded to include specific recommendations concerning the marine environment. EPA's 1985 Guidelines call for assessment of marine organisms in the same manner as freshwater organisms. However, a discussion of testing marine organisms was omitted from EPA's White Paper. We note that including consideration of testing marine organisms would

be consistent with the approach taken by the European Union as it developed its Water Framework Directive (European Commission, 2008). Due to specific issues unique to marine organisms, such as physiological requirements (e.g., maintenance of salt balance) and life-history strategies (e.g., reproduction tied to tidal cycles), more specific guidance for CECs is likely needed. The Committee suggests that this guidance may be best addressed by convening a "Pellston" type workshop (Society of Environmental Toxicology and Chemistry, 2008) that is comprised of experts from multiple disciplines and types of organizations. Since testing requirements for marine organisms are already being considered by EPA, this should be stated in the White Paper.

4.1.3 Use of Non-resident Species in Criteria Development

EPA's Guidelines limit the data used for aquatic life criteria development to tests with native species while allowing use of non-resident species data to provide additional narrative evidence for criteria development. In its White Paper, EPA suggests that excluding species from testing simply because they are not resident may be unnecessarily restrictive for the purposes of deriving national criteria, and may actually increase rather than decrease uncertainty. The White Paper recommends that these "non-resident" species data be used in the aquatic life criteria derivation process if the non-resident species data would enable better estimation of species sensitivity distributions (SSDs). EPA recommends that criteria derivation calculations focus on test data from species for which widely used and standardized test methods are available, and for which there is reason to believe that data would represent the sensitivity of comparable resident species. EPA specifically recommends accepting data for zebrafish (*Danio rerio*) and Japanese medaka (*Oryzias latipes*), to reflect international efforts in harmonization of test methods. As further discussed below, the Committee agrees with this recommendation.

Benefit of using non-resident species data

The Committee finds that the exclusion of non-resident species data from criteria derivation is biologically and practically inconsistent with the intent of the Guidelines (i.e., providing an objective, internally consistent, appropriate, and feasible way of deriving national criteria). Furthermore, we find that, as advocated by the White Paper authors, use of such data would greatly benefit the development of scientifically sound aquatic life criteria CECs. Although geographic differences in species tolerance to contaminants have been documented (Chapman et al., 2006), it is important to note that the U.S. covers a wide range of geographic areas (from tropical [Florida, Hawaii] to arctic [Alaska]). Previous criteria development has focused on temperate species. Thus, inclusion of non-resident species has the potential to cover not only data needs but also the geographic (e.g., temperature) range of biota in the U.S. and arguably could increase the protectiveness of the derived criteria.

The White Paper states that only "species with recognized international equivalency [will] be included in criteria derivation with the full weight given to data from resident species." This approach supports international test harmonization efforts. Specifically, the White Paper recommends use of zebrafish and Japanese medaka. These two species have been largely used for EDC testing and have shown sensitivity similar to native fathead minnows and other species. Tests conducted with the zebrafish and Japanese medaka provide insight into the biochemical

and physiological mechanisms involved in the toxicity of CECs. It is important to match the mode of action with the appropriate test species. The conservative nature of the endocrine system, a target for most endocrine disrupting chemicals and likely many CECs, renders the exclusion of non-resident species from aquatic life criteria development biologically indefensible. Certainly the use of any test species would be useful if it could aid in the interpretation of modes of action, relative taxa tolerance, and endpoint sensitivity comparisons. For example, studies with surrogate species have been conducted to demonstrate the toxicity of CECs to resident species, such as the Rio Grande silvery Minnow and the North American Sturgeon, that are too endangered for laboratory testing (Beyers, 1995; Dwyer et al., 2000). Additional studies of the sensitivity of marine and freshwater test species are cited in the recommendations below. In such cases test data from closely related non-resident species may provide laboratory evidence useful in the development of protective aquatic life criteria for the endangered resident species

Concerns regarding the use of non-resident species data

Although the Committee supports the use of non-resident species data for deriving aquatic life criteria for CECs, we note the following concerns that should be considered by EPA:

- Non-resident species are defined in different ways. The Committee notes that EPA's Guidelines define "non-resident" species as those not native to the continental United States and Canada. However, non-resident species have been defined in other ways. At the federal level, they have been defined as species that are not native to North America. Many states use the term non-resident species to mean species not native to their specific region. Hence local criteria are sometimes derived substituting species found locally. The definition of "non-resident" (or non-native) and invasive species should be clearly stated in EPA's White Paper. The White Paper should indicate whether organisms that have migrated (or invaded or been stocked) are considered "resident." In this regard, the Committee notes that global climate change and other factors associated with the migration of organisms potentially make the definition of resident or non-resident species a moving target.

- It is important to consider the concept of "representative" species in criteria derivation. An underlying assumption in the exclusion of non-resident species data from criteria derivation is that non-resident species do not represent the response expected from native species in a geographic area. It is more important to consider the ecophysiological make-up of a species and its alignment with the ecological conditions in which the exposure occurs than the geographic home range of the species. It would be easy to postulate a case where resident or native warm water species are not as representative of risks to resident cold water species as the response of a non-resident cold water species which occupies the same or similar niche in a different geography.

- Non-resident species data may dominate the criteria derivation process. The Committee is concerned that non-resident species and their large respective databases could dominate the criteria derivation process. The recommendation to use non-resident species data, as presented in the White Paper, is reasonable when looking at criteria derivation from a continental perspective. However, including non-resident species data in the criteria

derivation process could lead to inappropriately biased criteria development in certain sensitive geographic areas, such as cold water and oligotrophic systems. More detailed information is needed in the White Paper to address this concern.

- Variation in test organism response is often unknown. The Committee notes that variation among the strains of test organisms used in laboratory studies is often unknown. Therefore, it is difficult to understand whether the variation observed between native and non-native species is within the uncertainty of the test data for either species. Differences in husbandry, health, parasite and pathogen load (i.e., other stressors) may contribute to differences in test results between resident and non-resident species. Within Pacific herring of Puget Sound there are apparent stock differences in the frequency of malformations of new hatchlings that are not related to spawning site (Hershberger et al., 2005). Differences in sensitivity have also been observed for clones of *Daphnia magna* (Baird et al., 1990). While the issue of response variation should be considered, many studies have shown parallel responses when fairly close relatives are used.

Committee recommendations regarding the use of non-resident species data

Excluding the use of use non-resident species data from the process of developing aquatic life criteria for CECs may result in failure to meet the minimum data requirements. Therefore, the Committee finds that use of available data for non-resident species is warranted. Although the use of resident species information is preferable to non-resident species, data from tests using non-resident species, such as zebrafish and Japanese medaka, can provide extremely useful information on modes of action. The appropriate use of non-resident species data in criteria development will allow better estimation of species sensitivity distributions and also improve international harmonization and equivalency efforts. The Committee provides the following recommendations concerning the use of non-resident species data:

1. As noted above, non-resident species could potentially be over-represented in aquatic life criteria databases. The proportion of the data set that should include resident species is a matter that should be carefully evaluated by the expert advisory panel assembled to review each criterion.

2. In no case should a criterion be developed on the basis of non-resident species data alone. Certainly if it is shown that non-resident species are ecologically relevant and appropriately sensitive then they should be used for criteria derivation as long as the studies meet appropriate quality criteria. Test species used in toxicity testing tend to be easy to rear and test, and have appropriate sensitivity levels. However, other factors should be considered when ample data are available for prioritizing species responses for criteria development. These factors include vulnerability; endangerment status; and recreational, commercial or ecological value. In order to protect endangered species, studies should be completed to compare toxicity test responses of common test species and endangered organisms and thereby determine the relevance of surrogates in the criteria development process. Previously EPA and the U.S. Fish and Wildlife Service (Besser et al., 2005; Dwyer et al., 1999, 2005; and Sappington et al., 2001) compared the sensitivity of common freshwater and marine testing species with protected/endangered fish species and found that these surrogate

test species (e.g., rainbow trout) may equally protect endangered species. However, these surrogate fish species do not necessarily provide protection for other threatened and endangered non-fish species such as marine mammals, wildlife, and birds that reside and feed in aquatic ecosystems and provide ecosystem goods and services. Additional consideration of these other non-fish protected species is required in developing risk-based approaches for CECs that fully protect all threatened and endangered species.

3. The statement that criteria would be developed "…with full weight given to data from resident species" should include a qualifier concerning the validity of the data. An available resident species study with no obvious protocol, no measurement of test concentrations, or other protocol concerns should be assigned a lower priority than a fully valid Organization for Economic Cooperation and Development (OECD)/EPA guideline study with a non-resident species. However, the Committee qualifies this recommendation by emphasizing that all scientifically valid data should be used in setting criteria.

4. Differences in strains, husbandry, health, and parasite and pathogen load contribute to response variation and should be considered in the aquatic life criteria development process.

5. Non-resident as well as resident species test data must meet Guidelines requirements for data and method validity.

4.1.4 Defining Appropriate Chronic Toxicity Data

EPA's Guidelines state that acceptable chronic tests for derivation of aquatic life criteria are full life-cycle exposures (F_0 egg to F_1 offspring) for vertebrates and invertebrates, as well as partial life-cycle (adult to juvenile) and early life-stage (egg to juvenile) tests for fish. EPA's White Paper states that some CECs may have potent effects on life processes that lie outside the exposure period represented by early life stage tests or effects may not be manifested until later in development. Thus, early life stage tests might not be good predictors of chronic toxicity for these chemicals. In the White Paper, EPA recommends that the Guidelines requirements for chronic toxicity data be tightened by requiring at least one full life-cycle test for a fish (for invertebrates, life-cycle tests are already required) unless there is a compelling body of information indicating that life processes outside the early life stage or partial life-cycle exposure/observation window are not critical to capturing the biologically important effects of chronic exposure to the chemical.

The Committee strongly supports EPA's recommendation to amend the chronic data acceptability requirements in the Guidelines. However, we are divided in our assessment of the "guilty until proven innocent" approach in the White Paper (page 17). Some Committee members view it as appropriate while others view it as extremely precautionary. The White Paper states that "…it is probably wiser to require that the chronic toxicity data for fish include exposure and observation over a full life-cycle unless there is an affirmative reason to believe that it is not necessary." The statement is used in the context of requiring a full life cycle study instead of relying on an early life stage test for fish. Some Committee members find that the statement does not appear to fit the process of setting aquatic life criteria, whereas others find it to provide an important perspective for establishing aquatic life criteria.

The Committee also supports extending the recommendation to amend the chronic data acceptability requirement to all chemicals, not just endocrine disrupting chemicals and CECs. The Committee finds that EPA's recommendation is justified based on evidence showing that a number of chemicals may exert effects during the period of gonadal differentiation, and that these effects may not be manifested until much later in life. Including at least one full life cycle test in the test guidelines for fish ensures that these types of effects are captured.

Issues to be considered in defining appropriate chronic toxicity data

Although the Committee supports EPA's recommendations concerning use of chronic toxicity data for development of aquatic life criteria, we note the following issues that should be addressed in defining appropriate chronic toxicity test data:

- Transgenerational effects of CECs are potentially important and should be considered. There is evidence for some chemicals that exposure in one generation creates effects in a later generation that were not observed in prior generations even in the same life stage. Accordingly, the chronic toxicity data requirements include a full life-cycle test to be conducted for at least one species of fish. There is still some uncertainty as to whether a full life-cycle test might underestimate the chronic effects that would be seen in exposures extending over more than two generations (multigenerational testing). We do not recommend adding a requirement for multigenerational testing to the Guidelines, but suggest that EPA critically review data dealing with transgenerational responses of aquatic species and evaluate whether this additional testing provides significant new information that informs the evaluation process. This critical review should examine the utility of multigenerational tests relative to proposed fish full life-cycle (FFLC) tests as well as partial life-cycle (PLC) tests and early life-stage studies. The intent of this recommendation is to ensure that a full range of development (e.g., early life stage to adult) is evaluated sufficiently to assure adequate aquatic life protection. The Committee generally supports the concept of fish full life-cycle testing because it spans the entire exposure window in the early life-cycle to adults. The Committee also supports further development of a tiered testing approach to derive an appropriate rationale for the use of FFLC, PLC, and possibly multigenerational testing for chemicals with parallel modes of action. In this regard, it is noted that the decision to use data from partial versus full life-cycle and/or multigenerational tests requires a consideration of tradeoffs between the costs of additional testing and the social and biological values at risk and the potential losses from missing an important effect.

- Flexibility in test guidelines is needed to include key developmental events. Test guidelines must have the flexibility to include assessment of key developmental events (e.g., metamorphosis in amphibians, acquisition of saltwater tolerance), particularly if these processes are identified in a ROPC.

- Test methods should include non-traditional measures that may be linked to ecologically relevant endpoints. There is a need to ensure that the test methods include provisions to consider non-traditional endpoints such as immune function and organism behavior. These endpoints may directly impinge on ecologically-relevant endpoints such as growth,

reproduction and survival. In this case, professional judgment from an expert panel is needed to determine the relevance of these non-traditional endpoints.

The Committee also notes the following practical issues that should be addressed if the chronic toxicity data recommendation in the White Paper is to be implemented:

- Surrogate test species may be needed. A key issue to be addressed is the suitability of surrogate test species. Surrogates may be needed in the case of: 1) long-lived species with delayed sexual maturity; 2) organisms of large size (which precludes their suitability as a test species in the laboratory), 3) endangered species, and 4) species for which there is little knowledge of the husbandry conditions or background biology. There is also uncertainty in how differences in the physiology and life history strategies (i.e., long-lived versus short-lived species, differences in maternal-fetal transport of contaminants) may affect the response of aquatic species to CECs and endocrine disrupters. Many of these issues represent significant data gaps that need to be addressed. In these cases, expert opinion may be needed to assist EPA in determining the suitability of surrogate test species for use in criteria development.

Committee recommendations regarding defining appropriate chronic toxicity data

As discussed above, the Committee strongly supports EPA's recommendation concerning the use of at least one full life cycle test for a fish in appropriate cases for testing all kinds of chemicals when deriving water quality criteria for the protection of aquatic life in marine and freshwater environments. We provide the following recommendations to implement the requirement for chronic toxicity data:

1. As discussed above, EPA should critically review data dealing with transgenerational responses of aquatic species and evaluate whether or not this additional testing provides significant new information that informs the evaluation process.

2. EPA should support research that addresses the suitability of the use of surrogate species in assessing the response of aquatic species (e.g., endangered or long lived species; species with varying life history strategies) to CECs.

3. Test guidelines should include flexibility to include assessment of key developmental events, and professional judgment from an expert panel should be used to evaluate the relevance of non-traditional endpoints such as immune function and organism behavior.

4.1.5 Selection of Effect Endpoints for Criteria Development

In the White Paper, EPA has stated that the selection of endpoints appropriate to the derivation of aquatic life criteria must be tied to the goal of aquatic life criteria (i.e., to protect aquatic organisms and their uses). EPA further states that survival, growth, and reproduction are processes directly related to this goal. The Agency notes, however, that there are many more biological responses that have been observed in response to toxicant exposure. In the White Paper, EPA has identified a number of sublethal endpoints that could be considered in

developing aquatic life criteria for CECs. The Agency has recommended that the use of such endpoints be more thoroughly explored for development of aquatic life criteria.

Points to be considered in selecting effect endpoints

Generally, the Committee agrees that EPA should continue to explore the possibility of using sublethal endpoints to help set aquatic life criteria. However, we caution EPA that non-traditional endpoints must ultimately be linked to the population, and not solely to individual-level endpoints. The ultimate goal of any aquatic life criterion is to protect populations of aquatic organisms from the "harmful" effects of chemicals (or other stressors). Thus, reproduction, growth and survival are the predominant effect endpoints currently utilized in laboratory studies supporting criteria development. The Committee discussed: 1) the usefulness of information provided by the non-traditional endpoints identified in the White Paper; and 2) whether the endpoints might provide information to assess effects on populations, particularly when considering mixtures and indirect effects. We provide the following comments to be considered by EPA in selecting effect endpoints to develop criteria for CECs:

- Contaminants effects should be linked to different levels of biological organization. Definitions of "biologically important effect" and what constitutes a "good population" are needed. We also note that not all biological responses represent an "adverse" effect. This is consistent with a principle laid out in the White Paper (i.e., the White Paper states that chemicals such as endocrine disrupters have been shown to produce a wide variety of measurable changes at many different levels of biological organization, and the challenge is to select from among those endpoints that have sufficiently clear connection to expected effects on populations or communities of aquatic organisms).

- Activational biological effects can provide useful information. CECs often induce changes in behaviors, secondary sexual characteristics, or levels of hormones or hormone-induced products. Many of these responses are transitory or may revert to their prior or normal condition with cessation of exposure. Accordingly, it is often difficult to interpret these activational responses in relation to higher level biological effects. Nevertheless, these endpoints do provide useful information, particularly regarding mode of action. Consideration of such effects would certainly help reduce uncertainty in a risk assessment paradigm. While it is clear that these endpoints alone could not be utilized to set criteria, the Committee notes that sublethal endpoints integrated with toxicodynamic and kinetic factors could provide useful data in a problem formulation step related to some CEC, and could also be used to help identify data gaps that may be filled to reduce uncertainty and aid in criteria development.

- Use of non-traditional sublethal endpoints holds promise but further validation of such endpoints is needed. Behavioral endpoints related to population (e.g., predator-prey interactions) and reproduction may hold some promise for criteria development if the assays can be validated and variability can be understood. The implicit model for considering behavioral endpoints is that biological changes in individual organisms in response to contaminants may produce changes in individual characteristics and behavior which may have implications for populations and ecosystems. It is also noted, however, that social

factors can affect the behavior of individuals, which in turn can affect neurological and other systems and functions. Immune function and genetic variation are also endpoints that should be explored (Filby et al., 2007). In addition, models capable of extrapolating laboratory endpoints to the population level should be targeted for development (Ankley et al., 2008; Chandler et al., 2004). Exploration of endpoints related to ecological processes (e.g., primary productivity, decomposition rate) is also warranted.

- Research is needed to determine how aquatic life criteria for CECs can take into account the fact that aquatic organisms are exposed to mixtures of these chemicals. As noted previously, in developing aquatic life criteria for CECs it will be particularly important to consider the effects of mixtures. The Committee provides a number of comments in this regard. We note that understanding the mode of action of a compound is extremely important in estimating mixture interactions. Mixtures of CECs with comparable modes of action may result in higher environmental concentrations than would be expected for any single compound. In fact, pharmacological mode of action is the basis for evaluating multiple drug prescriptions in humans by pharmacists. For example, if it is known that a vertebrate is exposed to aryl hydrocarbon receptor (AhR) agonists and estrogen receptor (ER) agonists, it is likely that antagonism of each effect could occur. Information regarding mode of action should be made available to EPA from manufacturers or other governmental agencies (e.g., available from the U.S. Food and Drug Administration [FDA] or from testing under the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]). It is through use of this information that non-traditional measures can confirm similar or different modes of action in targeted ROPCs. The Committee strongly recommends enhancing the communication and data transfer capabilities between agencies such as FDA and EPA to provide these data.

- Mode of action fingerprints developed by evaluating combined sublethal endpoints should be linked to *in vivo* species testing. The Committee notes that much of the toxicity testing for compounds such as pharmaceuticals and personal care products has been conducted using mammals and other vertebrates. Additional data are needed for other "keystone" species. We suggest that the choice of species, critical life stages, and complicating stressors (i.e., salinity and temperature) could be potentially identified in a problem formulation/conceptual model stage of a risk assessment paradigm. If these data are not available, research and development could be undertaken to obtain mode of action "fingerprints" for a CEC or any other compound through combined sublethal endpoints (i.e., genomic-transcriptomic, proteomic, metabolomic) and toxicodynamic/kinetic feature evaluations within sentinel species (to cover taxonomic issues). It is likely that through this process additional "side-effects," or species-specific modes of action, could be obtained. These data could be integrated with "fingerprints" of other compounds with different modes of action and utilized to help address mixture issues or potential indirect effects. The toxicity to a particular species at a particular trophic position could then be modeled to assess indirect impacts on other populations.

- Additional research is needed to link biomarkers to effects. The Committee notes that the concept of using biological responses occurring prior to impacts on growth, reproduction, and survival has been proposed for more than 20 years as a way to detect adverse effects in a population before the population is altered. While there are examples of such "biomarkers of

effect," we find that the linkages between biochemical, histological, and behavioral endpoints and reproduction, growth, and survival are likely life-stage dependent and are difficult to validate, particularly in the field. We note that "biomarkers of exposure" are available but research is needed to interpret their significance.

- Vitellogenin production is an excellent biomarker of exposure to feminizing chemicals. One of the best examples of exposure biomarkers is the biological response of vitellogenin production in male or juvenile animals. Vitellogenin is an excellent *in vivo* biomarker for exposure to feminizing chemicals. If the response is measured in the whole animal, it incorporates estrogenic as well as anti-androgenic or other modes of action that can cause a feminized response (production of an egg-yolk precursor). It is important to point out that this assay is not identical to estrogen receptor (ER) - based *in vitro* bioassays. Some compounds such as EE2 are very potent ER agonists but also have other modes of action that may alter endocrine systems (Tabb and Blumberg, 2006) such as the inhibition of several isoforms of cytochrome P450 (e.g., CYP3A), which are important in the clearance of endogenous steroids (Parkinson, 2001). Nonylphenols also have multiple modes of action other than direct binding to the ER that lead to enhanced estradiol synthesis (Harris et. al, 2001; Kazeto et al., 2004; Martin-Skilton et al., 2006; Meucci et al., 2006; Thibaut and Porte, 2004). So the observation of vitellogenin induction within an oviparous male or juvenile organism does not indicate total specificity with regard to mode of action. Anything that increases endogenous estrogen biosynthesis or diminishes clearance would also provide this biological response. The Committee notes that the reduction of vitellogenin in females may not indicate anti-estrogenic effects or even alterations of endocrine activity, as basic hepatotoxicants in females can elicit a similar effect. However, we point out that the correlations between fecundity and vitellogenin in females have been observed to be strong even though this may not indicate mode of action (Miller et al, 2007) (see discussion below). Additional studies are needed to examine hepatotoxicants or compounds with modes of action exclusive of endocrine targets.

- The linkage of vitellogenin production to biological effects is limited. While the linkage of vitellogenin to exposure is reasonably solid, linkages of vitellogenin in males/juveniles to higher biological effects such as altered reproduction, survival and growth are limited, even though the relationship may make intuitive sense. Several studies have shown relationships between vitellogenin and reproduction in the laboratory, often at concentrations beyond probable effect concentrations (Thorpe et al., 2007), but few examples of population alterations have been noted in the field. Even in the United Kingdom, where gender shifts to females were originally noted and correlated with vitellogenin induction within males, intersex individuals, and other histological anomalies, overall abundance declines within the species of interest have not been reported. In fact, only one study (Kidd et al., 2007) has linked population crash with vitellogenin or histopathological alterations in fish. A similar occurrence has been noted in laboratory studies where vitellogenin expression may or may not be linked to intersex (Grim et al., 2007), which in turn may or may not lead to gender shifts. Even the relatively clear signal of gender shift, while clearly impacting reproduction in laboratory animals optimized to a specific gender ratio, may not significantly impact field populations in an uncharacterized species (Munday et al., 2006). Clearly, a better understanding of the population dynamics of a ROPC is needed to determine the phenotypic

plasticity of the gender ratio. Thus, gender shifts should be viewed with caution, particularly in species that have not been well studied.

Committee recommendations regarding selection of endpoints

The Committee agrees that EPA should continue to explore the possibility of using sublethal endpoints in helping to set aquatic life criteria. We provide the following recommendations in this regard:

1. EPA should pursue the use of "non-traditional measures," or endpoints for criteria development, as discussed in the White Paper. The Agency should ensure that such measures can be tied to impacts on populations or ecological processes, not just to effects on individual organisms.

2. EPA should use "non-traditional measures" when appropriate to develop an understanding of and confirm mode of action.

3. EPA should use human health information and toxicology tools (genomics/ PBPKs) when appropriate and available to reduce the uncertainty of aquatic life criteria.

4. EPA should consider the following key points concerning use of the non-traditional endpoints discussed in the White Paper: 1) vitellogenin in males and juveniles is an indicator of exposure to a feminizing stressor(s), but its linkage to population effects is limited; 2) strong correlations between vitellogenin and fecundity have been observed in females, but this is not necessarily tied to altered endocrine mode of action; 3) Anomalous intersex is indicative of a gender stressor(s), but has not been strongly tied to population effects; and 4) gender ratio can be indicative of endocrine alteration, but baseline information on appropriate life history is necessary for this evaluation.

4.1.6 Involvement of an Expert Panel

Because development of aquatic life criteria for CECs may be dependent on technical interpretations of a wide range of toxicological information, EPA has proposed that expert panels be used to provide professional judgment during criteria development. The Committee concurs that strong, active participation by a panel of outside experts will be necessary to ensure that the approaches used (including the designs for toxicity testing, the selected endpoints, and the necessary species and tests to be used, i.e., the ROPCs) are the most appropriate for the compound under scrutiny. As the EPA moves away from firm requirements for species and tests, it will become increasingly important that expert panels comprising diverse expertise be utilized to ensure that the best data are selected for necessary decisions. The National Academy of Sciences and Society of Environmental Toxicology and Chemistry have suggested similar approaches. In a recent report dealing with ecological risk assessment in environmental decision making (U.S. EPA Science Advisory Board, 2007), the SAB strongly recommended that expert panels be used to provide assistance to EPA during the problem formulation phase of ecological risk assessments. The same recommendations are appropriate for development of aquatic life criteria. Involving a suite of experts with a balanced range of perspectives during the very early

stages of problem formulation, and continuing their involvement as external reviewers at strategic junctures throughout the process, will significantly improve quality, utility, and defensibility of the criteria. It is noted that implementing a risk-based approach to deriving aquatic life criteria that protect ecosystems and their valued services will necessitate including social scientists, economists, and relevant publics/stakeholders on expert panels.

Committee recommendations concerning the use of expert panels

As stated above, the Committee concurs with the use of expert panels to provide professional judgment during the process of developing aquatic life criteria. We offer the following recommendations concerning the formation and use of expert panels:

1. The process for the use and selection of expert panels should be described in detail and should be transparent. The process used to select and convene the panels, the general attributes of panel composition, and methods used to address issues such as identification and elimination of conflicts of interest must be described (U.S. EPA, 2006). In this regard, one possible model to be considered is the process used to select SAB committees and panels, whereby national and international experts are identified from multiple sectors representing broad disciplinary expertise and professional affiliation (e.g., academic, appropriate governmental agencies [such as FDA], non governmental organizations, and private industry).

2. The charge to the panel and the expected end result must be clearly defined.

3. There are likely similar expert panel processes occurring elsewhere. The Committee recommends that EPA determine whether similar processes are underway in Europe and Asia, and if so, consider them as models to provide additional insight and/or expertise.

4. The Committee is concerned that the use of expert panels could lead to less consistency in how aquatic life criteria are determined. To help alleviate this potential problem, we recommend that EPA develop specific guidance on the roles of expert panels in problem formulation, data evaluation, and the generation of recommendations leading to criteria derivation.

4.2 Charge Question 2. Please comment on whether EPA has identified the appropriate issues to be addressed in deriving ALC for CECs. Are there additional important issues that EPA has not identified?

As stated previously, EPA's White Paper identifies technical issues that need to be addressed in deriving aquatic life criteria for CECs. The Committee was asked to comment on whether the Agency has identified the appropriate issues in the White Paper and whether there are additional important issues that EPA has not identified. The Committee finds that appropriate technical issues have been identified in the White Paper. However, EPA could clarify the process of developing aquatic life criteria for CECs by articulating a set of principles that could be applied when modifying the 1985 Guidelines to develop water quality criteria for such contaminants. We also emphasize the importance of developing a conceptual model to guide the process of

developing aquatic life criteria for CECs. The conceptual model should address more than the fate and direct effects of CECs. It should include consideration of probable direct and or indirect impacts on food webs, ecological processes and services, unique, endangered or keystone species or species of special societal value or concern. The example provided in Figure 1 illustrates components that could be included in such a conceptual model. Use of a conceptual model to

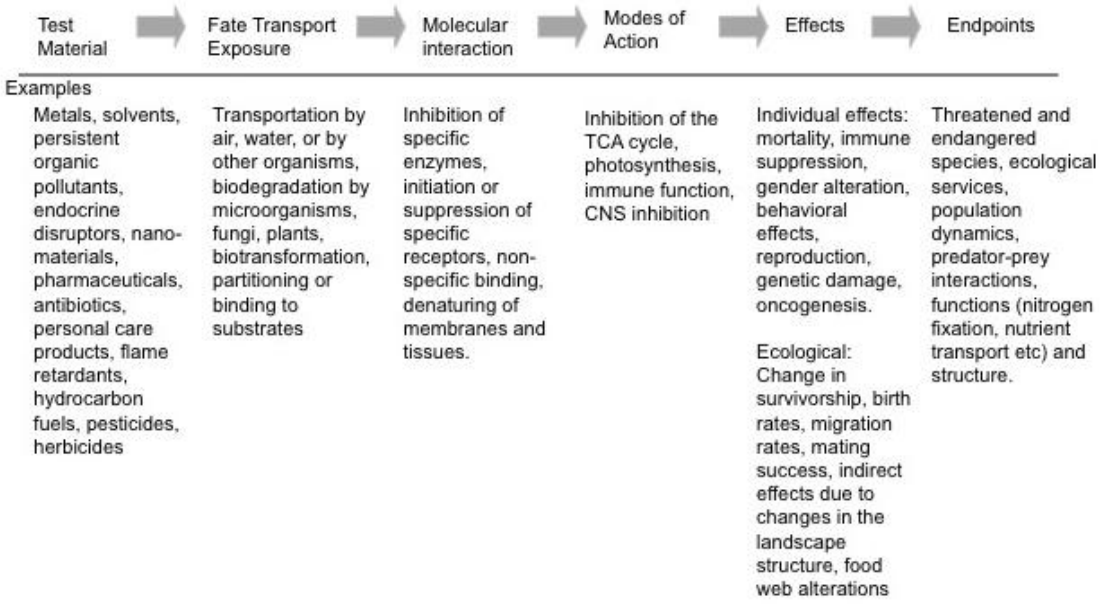

Figure 1. A Generalized Conceptual Model for Deriving Aquatic Life Criteria With Examples for Each Step

support criteria development would improve EPA's ability to address emerging questions about unique mechanisms, fate processes, and effects endpoints. Use of the conceptual model is further discussed below.

Committee recommendations concerning additional issues to be addressed

Although the Committee finds that EPA has identified appropriate technical issues in the White Paper, we recommend that the Agency address the additional issues listed below in order to customize and update the 1985 Guidelines and thereby increase the flexibility and specificity of the aquatic life criteria derivation process. It is important to note that several of the following recommendations (e.g., the recommended shift toward an ecological risk assessment model and the recommendation to seek inputs from diverse perspectives) will require explicit and systematic assessment of the concerns of relevant publics/stakeholders. This in turn will require greater involvement of social and economic sciences in the aquatic life criteria setting process, especially in the context of identifying and prioritizing contaminants of emerging concern.

1. In the White Paper, EPA should articulate principles that can be applied when modifying the 1985 Guidelines to develop water quality criteria for CECs. The Committee recommends that these principles be directly linked to EPA's Guidelines for Ecological Risk Assessment (U. S. EPA, 1992, 1998). The committee in fact recommends that the 1985 Guidelines be

updated to incorporate risk assessment principles and guidelines that did not exist when the Guidelines were developed over 20 years ago. In other words, the derivation of aquatic life criteria needs to be fully risk-based, using a transparent and consistent framework that provides necessary flexibility not presently possible within the algorithm approach of the 1985 Guidelines. A recent SAB report, *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making: A Report of the U.S. EPA Science Advisory Board*, (U.S. EPA Science Advisory Board, 2007) contains additional recommendations that may be considered in order to enable more effective use of ecological risk assessment in the derivation of aquatic life criteria.

2. In line with using a risk-based approach, principles for developing aquatic life criteria for CECs should include the following: seek a wide range of inputs from diverse perspectives; determine appropriate ROPCs; develop a robust conceptual model; develop multiple lines of evidence; and identify uncertainties (quantitative and qualitative) associated with criteria development. Each of these risk assessment-based principles is further discussed below:

   - Seek a wide range of inputs. EPA should seek input from a diversity of experts representing: Agency scientists, academic scientists, scientists in business and industry, state and tribal scientists, and the environmental community on the problem formulation, conceptual model development, modifications to the Guidelines dictated by the properties of a CEC, and the resulting recommendation for the aquatic life criterion. Adherence to this principle will ensure that the process stimulates a robust discussion and is informed by and acceptable from a diversity of perspectives. This diversity should include input from chemists, modelers, toxicologists, ecologists, and risk assessors.

   - Determine appropriate ROPCs. The process needs to clearly identify the need to determine appropriate receptors of potential concern and not simply focus on "traditional" test organisms.

   - Develop a robust conceptual model. At the start of the criterion development process, the available data on fate and effects should be examined and used to develop a conceptual model (e.g., Figure 1). Structure activity data and modes of action of similar compounds/materials should be consulted to inform model development. An expert panel should be convened to assist in the problem formulation and conceptual model development step. Uncertainty should be identified in the model and used to identify strategic efforts to reduce uncertainty. The conceptual model should include more than fate and effects data. It should include consideration of probable direct and or indirect impacts on food webs, ecological processes and services, and unique, endangered or keystone species or species of special societal value or concern (charismatic species).

   - Develop multiple lines of evidence. The committee finds that a multiple line of evidence approach has the potential to inform decision making and the criterion recommendation. It also can serve to reduce uncertainty when the lines converge and reinforce each other.

   - Identify uncertainties and conduct uncertainty analysis. As further discussed below, EPA should identify the uncertainties associated with the criteria developed for CECs. At all

stages of criteria development, uncertainty should be quantified and/or qualitatively discussed. Uncertainty should be used to focus and prioritize data generation efforts.

3. EPA should develop a system or process to assist the development of criteria for CECs. The system would establish a set of rules to enable analysis of information supplied by the user and lead to recommendations concerning one or more courses of user action. The Committee finds that such a system would be an important tool for capturing and maintaining the state of the art in aquatic life criteria development. It would serve as a vehicle for connecting fate and effects assessment tools and capturing expert knowledge, and it could serve as a platform for deriving priorities for future research in assessing the risks of contaminants to aquatic life and ecosystems.

4. The Committee strongly recommends that understanding and presentation of uncertainty become an intrinsic part of the aquatic life criteria development process. The presentation of uncertainty needs to be an explicit and transparent part of the analysis. For example, the uncertainties inherent in understanding modes of action, determination of concentration-response relationships, development of species sensitivity distributions, and derivation of ecological effects should be quantified or described in a narrative sense. An important aspect of this is developing an a priori understanding of the amount and types of uncertainties that preclude the derivation of an aquatic life criterion. These uncertainties can be classified into the categories listed below:

   - Uncertainties that preclude the derivation of an aquatic life criterion.

   - Areas in which uncertainties may be important and can be resolved with additional modeling, research or a better understanding of the relationship of the uncertainty to the standard setting process.

   - Uncertainties that do not preclude the setting of an aquatic life criterion but form the basis for future research programs.

   Identification of uncertainties in these categories can be addressed in development of the conceptual model in consultation with the expert panel.

5. EPA should bolster the consideration of mode of action and ecology in the aquatic life criteria derivation process. A better understanding of the molecular interactions and modes of action will reduce uncertainty in that aspect of the conceptual model. A better understanding of the ecological effects and context will allow more specific and flexible predictions of risks to individuals, populations and ecological structure and function. This will reduce predictive uncertainty. The Committee encourages the developers of the aquatic life criteria to further integrate these advances into the criteria derivation process.

6. In the White Paper, EPA should discuss the importance of considering environmental context (i.e., site specific considerations) in deriving aquatic life criteria for CECs. These modifying factors should be mentioned in the CEC criteria themselves. For example, characteristics of the receiving environment affect bioavailability and toxicity to organisms (e.g., trophic

status, dissolved organic carbon, pH, and substrate types) as well as longevity of their exposure due to impacts on the degradation and partitioning rates of these chemicals. Several CECs have the potential, based on their physical-chemical properties, to bioaccumulate and bioconcentrate, and this may result in diet-borne toxicity to a predator. Degradation/biotransformation products of CECs should be considered because there are instances where their toxicity is greater than the parent compound. In addition, the Committee recommends considering analytical chemistry because some aquatic life criteria have the potential to be set at concentrations that are at or below current (widely available) abilities to easily quantify CECs.

7. The Committee recommends that EPA keep abreast of the new science related to CECs in order to ensure that the latest approaches for assessing the effects of these chemicals are considered in criteria derivation. These types of effects may include impacts on natural selection and genetic diversity, indirect effects through changes in prey quality and quantity, and alteration of ecosystem function. We also point out that effects of CECs may be non-linear, which would pose challenges in derivation of aquatic life criteria. We note that consideration needs to be given to the diversity of phylogenies, functions, and habitats represented in the data used to establish an aquatic life criterion in order to ensure that the overall goals of the process (adequate, appropriate level of population-level protection) are met.

8. As mentioned previously, the Committee recommends that EPA use mammalian pharmacology data available from the drug discovery process, genomics/proteomics/metabolomics and QSARs to screen CECs for modes of action and assess potential multiple modes of action for individual CECs. This would facilitate exploration of the use of parallel processes to develop aquatic life criteria for CECs with similar modes of action. To increase efficiency when determining an aquatic life criterion for one compound (such as EE2), the process could be repeated (or developed in parallel) for compounds (such as estradiol or E2) with similar modes of action. In addition, some guidance should be provided for site-specific applications where mixtures of compounds occur that may have additive effects that exceed individual aquatic life criteria.

9. Natural history of a ROPC can determine the magnitude of effects of CECs and should therefore be considered in the derivation of aquatic life criteria. The timing of breeding seasons, immaturity periods, intrinsic rates of reproduction, survivorship, and life span all influence the magnitude and direction of possible changes in population size and age structure. Fisheries take should be considered for recreationally or commercially important species.

10. In developing aquatic life criteria for CECs, EPA should give special consideration to the protection of threatened and endangered species. Unlike other species, threatened and endangered species are managed so that effects on individuals, not populations, are avoided. Specific mortality of threatened and endangered individuals, along with the contribution of each to the survival of the population, are parameters requiring accuracy with a minimum of uncertainty. In certain cases specific populations or evolutionarily significant units are the assessment endpoints to be considered.

4.3 Charge Question 3. Part II of this white paper was specifically developed as a companion to Part I and focuses on the use of ethynylestradiol as a model chemical to illustrate the technical issues presented by the workgroup, as well as providing a basis for understanding the recommendations. Does the *Committee* have suggestions that may improve the utility of Part II of this white paper for the purposes stated above?

The Committee finds that Part II of EPA's white paper, which is intended to illustrate application of EPA's recommendations concerning aquatic life criteria for CECs (rather than serve as a comprehensive case-study) is a generally well-written and thorough review of the existing literature on EE2; however, some improvements are recommended to enhance clarity. The Committee agrees that EE2 is an appropriate initial focal CEC given: 1) the extensive data available relative to other CECs; and 2) the ease with which it illustrates the complexities inherent in generating CEC-specific water quality criteria to protect aquatic life. Nevertheless, there may be limitations as to how readily the insights gained from the EE2 illustration can be applied to other CECs. Therefore, the EE2 illustrative example should be presented more clearly as an illustration of the aquatic life criteria setting process, rather than the derivation of a criterion for a specific CEC that is important in its own right (although the latter is certainly true). In this regard, more frequent and elaborated discussions of how the EE2 example illustrates points raised in Part I would be very useful. That is, the EE2 example could be used more forcefully to illustrate important issues and principles applicable across the breadth of CECs. The following recommendations are provided to improve the usefulness of the EE2 example.

Committee recommendations to improve the usefulness of the illustrative example

1. In the White Paper, EPA should explicitly recognize that EE2 is unique in being a data-rich CEC. The White Paper should highlight the fact that the Agency's interest in CECs goes beyond endocrine-active substances, and discuss how the example of EE2 might be extrapolated to other substances, particularly to data-poor substances. EPA should consider conducting a similar assessment for a compound with a minimal data set (in contrast to the maximal set of data available for EE2) and evaluate the new approach accordingly. Other CECs with differing modes of action such as polybrominated diphenyl ethers (PDBEs), bisphenol A, and perfluorinated octynyl sulfonate (PFOS) could be considered. These are problematic and controversial CECs and concerns about these chemicals differ from the stated concern in the White Paper over pharmaceutical and personal care products entering the aquatic ecosystem from wastewater treatment plants. They are nonetheless important and instructive case studies that might shed new light on revising the 1985 Guidelines.

2. The Committee suggests that some of the illustrative pieces of Part II could also be included in Part I in the form of succinct text boxes illustrating key concepts derived from the various recommendations (e.g., why certain steps in the Guidelines were included and others were not). Further, we suggest that the recommendations could be best illustrated if the text boxes were not restricted to EE2 but rather included other CECs (e.g., non-endocrine-active

3. Regarding the scope of the material included in the EE2 example, we note that the White Paper fails to address how the influence of EE2 might be affected by mixtures of compounds, especially those with similar modes of action (e.g., estradiol, estrone), as well as environmental (e.g., temperature) and biological (e.g., disease, starvation) modifying factors. Although the Committee recognizes that various offices/groups within EPA are investigating mixtures of compounds, and the White Paper cannot address all relevant issues in the development of guidelines, the document needs to be explicit regarding the importance of considering multiple stressors as well as synergies among CECs. For example, the White Paper should, at the very least, state the rationale for not considering all estrogens within a given body of water, and should provide examples of mixtures and synergies that could affect the toxicity of EE2.

4. Regarding choice of taxa for criteria derivation, the Committee agrees that, although use of non-resident species to assess EE2 effects appears to fit this case example, such may not always be the case. As such, the document should indicate that: 1) resident species data, especially life-cycle tests from resident species, remain extremely valuable, and 2) results from non-residents, while providing useful information, may not be generalized to resident species unless data are available to compare the sensitivities of the non-resident and resident species. We are also concerned that certain sensitive taxa such as amphibians were not included in Table 3.2, and that the key issue of development time to sexual maturity for long-lived charismatic species, such as sturgeon, is not addressed in the document. Research should be conducted to develop comparisons between long-lived species and surrogate test species.

5. The Committee is concerned that transgenerational effects were not considered in Part II of the White Paper. On page 14 in Part II of the White Paper, EPA states that "it does not seem that the evidence for transgenerational effects is sufficient for requiring their inclusion in the definition of an acceptable chronic test." Given EE2's role as an endocrine disrupting chemical, it is surprising that transgenerational effects were not included in the treatment of EE2. Further, given the "guilty until proven innocent" rule mentioned previously, the Committee recommends that the possibility of transgenerational effects be explicitly addressed in this illustration. Although transgenerational effects may not be expected in the case of EE2, potential transgenerational consequences must be addressed in a clear and transparent manner to ensure the development of a process that can also be applied to substances for which transgenerational effects are expected.

6. The Committee recommends that a broader array of endpoints be included in Part II. For example, although EE2 is a potent estrogen receptor agonist, it also can affect the central nervous system through indirect effects (steroid biotransformation). Non-traditional endpoints such as genomic or physiologically based pharmacokinetic modeling (PBPK) studies might be considered. As noted previously, use of non-traditional endpoints requires an understanding of their relevance to the health of the organism and ultimately the population. The illustration in Part II needs to answer the question as to whether or not it is

possible to calculate population-scale impacts with EE2 and, if not, how a criterion can be developed that will truly protect populations within a reasonable level of uncertainty (consistent with the intent of the Guidelines).

7. Two key recommendations regarding Part I of the White Paper are repeated here for the sake of consistency. First, the use of weight of evidence is implicit in the evaluation, but it needs to be explicit in the Part II of the document. Interactions between weight of evidence and the Precautionary Principle (i.e., appropriate levels of uncertainty) should be clarified. Second, when appropriate data are available, ECx values (i.e., the concentration causing an effect in x percent of the test organisms) should be used rather than NOECs/LOECs (i.e., no observed effects concentrations/lowest observed effects concentrations). The EC_x value reflects the information in the entire concentration-response curve and confidence intervals can be calculated as part of the curve fitting process. In contrast, the use of NOECs or LOECs by hypothesis tests are dependent upon the test concentrations that are used, the variability of the experimental technique, and the power of the statistical test. It is also not possible to generate confidence intervals for the NOEC/LOEC determinations. When available, the data used in a NOEC/LOEC determination should be used to calculate the EC_x value. Curve fitting, which uses more of the information contained in a data set and enables derivation of confidence intervals in the estimation of the EC_x, is the preferred method for representing dose (concentration)-response information. The selection of a specific EC_x value for derivation of an aquatic life criterion depends upon the level of protection or effect that decision makers are willing to accept or detect in the field. However, an EC_{20} has been used for most species and an EC_{10} has been used for threatened and endangered species.

8. The Committee finds that the clarity and transparency could be improved in several areas. In particular, the authors need to more explicitly describe how the illustration was developed from the recommendations in Part I. Part II also needs to be more explicit regarding how specific conclusions and assessments were derived from the data. The following specific revisions are suggested:

   - Data used to arrive at the values shown in Table 3.1 need to be provided in an appendix.

   - Table 1 arguably includes chronic data (*Lytechinus* and *Strongylocentrotus* echinoderm embryo development tests and the *Acartia* embryo test) that, not surprisingly, provide the most sensitive responses. While the Committee concurs that there is "ample evidence that a CMC is not needed and that it is unnecessary to conduct further tests to meet the minimum data requirements," the differentiation between acute and chronic data needs to be clearer and more transparent along with the implications of including equivocal data. Confusion between acute and chronic data can result in unnecessary levels of uncertainty and variability in criteria development. We note that slide 11 of the presentation provided by Dr. Russell Erickson of EPA ORD at the Committee meeting on June 30 provides the requisite level of clarity and transparency and could usefully be included in the document.

   - More explicit discussion of what constitutes "sufficient information" at various decision points would be helpful.

- The validity of using non-resident species is justified by text referring to complex tables, which do not provide the level of clarity and transparency necessary. Given the importance of validating the use of non-resident species, a graphic representation of the data is required (e.g., SSDs or horizontal lines indicating ranges for survival, growth and reproduction showing where the non-resident species fit).

- The Committee suggests that the authors add a concluding section that summarizes how the process of developing an aquatic life criterion for EE2 was modified by use of the new/revised guidelines. Part II should also provide an overview of how the process is expected to ultimately influence the criteria derived (in other words, how the new recommendations changed the final outcome).

- The EE2 example in Part II relies on nominal concentrations in addition to measured concentrations. The Committee assumes that criteria will not be based on nominal concentrations. However, it is acknowledged that as long as measured concentrations are within 20% of the nominal concentrations employed in a study, the concentrations reported could be the nominal concentrations. This needs to be made clear in the document.

- The first two paragraphs on page 13 of Part II would benefit from additional information on the timing of exposures to clarify that a 16% reduction in growth occurred after 28 days (paragraph 1, line 4). The timing for lower reproduction at 0.2 and 1 ng/L (paragraph 1, line 9) should also be clarified. We have a similar suggestion for effects on fertilization success (paragraph 2, lines 7-8).

- EPA should include in the appendix the residency status of each species or genus. The authors refer to residency in interpretations, but this information is missing from the document.

- A list of acronyms such as that provided for Part I also would be useful for Part II.

- A few questions are raised regarding citations: (1) Wenzel et al. (2002) is cited in the text (p. 14, paragraph 3, line 3) but not in the References; should the date of the reference be 2001? (2) Is the Kolpin et al. (2002) reference correct (both here and in Part I) - it does not seem to apply as it is a 2-page response to a comment, not a full paper? (3) Lee and Choi (2006) is listed in the References as “in press” but surely this is not still the case 2 years later? (4) The reliance on McKim et al. (1978) is questioned regarding the assertion that a “factor of 2 difference is generally found for other chemicals” (page 13, incomplete paragraph beginning the page, last line). We note that the McKim et al. (1978) paper only referred to one chemical, copper, and was published thirty years ago in a journal that does not have a high level of peer review.

4.4. Charge Question 4. Does the Committee have suggestions that would assist EPA in implementing the proposed recommendations discussed in the white paper, particularly with respect to developing the necessary scientific data and information

and/or providing expert scientific input at the appropriate stages of the risk assessment process?

The Committee has provided comments and recommendations to assist EPA in implementing the proposed recommendations discussed in the White Paper. Many of our comments focus on actions that would assist in implementation of the recommendations in the White Paper. However, we have also provided broader suggestions to facilitate future development of aquatic life criteria for CECs. Some of our comments and recommendations elaborate upon points discussed in previous sections of this advisory report.

Points to be considered in implementing the proposed recommendations in the White Paper

- Developing new criteria for CECs will require intensive data collection/generation activities. In an ideal world, it would be the Committee's recommendation that the same level of effort required to register a new chemical or pesticide also be required to develop aquatic life criteria for CECs. Acknowledging that this may not be possible in a world of limited resources, it will be important that OW/ORD prioritize the list of CECs for which aquatic life criteria will be developed. EPA should also identify data needs for these chemicals and leverage research development activities to develop the necessary data. Prioritization of CECs and data needs is further discussed below. In addition, EPA should conduct research to evaluate the sensitivity of test organisms that could be used as surrogates for resident and endangered species. Research should also compare the sensitivity of traditional and non-traditional test endpoints.

- Leveraging research efforts of other agencies is essential. In a time of decreasing research funds within the federal government, it is important that OW/ORD seek opportunities to leverage research efforts of other government agencies (e.g., FDA, U.S. Department of Agriculture [USDA], National Oceanic and Atmospheric Administration [NOAA]). The Committee was informed that EPA and the FDA are coordinating data sharing. We recommend that this activity continue and further that it be broadened to include other government agencies. We further support international collaboration between EPA, the European Union, Environment Canada and other appropriate non-U.S. environmental agencies. In addition, it is apparent that the regulated community, industries, animal husbandry organizations (e.g., National Cattlemen's Beef Association) and Publicly Owned Treatment Works, are actively engaged in independent evaluation of CECs. Establishing a government/industry consortium may be a way of leveraging limited funds for broader data development opportunities.

- Aquatic life criteria derivation for CECs should be conducted with knowledge of data provided by the Toxic Substances Control Act (TSCA) new product review process. Chemical manufacturers provide data to EPA on new products in accordance with the TSCA pre-manufacture notification requirements. The search for possible CECs should begin at this stage. At a minimum, aquatic life toxicity data provided by manufacturers in this process could be used to help derive aquatic life criteria. EPA could also consider integrating parts of the aquatic life criteria setting process into the TSCA new product review to aid in the assessment of new product notifications. Data and other information supplied for the

new product review under TSCA could also help the Agency prioritize CECs for aquatic life criteria derivation.

- Linkages between ecological risk assessment and development of aquatic life criteria need to be articulated. The Committee finds that, in many ways, the 1985 Guidelines contain the same principles of evaluating ecological risk that were subsequently incorporated into the 1989 *Risk Management Guidance for Superfund, Volume 2: Environmental Evaluation Manual*, (U.S. EPA, 1989), and in the 1992 *Framework for Ecological Risk Assessment* (U.S. EPA, 1992). Furthermore, it was apparent from the presentations made by EPA to the Committee that the ecological risk assessment principles have been considered by OW and ORD in planning further development of aquatic life criteria for CECs. However, the link between the 1989 Risk Management Guidelines and the aquatic life criteria derivation process is not apparent. The white paper needs to explicitly consider and illustrate risk assessment principles (e.g., identification of ROPCs, development of a conceptual diagram as previously recommended by the Committee).

- Tissue-based criteria should be considered for bioaccumulative CECs where food chain transfer is a concern. As mentioned previously, EPA should consider developing tissue-based criteria (i.e., expressing the criterion as a concentration of the pollutant in fish tissue rather than a concentration in the water). Aquatic life may be impaired directly by eating contaminated food, or indirectly by loss of prey or other ecosystem alterations that could stem from CECs. EPA is developing residue-based criteria for selenium (2002 and 2004 draft criteria documents [U.S. EPA, 2007]). Arguably, selenium can be considered a contaminant of emerging concern, but it does not fit the definition provided in Section 1.1 of Part I of the White Paper. The Committee finds that it may be useful to consider using selenium as an example for development of tissue-based aquatic life criteria for CECs.

- Quantitative linkages are needed between mode of action indicators and population-level endpoints. The proposed recommendations in the White Paper are consistent with bettering the risk assessment process. However, it will be important to set priorities for technical research that addresses significant gaps in knowledge needed to develop: 1) new indicators; 2) modeling capabilities; and 3) tools that provide integration and linkage of data sources. As mentioned previously, one of the most important challenges facing EPA will be linking mode of action indicators of exposure/effects to known population-level effects measurement endpoints such as survival, growth, reproduction and development. Developing conceptual models will guide criteria development but quantitative linkages will be needed to discern how mode of action indicators connect with population-level end points. The White Paper (p. 20, lines 21- 21) states that it is important to clearly link mode of action indicators such as histopathology to growth, reproduction and development. The Committee notes that in some instances it may be possible to define scaled risk (e.g., level of biological response in cell, tissue, etc.) and relative risk. This will make it possible to develop mode of action fingerprints that may provide earlier warning and greater sensitivity in predicting population-level effects.

- Additional factors may need to be considered to protect certain species. As noted previously, development of aquatic life criteria to provide adequate levels of protection for endangered,

highly managed, protected and "charismatic" species (e.g., marine mammals, eagles, polar bears, sturgeon) may require consideration of additional factors. For example, in marine mammals a dive reflex can force more contaminant into tissue due to pressure gradients. Endangered species may have very different lag times for sexual differentiation and uptake characteristics of CECs than the commonly used test species. For example, sturgeons are both endangered and charismatic fishes, and they are known to readily accumulate many CECs for an extended developmental period prior to reproduction. Given their long lifespan, a life cycle chronic test to determine uptake would be impossible, and an early life cycle test would be inappropriate.

- There is a need to compile a list of priority CECs. To facilitate development of aquatic life criteria, the Committee finds that it would be useful for federal agencies working on CECs (e.g., EPA, the U.S. Geological Survey, the U.S. Food and Drug Administration, the National Oceanic and Atmospheric Administration, and others) to compile a list of priority CECs that may pose the greatest risks to aquatic life – in other words, use a risk assessment approach in a problem formulation exercise to determine contaminants of potential concern. It is noted that compilation of a list of priority CECs can be further facilitated by greater involvement of public/stakeholders and relevant social sciences. Related to effective prioritization of CECs for criteria derivation is the need for consistent classification of CECs into categories relevant to aquatic life criteria. As suggested in other parts of this advisory report, mode of action may be a very useful basis for such classifications, as well as for addressing the issues of mixtures of multiple contaminants and of environmental pulses and concentrations. Analytical chemistry methods should be developed for CECs that are not already being measured in aquatic environments. The Committee suggests that calculation of the ratios of the Maximum Environmental Concentrations to meaningful measures of biological effects (e.g., CCCs, or LC_xs from toxicity testing) could initially be used to develop a list of high priority CECs. This kind of exercise would likely, but not certainly, show that estrogens should be a top priority for aquatic life criteria, as indicated in the White Paper.

- There is a clear need for continued development of analytical capabilities to measure levels of CECs in the aquatic environment. The ability to detect many of the CECs at appropriate concentrations in a controlled laboratory setting may be entirely different from detecting those same low concentrations in the aquatic environment. Addressing such issues will help current long term monitoring programs (e.g., NOAA National Status and Trends and Mussel Watch programs, U.S. Geological Survey National Water Quality Assessment Program, EPA Environmental Monitoring and Assessment Program) implement a coordinated approach to better define CEC exposures in the environment. Efforts to develop methodological approaches for lowering limits of detection and standards for CECs should involve discussion among agencies as well as the regulated community. It may be important to include the National Institute of Standards and Technology in the development of environmental standards for new CECs.

- Input into the aquatic life criteria development process is needed from private industry and state government. The perspective of these important stakeholders is needed before finalizing the White Paper. These groups should be asked to provide input on the science

associated with the modifications of the Guidelines related to CECs because aquatic life criteria will be used to develop state water quality standards.

- It would make sense to consider using parallel processes to develop aquatic life criteria for compounds with similar modes of action (e.g., the estrogens, SSRIs). Since estrone, estradiol and EE2 all act through the estrogen receptor in the most sensitive taxa, fish, and there is growing evidence in the literature that their effects are additive (Thorpe et al., 2003), it would make sense to develop aquatic life criteria for the natural and synthetic estrogens using parallel processes. Similar approaches may be possible for other CECs with highly specific modes of action such as different classes of antibiotics, statin drugs, and other pharmaceuticals that are CECs.

- Further questions to consider. As EPA develops a research plan to support derivation of aquatic life criteria for CECs, it may be useful to consider the following questions mentioned previously: How can aquatic life criteria be developed to take into account the fact that aquatic organisms are exposed to mixtures of CECs and mixtures of CECs, known contaminants, and other stressors? What are the likely modes of action of CECs that are known to be present in the environment? How can field study results be used to inform the derivation of an aquatic life criterion for a CEC?

Committee recommendations to assist EPA in implementing proposed approaches to developing aquatic life criteria for contaminants of emerging concern

The Committee provides the following specific recommendations to assist EPA in implementing the Agency's proposed approaches to developing aquatic life criteria for CECs. Some of these recommendations have been discussed in the context of responses to the other charge questions in this report.

1. EPA should develop a list of high priority CECs that may pose the greatest risks to aquatic life. Additional work should then be completed to further assess the potential risks posed by these chemicals and fund the research and data collection activities needed to support future development of aquatic life criteria. In this regard, we recommend that EPA's Office of Water and Office of Research and Development look for opportunities to leverage existing research with those ongoing in other federal programs, similar programs in international agencies, and industry groups, to gather the data needed to develop the aquatic life criteria. In particular, aquatic life criteria derivation for CECs should be conducted with knowledge of data provided by the Toxic Substances Control Act new product review process. The Agency should also work with other federal agencies to develop analytical chemistry detection methods and standards for these chemicals.

2. EPA should explicitly incorporate the principles for conducting Ecological Risk Assessment into the process of deriving aquatic life criteria for CECs. The Committee recommends that the EPA develop a separate process document that discusses the intended application of aquatic life criteria for CECs, and cross-links the 1985 Guidelines, EPA's 1992 Ecological Risk Assessment Principles, and the 2008 aquatic life CEC criteria White Paper. This cross-link document should also incorporate relevant ecological risk principles from other similar

documents developed for FDA, the Toxic Substances Control Act, or the Federal Insecticide, Fungicide, and Rodenticide Act. The document should not only outline the process of aquatic life criteria development, but address elements such as contaminant exposure through food uptake, Water Effects Ratios, Whole Effluent Testing, mixtures of compounds with similar modes of action, and application of aquatic life criteria for CECs in sediment management programs. The Committee is not recommending the development of a large, comprehensive document, rather something short and concise similar to the Eco Update Bulletins that have been published by EPA's Office of Solid Waste and Emergency Response (OSWER).

3. As previously discussed, the Committee recommends that EPA incorporate the use of conceptual models and ecosystem-based criteria into the process of deriving aquatic life criteria for CECs. We note that EPA programs are moving toward developing more comprehensive ecosystem-relevant criteria that take into consideration population-community structure, ecosystem functions-processes, and ecosystem services. The data available to develop CCCs are often "traditional" toxicity test data. It is important to develop the link between the protected resource, the assessment endpoint, and the measurement endpoint. An appropriate conceptual model for deriving aquatic life criteria for a CEC (see Figure 1) may be used to develop the fate and effects data and data quality objectives needed to support the aquatic life criterion.

4. As previously discussed, EPA should consider (where appropriate) developing tissue residue-based aquatic life criteria for CECs. The Agency should consider developing tissue-based criteria using the selenium example and expanding the definition of contaminants of emerging concern to include "chemicals and other substances of increasing environmental concern due to anthropogenic activities and for which current regulatory approaches are inadequate." Tissue residue-based criteria should be considered for CECs that have potential to bioaccumulate (e.g., carbamazepine) and bioconcentrate (e.g., flame retardants). At a minimum, the conceptual model could be used to help determine how to evaluate the available environmental data and models to assess the main routes of exposure for aquatic organisms.

5. EPA should use a "mode of action" approach to develop more effective aquatic life criteria not only for CECs, but also for legacy contaminants and mixtures. Additional studies in genomic and toxicodynamics processes would provide necessary data for the identification of "mode of action" fingerprints and aid in this process, particularly in the problem formulation stage of risk assessment. This should help guide regulators to carry out the most efficient bioassays which will be used in setting thresholds or criteria.

6. The Committee recommends that EPA appropriately use novel environmental indicators (molecular, genomics, proteomics) developed by other agencies, industry, and academia in future development of criteria. For example, NOAA has developed a robust health effects assessment for bottle nosed dolphins that addresses many CECs including flame retardants and antibiotic resistance (Fair et al., 2006; Goldstein et al., 2006; Houde et al., 2006; National Oceanic and Atmospheric Administration, 2008; Reif et al., 2006). This assessment involved analysis of immune function data and other animal health information such as

clinical evaluation, blood chemistry, contaminant and hormone data. Since dolphins are apex predators that breathe the air, swim in the water and constantly eat seafood, they provide a most exposed individual model. This type of insight may be pivotal in enhancing what EPA can do using the approach outlined in Part I of the White Paper.

7. EPA should take into consideration appropriate additional factors to ensure that aquatic life criteria are protective of sensitive and commercially/recreationally important species. These species are protected by additional laws (e.g., Magnuson Stevens Fishery Conservation and Management Act, Marine Mammal Protection Act) and this may invoke other special considerations when developing aquatic life criteria.

8. Before finalizing the White Paper, EPA should obtain input from private industry and state government on the Agency's proposed approaches for developing aquatic life criteria for CECs .

9. EPA should consider developing a mixture strategy to develop aquatic life criteria for classes of compounds with similar modes of action. As previously mentioned parallel processes could be used to develop aquatic life criteria for broad classes of CECs with similar modes of action (e.g., the estrogens, SSRIs).

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EPA
United States
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U.S. Environmental Protection Agency and Emerging Contaminants

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National Exposure Research Laboratory

United States Environmental Protection Agency

Outline of Presentation

- USEPA Background
- Water Regulation 101
- How Emerging Contaminants *may* be regulated in the future
- Research on Emerging Contaminants in Drinking Water

Regulatory History

1914
Treasury Department
Public Health Service

1948
Federal Security Agency
Public Health Service
Division of Water Supply and Pollution Control

1953
Dept of Health, Education and Welfare
Public Health Service
Division of Water Supply and Pollution Control

1965
Dept of Health, Education and Welfare
Federal Water Pollution Control Administration

1970
Department of Interior
Federal Water Quality Administration

USEPA Organizational Chart

Office of Administration and Resource Management	Office of International Affairs	Region 1
Office of Air and Radiation	Office of Environmental Information	Region 2
Office of Enforcement and Compliance Assurance	Office of Prevention, Pesticides, and Toxic Substances	Region 3
Office of Chief Financial Officer	Office of Research and Development	Region 4
Office of General Council	Office of Solid Waste and Emergency Response	Region 5
Office of Inspector General	Office of Water	Region 6
		Region 7
		Region 8
		Region 9
		Region 10

Office of Research and Development (ORD)

National Exposure Research Laboratory

National Health and Environmental Effects Research Laboratory

National Risk Management Research Laboratory

National Center for Computational Toxicology

National Center for Environmental Assessment

National Center for Environmental Research

National Homeland Security Research Center

Office of Science Policy

Office of Resources Management Administration

United States Environmental Protection Agency

Mission of ORD

- **Perform research and development** to identify, understand, and solve current and future environmental problems.
- **Provide responsive technical support** to EPA's mission.
- **Integrate the work of ORD's scientific partners** (other agencies, nations, private sector organizations, and academia).
- **Provide leadership** in addressing emerging environmental issues and in advancing the science and technology of risk assessment and risk management.

United States Environmental Protection Agency

Water Regulation 101

United States Environmental Protection Agency

Disclaimers and Caveats

- ORD (and Susan) does not promulgate regulations and standards.
- ORD (and Susan) does not monitor compliance.
- ORD (and Susan) does not levy fines.
- Although this work was reviewed by USEPA and approved for publication, it may not necessarily reflect official Agency policy.
- The conclusions and opinions drawn are solely those of the author (Susan) and should not be construed to reflect the views of the Agency.

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EPA United States Environmental Protection Agency

History of US Water Pollution Law

- Refuse Act of 1899
- Public Health Service Standards beginning in 1914
- Water Pollution Control Act 1948
- Water Quality Act of 1965
- Water Quality Improvement Act of 1970
- Clean Water Act 1972 (Amended 1977)
- Safe Drinking Water Act 1974 (Amended 1996)

United States Environmental Protection Agency

Safe Drinking Water Act (SDWA)

- Protect the public's health by regulating the drinking water supply
- Rivers, lakes, streams, reservoirs, springs, and ground waters– any potential source of drinking water– are covered.
- Applies to all public water systems that have at least 15 service connections or serve at least 25 people per day for 60 days of the year. Over 160,000!

How are chemicals regulated under SDWA?

- USEPA identifies contaminants that occur, or may occur, in drinking water with a frequency and at levels that pose a threat to public health.
  - Contaminant Candidate List (CCL)
    - CCL3 released February 2008, listing 104 contaminants (11 microbial and 93 chemical)
    - Every five years, must decide to regulate (or not) at least five contaminants
  - Unregulated Contaminant Monitoring Regulation (UCMR)
    - Limited to 30 contaminants in any five year cycle
    - UCMR2 was finalized December 2006- sampling 2008

What is the drinking water regulation decision making process?

When making a “determination” to regulate, the law requires that three areas are considered:

- projected adverse health effects from the contaminant,
- the extent of occurrence of the contaminant in drinking water, and
- whether regulation of the contaminant would present a “meaningful opportunity” for reducing risks to health.

United States Environmental Protection Agency

Chemical X met the regulation criteria, now what?

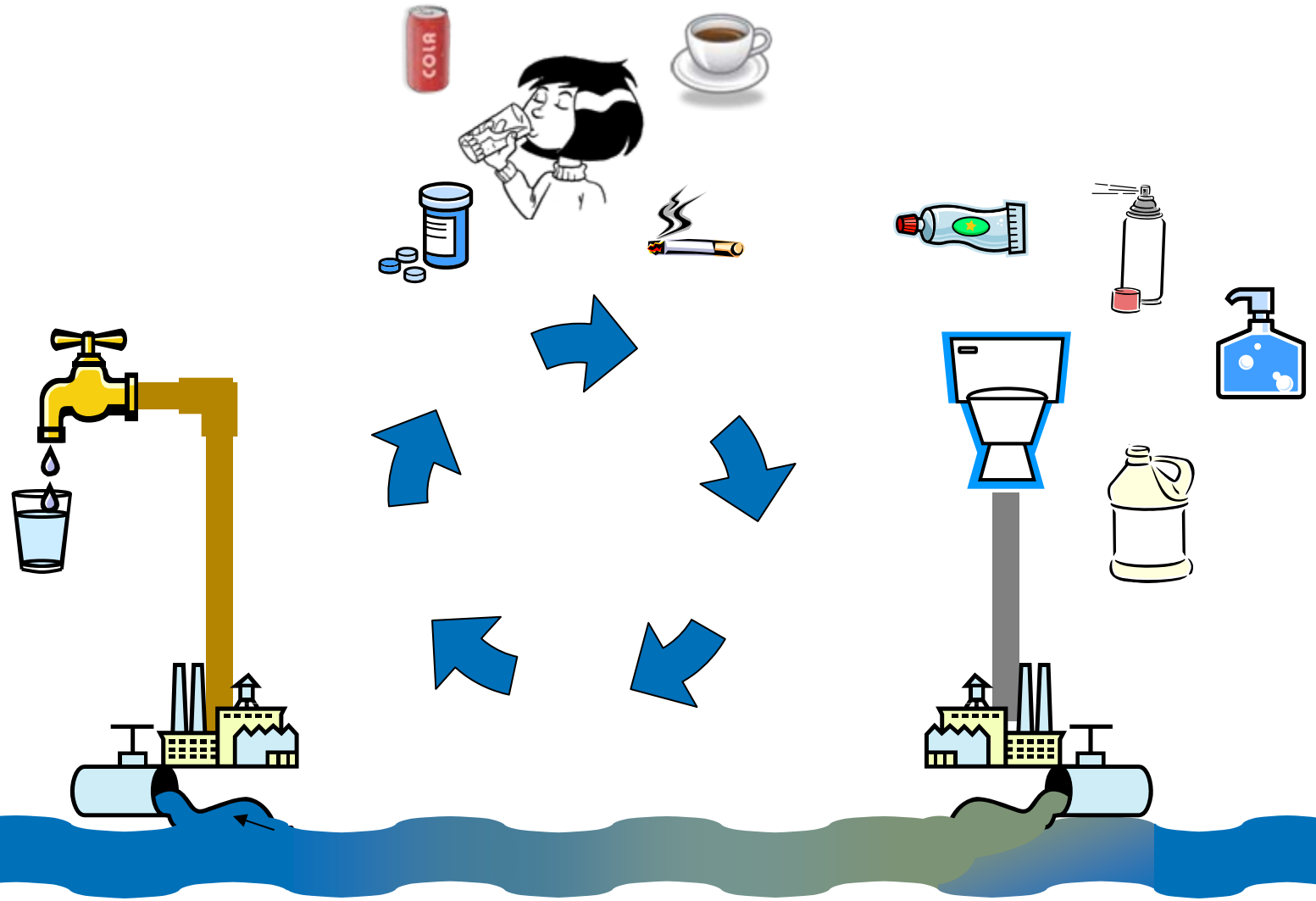
- Must determine the Maximum Contaminant Level Goal (MCLG) for each chemical
  - Concentration below which there is no known or expected risk to health
  - For many carcinogens and microorganisms, the MCLG is zero
- Next, set the Maximum Contaminant Level (MCL)
  - National Primary Drinking Water Regulations (NPDWRs)
  - Maximum concentration permitted in drinking water
  - If too difficult to measure, may impose a treatment technique (TT) requirement
- Every six years, the NPDWRs are revisited to make sure the public's health is still being protected

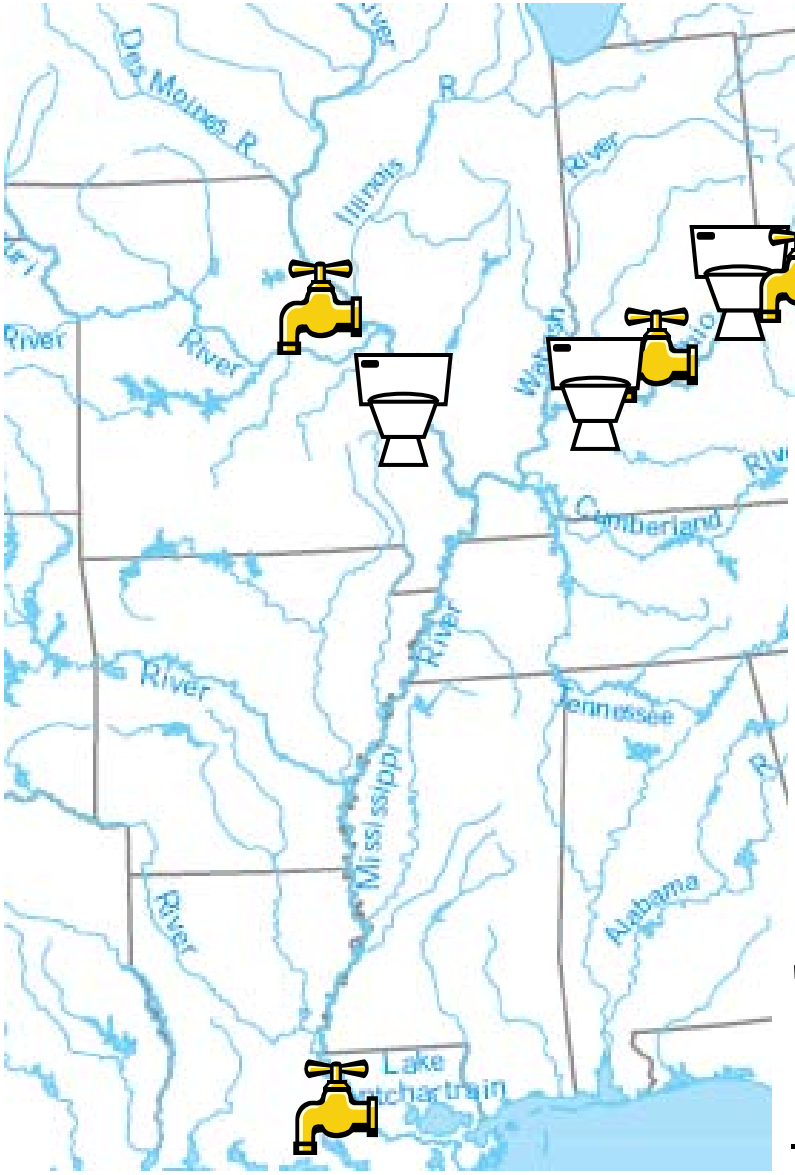
Advisories

- In addition to Regulations, USEPA issues advisories as guidance to Federal, State and local officials
- SDWA Health Advisories (HA)
  - One-Day HA: Designed to protect a 10 kg child consuming 1 L/ day from noncarcinogenic adverse effects from 1 day of exposure
  - Ten-Day HA: Designed to protect a 10 kg child consuming 1 L/ day from noncarcinogenic adverse effects from 10 days of exposure
  - Lifetime HA: Designed to protect a 70 kg adult consuming 2 L/ day from noncarcinogenic adverse effects from a lifetime of exposure
- CWA Fish Advisories: Consumption advisories to limit or avoid eating fish caught in specific water bodies

Emerging Contaminants in the Drinking Water Cycle

Water Cycle



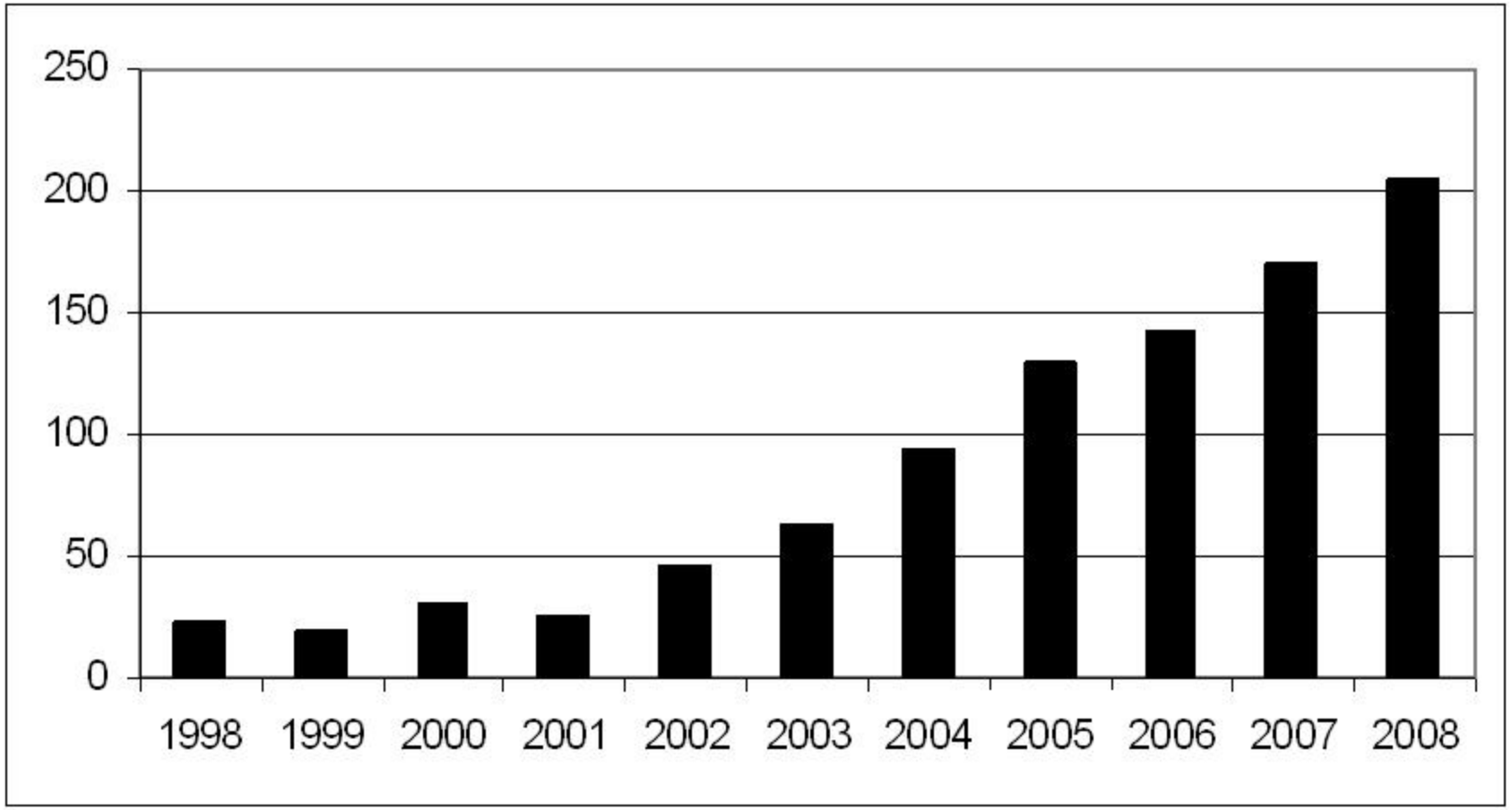


1980 USEPA survey found 20 communities (>7 million people) with drinking water source water containing 2.3-16% wastewater during average flow

(EPA-600/2-80-044)

"The best wine is the oldest, the best water the newest."
—William Blake (1757-1827)

Pharmaceutical Literature Citations

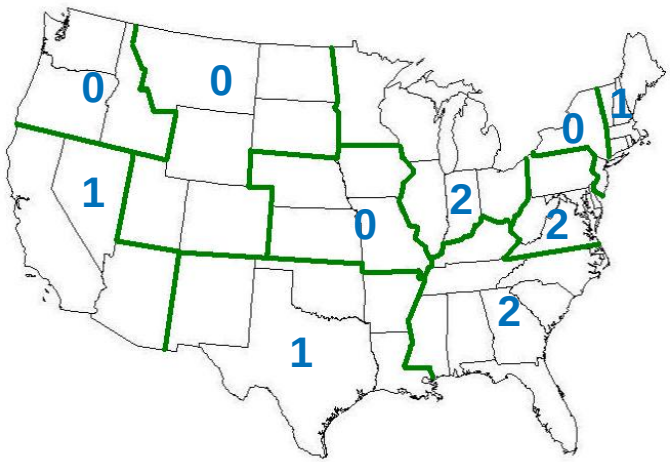


Currently, public interest on emerging contaminants in drinking water is high…

…but the drinking water regulation process is only equipped to evaluate a finite number of chemicals every 5 years

- Literally 1,000s of chemicals are considered ECs.
- Very little data on the presence of these chemicals in finished drinking water.
- There is a need to triage which ECs are frequently found and therefore *may* need to be more fully investigated under the SDWA.

Drinking Water Phase I - 2007

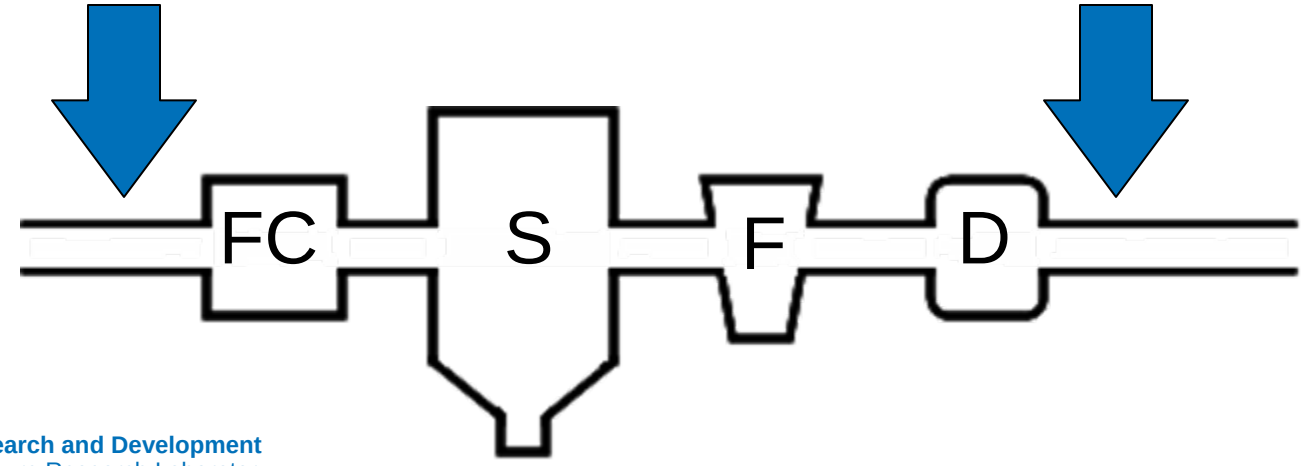


Number of Phase I sampling sites in each USEPA Region

- Nine DWTPs (one site sampled twice, n = 10)
- Source water had known or suspected wastewater contributions
- One groundwater
- Five used conventional treatment (coagulation, clarification, filtration, and chlorination)
- Three used advanced treatments (ozone, UV, carbon filtration)

Sampling Design

- Paired source and finished water samples, collected taking the residence time of the plant into account.
- Locations sampled only once.
- Included high percentage of QA/QC samples (25% spike, 25% duplicate, field blank from every location)



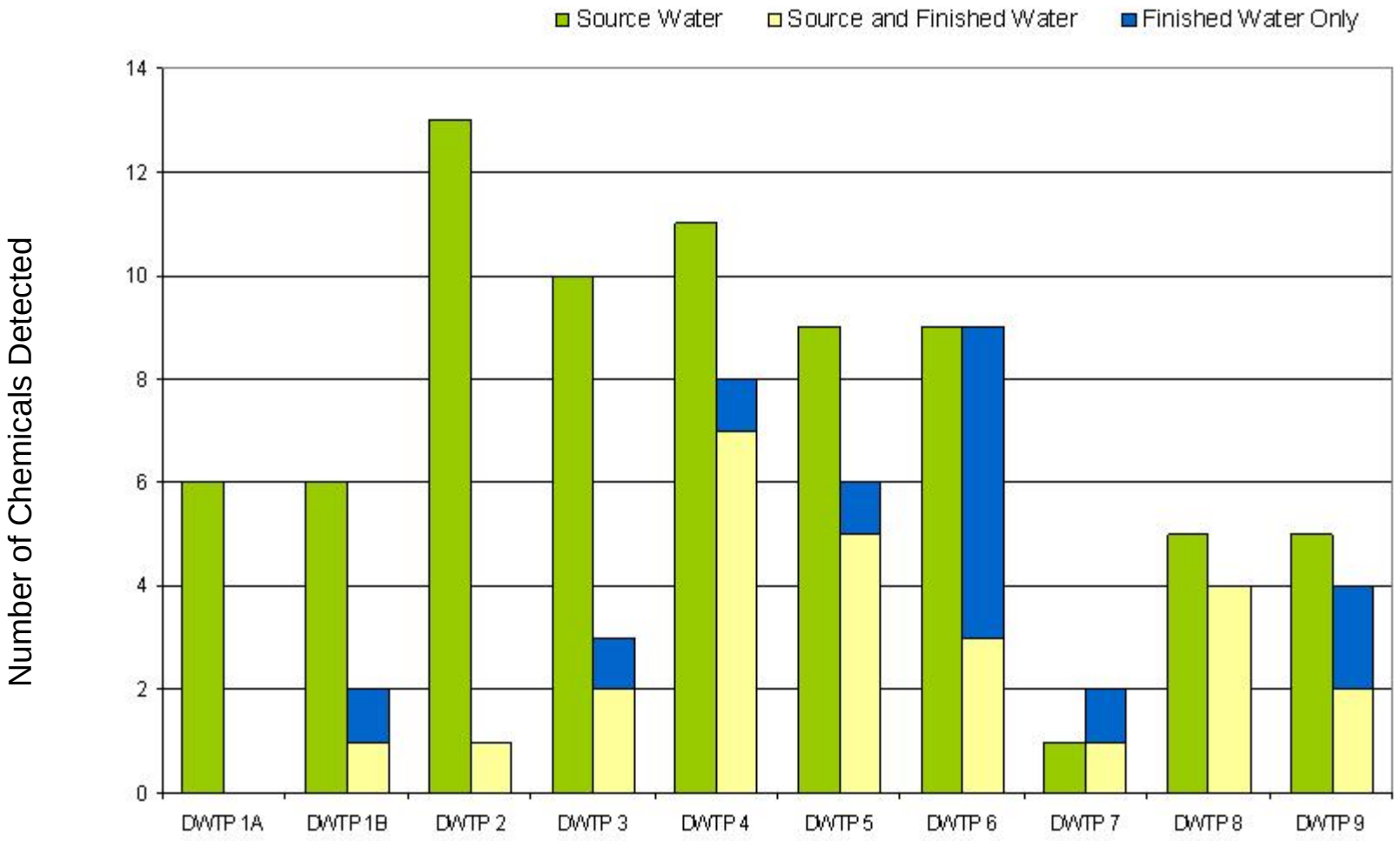
USGS Methods Used

- Pharmaceutical Method (SH 2080)
  - LC/MS
  - 13 Chemicals
- Wastewater Method (SH 1433)
  - GC/MS
  - 60 Chemicals
- New Antidepressant Method
  - LC/MS/MS
  - 10 Chemicals

83 Chemicals

- 18 prescription pharmaceuticals
- 6 nonprescription pharmaceuticals
- 14 industrial chemicals
- 10 fragrances
- 9 polycyclic aromatic hydrocarbons
- 7 pesticides
- 7 detergent metabolites
- 5 household chemicals
- 4 sterols
- 3 flame retardants

Site Specific Detections



Source/ Finished Water Comparisons

	S (n)	F (n)	Wilcoxon *p*-values (based on paired conc)
bupropion	**8**	**4**	**0.148**
venlafaxine	**8**	**nd**	***0.008***
caffeine	**6**	**2**	**0.078**
tri(2-chloroethyl)phosphate	**6**	**2**	***0.031***
carbamazepine	**7**	**6**	**0.406**
sulfamethoxazole	**5**	**1**	**0.436**
tributylphosphate	**4**	**1**	**0.625**
citalopram	**3**	**nd**	**0.250**
sertraline	**3**	**nd**	**0.250**

Comparison of Detections to Dose

- Carbamazepine
- WHO Defined Daily Dose: 1000 mg
- Maximum detected concentration in finished water 18 ng/L (Benotti et al *ES&T* 2009)

- To calculate the number of liters to consume single dose
  - 1000 mg X (1L/ 18 ng) X (10^6 ng/mg) = 55,555,556 L

- Assuming 2 L drinking water consumption per day
  - 55,555,556 L X (1 day/2 L) X (1 year/ 365 days) = 76,104 years

Margin of Exposure

- What is safe?
- Pomati (*ES&T* 2007) has provided the most conservative guideline.
- Divide lowest recommended therapeutic dose (LRTD) by
  - 10 for intrahuman viability
  - 10 for LRTD not being a no effect level
  - 10 for endocrine active and cytotoxic compounds
  - 10 for extrapolation of animal data to humans
  - 10 for the presence of mixtures in the environment
- MOE > 100,000 (or an environmental concentration < 10^{-5} of LRTD) should be protective of human health

For carbamazepine:

MOE = (1000 mg X 10^6 ng/mg)/ (2 L X 18 ng/ L) = 27,777,778

Pharmaceutical Detections in Perspective

Compound	Finished Water Maximum Conc (ng/ L)	Defined Daily Dose (mg)	Volume to Consume Single Dose (L)	Time to Consume Single Dose (years)	Margin of Exposure (MOE)
atenolol	18	75	4,166,667	5,708	2,083,333
carbamazepine	18	1000	55,555,556	76,104	27,777,778
diazepam	0.33	10	30,303,030	41,511	15,151,515
fluoxetine	0.82	20	24,390,244	33,411	12,195,122
gemfibrozil	2.1	1200	571,428,571	782,779	285,714,286
sulfamethoxazole	3	2000	666,666,667	913,242	333,333,333

Benotti et al *ES&T* 2009

Future Work

Drinking Water Phase II

- 20 to 30 Utilities
- Paired source and finished water samples
- > 200 chemical and microbiological analytes
- ~ 50 chemicals analyzed by more than one method
- Even more QA/QC than Phase I (duplicate and spike at every location, ~ 70% QC)
- Awaiting Information Collection Rule approval; sampling should begin Fall 2009

Take Home Messages

- Emerging contaminants are present in household wastewater, and are not entirely removed during wastewater treatment.
- Treatment “removal” may just be transformation.
- The chemicals present in treated wastewater can persist and travel through surface and ground waters, which can potentially be the source water for another communities drinking water.
- Concentrations of pharmaceuticals present in finished drinking water are much lower than the typical daily dose.

Collaborators and Contact Information

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- 513-569-7526

National Primary Drinking Water Regulations

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
Acrylamide	TT[4]	Nervous system or blood problems; increased risk of cancer	Added to water during sewage/ wastewater treatment	zero
Alachlor	0.002	Eye, liver, kidney, or spleen problems; anemia; increased risk of cancer	Runoff from herbicide used on row crops	zero
Alpha/photon emitters	15 picocuries per Liter (pCi/L)	Increased risk of cancer	Erosion of natural deposits of certain minerals that are radioactive and may emit a form of radiation known as alpha radiation	zero
Antimony	0.006	Increase in blood cholesterol; decrease in blood sugar	Discharge from petroleum refineries; fire retardants; ceramics; electronics; solder	0.006
Arsenic	0.010	Skin damage or problems with circulatory systems, and may have increased risk of getting cancer	Erosion of natural deposits; runoff from orchards; runoff from glass & electronics production wastes	0
Asbestos (fibers >10 micrometers)	7 million fibers per Liter (MFL)	Increased risk of developing benign intestinal polyps	Decay of asbestos cement in water mains; erosion of natural deposits	7 MFL
Atrazine	0.003	Cardiovascular system or reproductive problems	Runoff from herbicide used on row crops	0.003
Barium	2	Increase in blood pressure	Discharge of drilling wastes; discharge from metal refineries; erosion of natural deposits	2
Benzene	0.005	Anemia; decrease in blood platelets; increased risk of cancer	Discharge from factories; leaching from gas storage tanks and landfills	zero
Benzo(a)pyrene (PAHs)	0.0002	Reproductive difficulties; increased risk of cancer	Leaching from linings of water storage tanks and distribution lines	zero
Beryllium	0.004	Intestinal lesions	Discharge from metal refineries and coal-burning factories; discharge from electrical, aerospace, and defense industries	0.004
Beta photon emitters	4 millirems per year	Increased risk of cancer	Decay of natural and man-made deposits of certain minerals that are radioactive and may emit forms of radiation known as photons and beta radiation	zero
Bromate	0.010	Increased risk of cancer	Byproduct of drinking water disinfection	zero
Cadmium	0.005	Kidney damage	Corrosion of galvanized pipes; erosion of natural deposits; discharge from metal refineries; runoff from waste batteries and paints	0.005
Carbofuran	0.04	Problems with blood, nervous system, or reproductive system	Leaching of soil fumigant used on rice and alfalfa	0.04

LEGEND

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
Carbon tetrachloride	0.005	Liver problems; increased risk of cancer	Discharge from chemical plants and other industrial activities	**zero**
Chloramines (as Cl_2)	MRDL=4.0[1]	Eye/nose irritation; stomach discomfort; anemia	Water additive used to control microbes	**MRDLG=4[1]**
Chlordane	0.002	Liver or nervous system problems; increased risk of cancer	Residue of banned termiticide	**zero**
Chlorine (as Cl_2)	MRDL=4.0[1]	Eye/nose irritation; stomach discomfort	Water additive used to control microbes	**MRDLG=4[1]**
Chlorine dioxide (as ClO_2)	MRDL=0.8[1]	Anemia; infants, young children, and fetuses of pregnant women: nervous system effects	Water additive used to control microbes	**MRDLG=0.8[1]**
Chlorite	1.0	Anemia; infants, young children, and fetuses of pregnant women: nervous system effects	Byproduct of drinking water disinfection	**0.8**
Chlorobenzene	0.1	Liver or kidney problems	Discharge from chemical and agricultural chemical factories	**0.1**
Chromium (total)	0.1	Allergic dermatitis	Discharge from steel and pulp mills; erosion of natural deposits	**0.1**
Copper	TT[5]; Action Level=1.3	Short-term exposure: Gastrointestinal distress. Long-term exposure: Liver or kidney damage. People with Wilson's Disease should consult their personal doctor if the amount of copper in their water exceeds the action level	Corrosion of household plumbing systems; erosion of natural deposits	**1.3**
Cryptosporidium	TT[7]	Short-term exposure: Gastrointestinal illness (e.g., diarrhea, vomiting, cramps)	Human and animal fecal waste	**zero**
Cyanide (as free cyanide)	0.2	Nerve damage or thyroid problems	Discharge from steel/metal factories; discharge from plastic and fertilizer factories	**0.2**
2,4-D	0.07	Kidney, liver, or adrenal gland problems	Runoff from herbicide used on row crops	**0.07**
Dalapon	0.2	Minor kidney changes	Runoff from herbicide used on rights of way	**0.2**
1,2-Dibromo-3-chloropropane (DBCP)	0.0002	Reproductive difficulties; increased risk of cancer	Runoff/leaching from soil fumigant used on soybeans, cotton, pineapples, and orchards	**zero**
o-Dichlorobenzene	0.6	Liver, kidney, or circulatory system problems	Discharge from industrial chemical factories	**0.6**
p-Dichlorobenzene	0.075	Anemia; liver, kidney, or spleen damage; changes in blood	Discharge from industrial chemical factories	**0.075**
1,2-Dichloroethane	0.005	Increased risk of cancer	Discharge from industrial chemical factories	**zero**

LEGEND DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
1,1-Dichloroethylene	0.007	Liver problems	Discharge from industrial chemical factories	**0.007**
cis-1,2-Dichloroethylene	0.07	Liver problems	Discharge from industrial chemical factories	**0.07**
trans-1,2, Dichloroethylene	0.1	Liver problems	Discharge from industrial chemical factories	**0.1**
Dichloromethane	0.005	Liver problems; increased risk of cancer	Discharge from industrial chemical factories	**zero**
1,2-Dichloropropane	0.005	Increased risk of cancer	Discharge from industrial chemical factories	**zero**
Di(2-ethylhexyl) adipate	0.4	Weight loss, liver problems, or possible reproductive difficulties	Discharge from chemical factories	**0.4**
Di(2-ethylhexyl) phthalate	0.006	Reproductive difficulties; liver problems; increased risk of cancer	Discharge from rubber and chemical factories	**zero**
Dinoseb	0.007	Reproductive difficulties	Runoff from herbicide used on soybeans and vegetables	**0.007**
Dioxin (2,3,7,8-TCDD)	0.00000003	Reproductive difficulties; increased risk of cancer	Emissions from waste incineration and other combustion; discharge from chemical factories	**zero**
Diquat	0.02	Cataracts	Runoff from herbicide use	**0.02**
Endothall	0.1	Stomach and intestinal problems	Runoff from herbicide use	**0.1**
Endrin	0.002	Liver problems	Residue of banned insecticide	**0.002**
Epichlorohydrin	TT[4]	Increased cancer risk; stomach problems	Discharge from industrial chemical factories; an impurity of some water treatment chemicals	**zero**
Ethylbenzene	0.7	Liver or kidney problems	Discharge from petroleum refineries	**0.7**
Ethylene dibromide	0.00005	Problems with liver, stomach, reproductive system, or kidneys; increased risk of cancer	Discharge from petroleum refineries	**zero**
Fecal coliform and *E. coli*	MCL[6]	Fecal coliforms and *E. coli* are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes may cause short term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, and people with severely compromised immune systems.	Human and animal fecal waste	**zero[6]**

LEGEND

DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
Fluoride	4.0	Bone disease (pain and tenderness of the bones); children may get mottled teeth	Water additive which promotes strong teeth; erosion of natural deposits; discharge from fertilizer and aluminum factories	**4.0**
Giardia lamblia	TT[7]	Short-term exposure: Gastrointestinal illness (e.g., diarrhea, vomiting, cramps)	Human and animal fecal waste	**zero**
Glyphosate	0.7	Kidney problems; reproductive difficulties	Runoff from herbicide use	**0.7**
Haloacetic acids (HAA5)	0.060	Increased risk of cancer	Byproduct of drinking water disinfection	**n/a[9]**
Heptachlor	0.0004	Liver damage; increased risk of cancer	Residue of banned termiticide	**zero**
Heptachlor epoxide	0.0002	Liver damage; increased risk of cancer	Breakdown of heptachlor	**zero**
Heterotrophic plate count (HPC)	TT[7]	HPC has no health effects; it is an analytic method used to measure the variety of bacteria that are common in water. The lower the concentration of bacteria in drinking water, the better maintained the water system is.	HPC measures a range of bacteria that are naturally present in the environment	**n/a**
Hexachlorobenzene	0.001	Liver or kidney problems; reproductive difficulties; increased risk of cancer	Discharge from metal refineries and agricultural chemical factories	**zero**
Hexachloro-cyclopentadiene	0.05	Kidney or stomach problems	Discharge from chemical factories	**0.05**
Lead	TT[5]; Action Level=0.015	Infants and children: Delays in physical or mental development; children could show slight deficits in attention span and learning abilities; Adults: Kidney problems; high blood pressure	Corrosion of household plumbing systems; erosion of natural deposits	**zero**
Legionella	TT[7]	Legionnaire's Disease, a type of pneumonia	Found naturally in water; multiplies in heating systems	**zero**
Lindane	0.0002	Liver or kidney problems	Runoff/leaching from insecticide used on cattle, lumber, and gardens	**0.0002**
Mercury (inorganic)	0.002	Kidney damage	Erosion of natural deposits; discharge from refineries and factories; runoff from landfills and croplands	**0.002**
Methoxychlor	0.04	Reproductive difficulties	Runoff/leaching from insecticide used on fruits, vegetables, alfalfa, and livestock	**0.04**
Nitrate (measured as Nitrogen)	10	Infants below the age of six months who drink water containing nitrate in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue-baby syndrome.	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	**10**

LEGEND

DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
Nitrite (measured as Nitrogen)	1	Infants below the age of six months who drink water containing nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue-baby syndrome.	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	1
Oxamyl (Vydate)	0.2	Slight nervous system effects	Runoff/leaching from insecticide used on apples, potatoes, and tomatoes	0.2
Pentachlorophenol	0.001	Liver or kidney problems; increased cancer risk	Discharge from wood-preserving factories	zero
Picloram	0.5	Liver problems	Herbicide runoff	0.5
Polychlorinated biphenyls (PCBs)	0.0005	Skin changes; thymus gland problems; immune deficiencies; reproductive or nervous system difficulties; increased risk of cancer	Runoff from landfills; discharge of waste chemicals	zero
Radium 226 and Radium 228 (combined)	5 pCi/L	Increased risk of cancer	Erosion of natural deposits	zero
Selenium	0.05	Hair or fingernail loss; numbness in fingers or toes; circulatory problems	Discharge from petroleum and metal refineries; erosion of natural deposits; discharge from mines	0.05
Simazine	0.004	Problems with blood	Herbicide runoff	0.004
Styrene	0.1	Liver, kidney, or circulatory system problems	Discharge from rubber and plastic factories; leaching from landfills	0.1
Tetrachloroethylene	0.005	Liver problems; increased risk of cancer	Discharge from factories and dry cleaners	zero
Thallium	0.002	Hair loss; changes in blood; kidney, intestine, or liver problems	Leaching from ore-processing sites; discharge from electronics, glass, and drug factories	0.0005
Toluene	1	Nervous system, kidney, or liver problems	Discharge from petroleum factories	1
Total Coliforms	5.0 percent[8]	Coliforms are bacteria that indicate that other, potentially harmful bacteria may be present. See fecal coliforms and *E. coli*	Naturally present in the environment	zero
Total Trihalomethanes (TTHMs)	0.080	Liver, kidney, or central nervous system problems; increased risk of cancer	Byproduct of drinking water disinfection	n/a[9]
Toxaphene	0.003	Kidney, liver, or thyroid problems; increased risk of cancer	Runoff/leaching from insecticide used on cotton and cattle	zero
2,4,5-TP (Silvex)	0.05	Liver problems	Residue of banned herbicide	0.05
1,2,4-Trichlorobenzene	0.07	Changes in adrenal glands	Discharge from textile finishing factories	0.07

LEGEND

DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
1,1,1-Trichloroethane	0.2	Liver, nervous system, or circulatory problems	Discharge from metal degreasing sites and other factories	**0.2**
1,1,2-Trichloroethane	0.005	Liver, kidney, or immune system problems	Discharge from industrial chemical factories	**0.003**
Trichloroethylene	0.005	Liver problems; increased risk of cancer	Discharge from metal degreasing sites and other factories	**zero**
Turbidity	TT[7]	Turbidity is a measure of the cloudiness of water. It is used to indicate water quality and filtration effectiveness (e.g., whether disease-causing organisms are present). Higher turbidity levels are often associated with higher levels of disease-causing microorganisms such as viruses, parasites, and some bacteria. These organisms can cause short term symptoms such as nausea, cramps, diarrhea, and associated headaches.	Soil runoff	**n/a**
Uranium	30µg/L	Increased risk of cancer, kidney toxicity	Erosion of natural deposits	**zero**
Vinyl chloride	0.002	Increased risk of cancer	Leaching from PVC pipes; discharge from plastic factories	**zero**
Viruses (enteric)	TT[7]	Short-term exposure: Gastrointestinal illness (e.g., diarrhea, vomiting, cramps)	Human and animal fecal waste	**zero**
Xylenes (total)	10	Nervous system damage	Discharge from petroleum factories; discharge from chemical factories	**10**

LEGEND DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

NOTES

1 Definitions
- **Maximum Contaminant Level Goal (MCLG):** The level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs allow for a margin of safety and are non-enforceable public health goals.
- **Maximum Contaminant Level (MCL):** The highest level of a contaminant that is allowed in drinking water. MCLs are set as close to MCLGs as feasible using the best available treatment technology and taking cost into consideration. MCLs are enforceable standards.
- **Maximum Residual Disinfectant Level Goal (MRDLG):** The level of a drinking water disinfectant below which there is no known or expected risk to health. MRDLGs do not reflect the benefits of the use of disinfectants to control microbial contaminants.
- **Maximum Residual Disinfectant Level (MRDL):** The highest level of a disinfectant allowed in drinking water. There is convincing evidence that addition of a disinfectant is necessary for control of microbial contaminants.
- **Treatment Technique (TT):** A required process intended to reduce the level of a contaminant in drinking water.

2 Units are in milligrams per liter (mg/L) unless otherwise noted. Milligrams per liter are equivalent to parts per million (ppm).

3 Health effects are from long-term exposure unless specified as short-term exposure.

4 Each water system must certify annually, in writing, to the state (using third-party or manufacturers certification) that when it uses acrylamide and/or epichlorohydrin to treat water, the combination (or product) of dose and monomer level does not exceed the levels specified, as follows: Acrylamide = 0.05 percent dosed at 1 mg/L (or equivalent); Epichlorohydrin = 0.01 percent dosed at 20 mg/L (or equivalent).

5 Lead and copper are regulated by a Treatment Technique that requires systems to control the corrosiveness of their water. If more than 10 percent of tap water samples exceed the action level, water systems must take additional steps. For copper, the action level is 1.3 mg/L, and for lead is 0.015 mg/L.

6 A routine sample that is fecal coliform-positive or E. coli-positive triggers repeat samples--if any repeat sample is total coliform-positive, the system has an acute MCL violation. A routine sample that is total coliform-positive and fecal coliform-negative or E. coli-negative triggers repeat samples--if any repeat sample is fecal coliform-positive or E. coli-positive, the system has an acute MCL violation. See also Total Coliforms.

7 EPA's surface water treatment rules require systems using surface water or ground water under the direct influence of surface water to (1) disinfect their water, and (2) filter their water or meet criteria for avoiding filtration so that the following contaminants are controlled at the following levels:
- ***Cryptosporidium*:** 99 percent removal for systems that filter. Unfiltered systems are required to include Cryptosporidium in their existing watershed control provisions.
- **Giardia lamblia:** 99.9 percent removal/inactivation
- **Viruses:** 99.9 percent removal/inactivation
- ***Legionella*:** No limit, but EPA believes that if *Giardia* and viruses are removed/inactivated, according to the treatment techniques in the surface water treatment rule, *Legionella* will also be controlled.
- **Turbidity:** For systems that use conventional or direct filtration, at no time can turbidity (cloudiness of water) go higher than 1 nephelometric turbidity unit (NTU), and samples for turbidity must be less than or equal to 0.3 NTU in at least 95 percent of the samples in any month. Systems that use filtration other than the conventional or direct filtration must follow state limits, which must include turbidity at no time exceeding 5 NTU.
- **HPC:** No more than 500 bacterial colonies per milliliter
- **Long Term 1 Enhanced Surface Water Treatment:** Surface water systems or ground water systems under the direct influence of surface water serving fewer than 10,000 people must comply with the applicable Long Term 1 Enhanced Surface Water Treatment Rule provisions (e.g. turbidity standards, individual filter monitoring, *Cryptosporidium* removal requirements, updated watershed control requirements for unfiltered systems).
- **Long Term 2 Enhanced Surface Water Treatment:** This rule applies to all surface water systems or ground water systems under the direct influence of surface water. The rule targets additional *Cryptosporidium* treatment requirements for higher risk systems and includes provisions to reduce risks from uncovered finished water storages facilities and to ensure that the systems maintain microbial protection as they take steps to reduce the formation of disinfection byproducts. (Monitoring start dates are staggered by system size. The largest systems (serving at least 100,000 people) will begin monitoring in October 2006 and the smallest systems (serving fewer than 10,000 people) will not begin monitoring until October 2008. After completing monitoring and determining their treatment bin, systems generally have three years to comply with any additional treatment requirements.)
- **Filter Backwash Recycling:** The Filter Backwash Recycling Rule requires systems that recycle to return specific recycle flows through all processes of the system's existing conventional or direct filtration system or at an alternate location approved by the state.

8 No more than 5.0 percent samples total coliform-positive in a month. (For water systems that collect fewer than 40 routine samples per month, no more than one sample can be total coliform-positive per month.) Every sample that has total coliform must be analyzed for either fecal coliforms or E. coli. If two consecutive TC-positive samples, and one is also positive for E. coli or fecal coliforms, system has an acute MCL violation.

9 Although there is no collective MCLG for this contaminant group, there are individual MCLGs for some of the individual contaminants:
- **Haloacetic acids:** dichloroacetic acid (zero); trichloroacetic acid (0.3 mg/L)
- **Trihalomethanes:** bromodichloromethane (zero); bromoform (zero); dibromochloromethane (0.06 mg/L)

NATIONAL SECONDARY DRINKING WATER REGULATION

National Secondary Drinking Water Regulations are non-enforceable guidelines regarding contaminants that may cause cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water. EPA recommends secondary standards to water systems but does not require systems to comply. However, some states may choose to adopt them as enforceable standards.

Contaminant	Secondary Maximum Contaminant Level
Aluminum	0.05 to 0.2 mg/L
Chloride	250 mg/L
Color	15 (color units)
Copper	1.0 mg/L
Corrosivity	Noncorrosive
Fluoride	2.0 mg/L
Foaming Agents	0.5 mg/L
Iron	0.3 mg/L
Manganese	0.05 mg/L
Odor	3 threshold odor number
pH	6.5-8.5
Silver	0.10 mg/L
Sulfate	250 mg/L
Total Dissolved Solids	500 mg/L
Zinc	5 mg/L

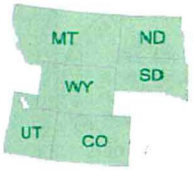
FOR MORE INFORMATION ON EPA'S SAFE DRINKING WATER:

visit: **epa.gov/safewater**

call: **(800) 426-4791**

ADDITIONAL INFORMATION:

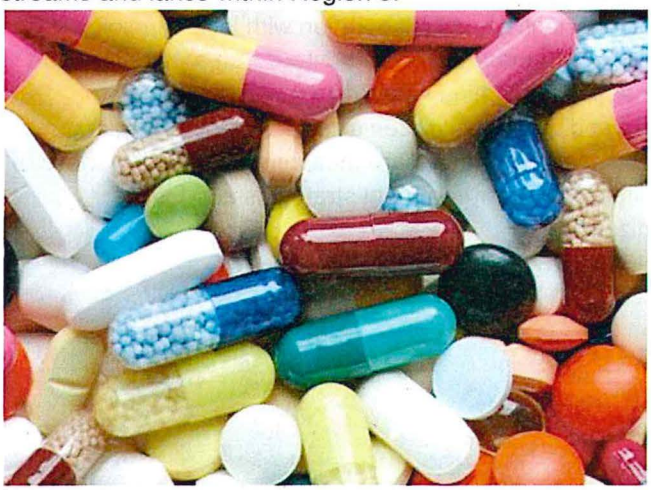
To order additional posters or other ground water and drinking water publications, please contact the National Service Center for Environmental Publications at: **(800) 490-9198**, or email: **nscep@bps-lmit.com**.



U.S. Environmental Protection Agency Region 8
Serving Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming and 27 Tribal Nations

The U.S. Environmental Protection Agency (USEPA) Region 8 Emerging Contaminants Project Summary

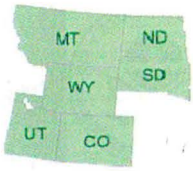
Over 98 million prescriptions were filled at pharmacies in Region 8 alone in 2010. Over one billion pounds of pesticides are used in the United States each year. Results obtained by the scientists in Region 8 demonstrate that pharmaceuticals, personal care products (PPCPs), pesticides and pesticide degradates, and other compounds of emerging concern are being detected in surface and ground waters within the Region. There is increasing concern that the potential exists for low-level, chronic exposure to mixtures of these chemicals to have adverse ecological or human health effects. For example, new information has shown that many of these chemicals may pose a threat to aquatic life, such as feminizing changes observed in male fish exposed to endocrine-active PPCPs in streams and lakes within Region 8.



The occurrence, fate, and transport of these chemicals are an important water quality concern, both nationally and regionally, and have gained public interest. The work conducted by Region 8 scientists is providing useful information to address those concerns and fill information gaps which can be used to inform the implementation of the SDWA and CWA, as appropriate. The Region 8 data was shared with the National Academy of Science (NAS) in a review of the science being performed by USEPA. The feedback was overwhelmingly positive and Region 8 was commended for this innovative work by the NAS committee. Furthermore, a Government Accountability Office report (GAO-11-346 August 8, 2011) recommended that EPA collect the pharmaceutical environmental occurrence data and address the issue of pharmaceuticals and their relationship to other contaminants in the nation's waterways. The work conducted by Region 8 directly addresses the recommendations outlined in the GAO report by collecting occurrence data and examining the co-occurrence of pharmaceuticals and other contaminants such as pesticides in surface water.

The Pesticide Program within the Office of Partnerships & Regulatory Assistance (OPRA), the Water Quality Unit within the Office of Ecosystems, Protection and Remediation (EPR), and the Laboratory Services Program within the Office of Technical and Management Services collaborated to develop a list of over 250 compounds for monitoring. Data has been collected in all 6 states in the Region, for 12 individual tribes, three municipalities, two universities, and two other federal agencies (DOI and USDA). The analytical methods serve as a foundation for gathering the data needed to start evaluating what chemicals are present, what concentration are they at if present, what is happening to them as they travel downstream, what are the human, ecological, and economic effects if any, and what synergistic effects are present if any. Example compounds include caffeine, ibuprofen, drugs of abuse such as cocaine and certain cocaine metabolites, anti-microbials such as triclosan, phosphate based flame retardants, and common pesticides such as 2,4-D, atrazine, and atrazine degradates.

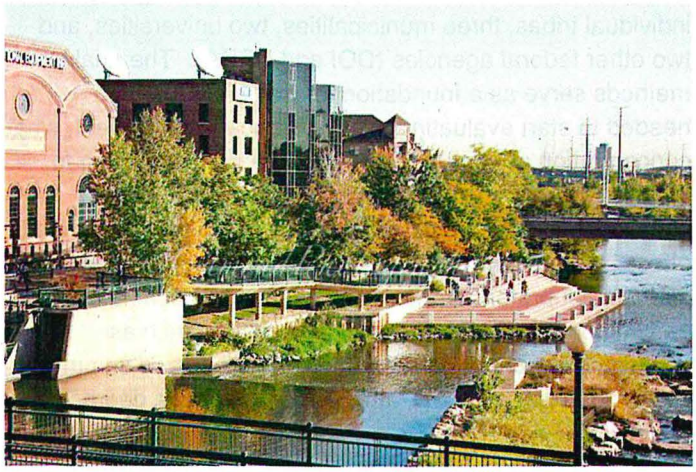
Data generated from this collaborative approach were used in the Region by states and tribes, but was also shared with other USEPA divisions and offices, and other federal agencies to assess risk to human health. This coordination expands the utility of the data to improve our scientific understanding of fate and effects from emerging contaminants, for use in regulatory decisions such as re-registration of pesticides and implementation of the CWA and SDWA, for regional and national water quality initiatives, and to serve as a national program model suggested by NAS. This teamwork-based effort is improving and maintaining improvements in water quality as well as fostering partnerships within the agency, between the agency and states and tribes, and between other federal partners. Three sub-projects are described on the reverse side.



U.S. Environmental Protection Agency Region 8
Serving Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming and 27 Tribal Nations

Urban Waters

The water quality issues associated with mountains and plains as well as pristine public lands and urban areas are challenging. Snowpack runoff and groundwater are the predominant water resources in Region 8. The use of these waters for drinking water, as well as for recreation, and in industries such as energy extraction, and animal husbandry all require the gathering of data to determine the effect that humans, wildlife, animal husbandry, and climate change may have on these valuable resources. Region 8 scientists are monitoring for select pharmaceuticals, waste indicators, and pesticides to start to understand how these compounds affect the use of the water resources in urban areas in Region 8.



National Parks

Region 8 contains some of the largest National Parks in the country. These include Rocky Mountain National Park, Yellowstone National Park, and Glacier National Park. The Parks are visited by millions of citizens each year. How these citizens affect the ecology of the lakes and streams is an important factor in protecting these national resources for future generations. Region 8 scientists, in collaboration with National Park colleagues, are monitoring for select man-made compounds to determine if there are pharmaceuticals, pesticides, and other man-made compounds present, and if there are, how much is present. This information will be used to determine how best to protect the delicate ecosystems within the Parks.

Local Municipalities

Region 8 scientists, in collaboration with local municipalities, are working to understand the sources, fates, and transport of emerging contaminants. Working with wastewater treatment plants, local citizen groups, and other Federal partners, ongoing studies are measuring the effectiveness of specific wastewater treatment strategies and their optimization.

The projects described are just a few of the many that Region 8 scientists are pursuing. More details for each project can be obtained by contacting the Region 8 Laboratory Director at 303-312-7799.

Contaminants of Emerging Concern under the Clean Water Act

Laura Gatz
Analyst in Environmental Policy

November 7, 2019

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CRS REPORT
Prepared for Members and
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SUMMARY

R45998

November 7, 2019

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Contaminants of Emerging Concern under the Clean Water Act

Recent decades have seen increased national attention to the presence of "emerging contaminants" or "contaminants of emerging concern" (CECs) in surface water and groundwater. Although there is no federal statutory or regulatory definition of CECs, generally, the term refers to unregulated substances detected in the environment that may present a risk to human health, aquatic life, or the environment and for which the scientific understanding of potential risks is evolving. CECs can include many different types of manufactured chemicals and substances—such as those in pharmaceuticals, industrial chemicals, agricultural products, and microplastics—as well as naturally occurring substances, such as algal toxins. Data on CECs that would help determine their risk to humans and aquatic life or other aspects of the environment are often limited. Increased monitoring and detections of one particular group of chemicals, per- and polyfluoroalkyl substances (PFAS), has recently heightened public and congressional interest in these CECs and has also prompted a broader discussion about how CECs are identified, detected, and regulated and whether additional actions should be taken to protect human health and the environment. While several statutes provide authorities to the U.S. Environmental Protection Agency (EPA) and states to address CECs, this report examines authorities available under the Clean Water Act (CWA)—which Congress established to restore and protect the quality of the nation's surface waters.

EPA has several CWA authorities it may use to address CECs, although it faces some challenges in doing so. Under the CWA, a primary mechanism to control contaminants in surface waters is through permits. The statute prohibits the discharge of pollutants from any point source (i.e., a discrete conveyance) to waters of the United States without a permit. The CWA authorizes EPA and states to limit or prohibit discharges of pollutants in the National Pollutant Discharge Elimination System (NPDES) permits they issue. These permits incorporate technology-based and water-quality-based requirements.

The CWA authorizes EPA and states to address CECs through technology-based effluent limitations using national Effluent Limitation Guidelines and Standards (ELGs) or by setting technology-based effluent limits in NPDES permits on a case-by-case basis. The CWA requires EPA to publish ELGs, which are the required minimum standards for industrial wastewater discharges. The CWA also requires EPA to annually review all existing ELGs and to publish a biennial plan that includes a schedule for review and revision of promulgated ELGs, identifies categories of sources discharging toxic or nonconventional pollutants that do not have ELGs, and establishes a schedule for promulgating ELGs for any newly identified categories. In cases where EPA has not established an ELG for a particular industrial category or type of facility, or where pollutants or processes were not considered when an ELG was developed, the permitting authority (EPA or states) may still impose technology-based effluent limits on a case-by-case basis. Although EPA and states have these authorities available to address CECs, there are some challenges to doing so, including a lack of data available to support new ELGs or updates to existing ELGs. Agency officials stated that it is difficult for the agency to keep pace with the growth of new chemicals in commerce.

The CWA also authorizes EPA and states to address CECs through water-quality-based requirements. States are required to adopt water quality standards for waters of the United States and review them at least once every three years. The CWA requires EPA to publish, and "from time to time thereafter revise" water quality criteria that reflect the latest scientific knowledge. States use EPA's criteria as guidance in developing their water quality standards. The CWA directs states to adopt criteria to protect their water bodies' designated uses and to also adopt criteria for all pollutants on the Toxic Pollutant List, for which EPA has published criteria. Once a state adopts water quality criteria for a contaminant as part of its water quality standards, several CWA tools are available to the state for achieving them. The primary tool is to establish water-quality-based effluent limitations in NPDES permits. Although EPA and states have authority to address CECs through water-quality-based requirements, they often lack data needed to support development of criteria or water-quality-based effluent limitations.

The CWA also authorizes EPA to designate contaminants as toxic pollutants or as hazardous substances, which may trigger other actions under the CWA and the Comprehensive Environmental Response, Compensation, and Liability Act.

Recent congressional interest in CECs has focused on addressing one particular group of CECs—PFAS—and on addressing them through other statutes. However, in the 116th Congress, H.R. 3616 and H.Amdt. 537, Section 330A, of the House-passed version of the National Defense Authorization Act for FY2020 (H.R. 2500), would direct EPA to add PFAS to the CWA Toxic Pollutant List and publish ELGs that establish effluent limitations and standards for PFAS within specified time frames.

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Introduction

Over the past couple of decades, national attention to "emerging contaminants" or "contaminants of emerging concern" (CECs) in surface water and groundwater has been increasing. Although there is no federal statutory or regulatory definition of CECs, generally, the term refers to unregulated substances detected in the environment that may present a risk to human health, aquatic life, or the environment. CECs can include many different types of manmade chemicals and substances—such as those in personal care products, pharmaceuticals, industrial chemicals, lawn care and agricultural products, and microplastics—as well as naturally occurring substances such as algal toxins or manganese.

CECs often enter the environment, including ground and surface waters, via municipal and industrial wastewater discharges and urban and agricultural storm runoff. Although municipal and industrial wastewater are both treated prior to discharge into waterways, treatment facilities are often not designed to remove CECs. The availability of data on CECs—such as concentration and pervasiveness in the environment or exposure or toxicity data that would help determine their risk to humans and aquatic life—may be limited.

In some cases, detections of CECs in the environment have triggered a call for action from federal, state, and local government, as well as Congress. Increased monitoring and detections of one particular group of chemicals, per- and polyfluoroalkyl substances (PFAS), has recently heightened public and congressional interest in these CECs and has also prompted a broader discussion about how CECs are identified, detected, and regulated and whether additional actions should be taken to protect human health and the environment.[1]

Several statutes—including the Safe Drinking Water Act;[2] the Toxic Substances Control Act (TSCA);[3] the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA);[4] and the Clean Water Act (CWA)[5]—provide authorities to the U.S. Environmental Protection Agency (EPA) and states to address particular CECs. In the 116th Congress, Members have introduced more than 40 bills to address PFAS through various means. Multiple bills, including House- and Senate-passed National Defense Authorization Act (NDAA) bills for FY2020 (H.R. 2500 and S. 1790, respectively), would direct EPA to take regulatory and other actions to address PFAS under several environmental statutes. Two of these bills (H.R. 2500 and H.R. 3616) would direct EPA to address PFAS using authorities provided to the agency under the CWA, which Congress established to restore and protect the quality of the nation's surface waters.

Global concern about another group of CECs—microplastics—and their potential impacts has also been mounting.[6] Recent studies have found that treated effluents from wastewater treatment

[1] See CRS Report R45793, *PFAS and Drinking Water: Selected EPA and Congressional Actions*, by Elena H. Humphreys and Mary Tiemann, for an overview of EPA's ongoing and proposed actions to address PFAS under Safe Drinking Water Act authorities, with particular focus on the statutory process for evaluating PFAS for potential regulation.

[2] 42 U.S.C. §300f-300j.

[3] 15 U.S.C. §2601 *et seq.*

[4] 42 U.S.C. §9601 *et seq.*

[5] 33 U.S.C. §1251 *et seq.*

[6] While researchers and the government have been working to address plastic pollution for decades, more recently, the accumulation and potential impacts of plastic pollution have become an emerging issue. Recent studies have shown

plants can be key sources of microplastics, as can runoff from agricultural sites where sewage sludge from the wastewater treatment process has been applied as fertilizer.[7] As with many other CECs, wastewater treatment facilities are generally not designed to screen for microplastic debris, such as microbeads, plastic fragments, or plastic fibers from clothing. Congress has shown interest in addressing the impacts of plastic pollution. In 2015, Congress passed legislation to ban plastic microbeads from rinse-off personal care products ("Microbead-Free Waters Act of 2015," P.L. 114-114). More recently, some Members in the 116th Congress announced plans to introduce comprehensive legislation to address plastic waste in fall 2019.[8]

Some stakeholders have asserted that EPA could be more effective in using its existing CWA authorities to address CECs, while others have suggested a need to identify and address potential gaps in CWA authorities through amendments to the statute.[9] This report examines authorities available to address CECs under the CWA.

Addressing CECs through the Clean Water Act

EPA has several CWA authorities it may use to address CECs, although it faces some challenges in doing so. The CWA's stated objective is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[10] To help achieve this objective, the CWA prohibits the discharge of pollutants from any point source (i.e., a discrete conveyance, such as a pipe, ditch, etc.) to waters of the United States without a permit.[11] Under the CWA, one of the primary mechanisms to protect or improve surface water quality is to limit or prohibit discharges of contaminants, including CECs, in National Pollutant Discharge Elimination System (NPDES) permits.[12] The CWA authorizes EPA and delegated states to set limits or prohibit discharges of pollutants in permits through technology-based effluent (i.e., discharge) limitations and standards and through water-quality-based effluent limitations, which are established through water quality standards and criteria. Technology-based effluent limitations are specific numerical limits (i.e.,

that microplastics (i.e., plastic particles less than 5 millimeters in size in any one dimension) are widespread in marine and freshwater ecosystems and may also have negative ecological impacts. See EPA, *State of the Science White Paper: A Summary of Literature on the Chemical Toxicity of Plastics Pollution to Aquatic Life and Aquatic-Dependent Wildlife*, December 2016, https://www.epa.gov/trash-free-waters/epa-reports#wp. Also see EPA Office of Wetlands, Oceans and Watersheds, *Microplastics Expert Workshop Report*, December 2017, https://www.epa.gov/sites/production/files/2018-03/documents/microplastics_expert_workshop_report_final_12-4-17.pdf.

[7] EPA, *State of the Science White Paper*. See also Paul Kay et al., "Wastewater Treatment Plants as a Source of Microplastics in River Catchments," *Environmental Science and Pollution Research*, vol. 25, no. 20 (July 2018), pp. 20264-20267.

[8] Office of Senator Tom Udall, "Udall, Lowenthal Release Outline of Legislation to Tackle Plastic Waste Pollution Crisis," press release, July 18, 2019, https://www.tomudall.senate.gov/news/press-releases/udall-lowenthal-release-outline-of-legislation-to-tackle-plastic-waste-pollution-crisis.

[9] Association of Clean Water Administrators (ACWA) and Association of State Drinking Water Administrators (ASDWA), *Recommendations Report—Contaminants of Emerging Concern Workgroup*, May 2019, https://www.asdwa.org/wp-content/uploads/2019/05/ASDWA-ACWA-Report-on-Contaminants-of-Emerging-Concern-2019.pdf, p. 9.

[10] CWA §101(a); 33 U.S.C. §1251(a).

[11] CWA §301; 33 U.S.C. §1311. *Point source* is defined at CWA §502(14); 33 U.S.C. §1362(14).

[12] 33 U.S.C. §1342. Under CWA Section 402, states and EPA issue NPDES permits to municipal and nonmunicipal point sources to authorize their discharges. Note that 47 states are authorized to administer their own NPDES permits. EPA administers NPDES permits in Massachusetts, New Hampshire, New Mexico, the District of Columbia, and certain territories and Indian lands. Per CWA Section 502(3) (33 U.S.C. §1362(3)), *state* is defined to include a state, the District of Columbia, or any of the U.S. territories. Per CWA Section 518 (33 U.S.C. §1377), EPA is authorized to treat an Indian tribe as a state for certain sections of the CWA, including the sections pertaining to CWA permitting.

maximum allowable levels of specific pollutants) that represent the minimum level of control that must be established in a permit.[13] In cases where technology-based effluent limitations are not adequate to meet applicable water quality standards, the permits also incorporate water-quality-based effluent limitations.[14] Water-quality-based effluent limitations are specific limits established in a permit that, if not exceeded in the discharge, allow for attainment of water quality standards in the receiving water.[15] Water quality standards—established by states, territories, tribes, and EPA—define the desired condition or level of protection of a water body and what is needed to achieve or protect that condition.[16] In addition, the CWA authorizes EPA to designate contaminants as toxic pollutants (CWA §307) or as hazardous substances (CWA §311), which may trigger other actions under the CWA and CERCLA.[17] This section first identifies the authorities available under the CWA, their applicability to CECs, and potential challenges with EPA use of these authorities.

Technology-Based Requirements

The CWA requires EPA to establish technology-based effluent limitations for various categories of point sources/dischargers.[18] Technology-based requirements consider the performance of specific technologies as well as economic achievability. These limits do not specify what technologies must be employed; rather, they establish the levels of specific pollutants that are allowable in the discharge based on the performance of technologies identified as representing specified levels of control (e.g., best available technology economically achievable, best conventional pollutant control technology). CWA Section 301 prescribes the levels of control required. EPA broadly classifies NPDES permittees as either (1) publicly owned treatment works (POTWs)[19] or (2) non-POTWs, which include all other point sources and are also often called nonmunicipal facilities or industrial facilities.[20]

[13] CWA §301(b); 33 U.S.C. §1311(b); 40 C.F.R. §125.3.

[14] 40 C.F.R. §122.44(d).

[15] 40 C.F.R. §122.44(d). Water-quality-based effluent limitations apply at the point of discharge, such as the end of the outfall pipe discharging into a water body.

[16] 40 C.F.R. §131.3(i)-(j). Water quality standards apply throughout the water body and reflect the maximum levels of specific pollutants that can be present in a water body and still allow that water body to meet its designated use.

[17] 33 U.S.C. §1317; 33 U.S.C. §1321. Such designations also trigger hazardous substance designations (and liability) under CERCLA.

[18] CWA §301(b); 33 U.S.C. §1311(b); CWA §304(b); 33 U.S.C. §1314(b); CWA §306; 33 U.S.C. §1316; CWA §307; 33 U.S.C. §1317.

[19] Per 40 C.F.R. §403.3(q), a POTW is a treatment works as defined by CWA Section 212, which is owned by a state or municipality (as defined by CWA Section 502(4)). The definition includes any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature. It also includes sewers, pipes, and other conveyances only if they convey wastewater to a POTW. The term also means the municipality that has jurisdiction over the indirect discharges to and the discharges from the treatment works.

[20] Non-POTWs include other point sources, such as industrial and commercial facilities, industrial stormwater, concentrated animal feeding operations, and vessel discharges. Federal facilities fall under the non-POTW source category. EPA, *NPDES Permit Writers' Manual*, 2010, https://www.epa.gov/sites/production/files/2015-09/documents/pwm_2010.pdf.

The CWA requires POTWs to meet secondary treatment standards as determined by EPA.[21] Secondary standards are based on performance data for POTWs that use physical and biological treatment to remove or control conventional pollutants.[22]

As shown in **Figure 1**, the CWA requires non-POTW dischargers to achieve specified levels of control based on (1) whether a discharger directly or indirectly discharges into a water of the United States (an indirect discharger discharges to a POTW for treatment prior to discharge into a water of the United States), (2) whether the discharger is a new or existing source, and (3) the category of pollutant (conventional, toxic,[23] or nonconventional[24]).[25]

[21] CWA §301(b)(1)(B); 33 U.S.C. §1311(b)(1)(B). As directed by CWA Section 304(d)(1), EPA promulgated secondary treatment standards for biochemical oxygen demand, total suspended solids, and pH. See 40 C.F.R. §133 for secondary treatment standards. The CWA and federal regulations allow adjustments to secondary treatment requirements for biochemical oxygen demand and total suspended solids for equivalent to secondary facilities, per 40 C.F.R. §133.105.

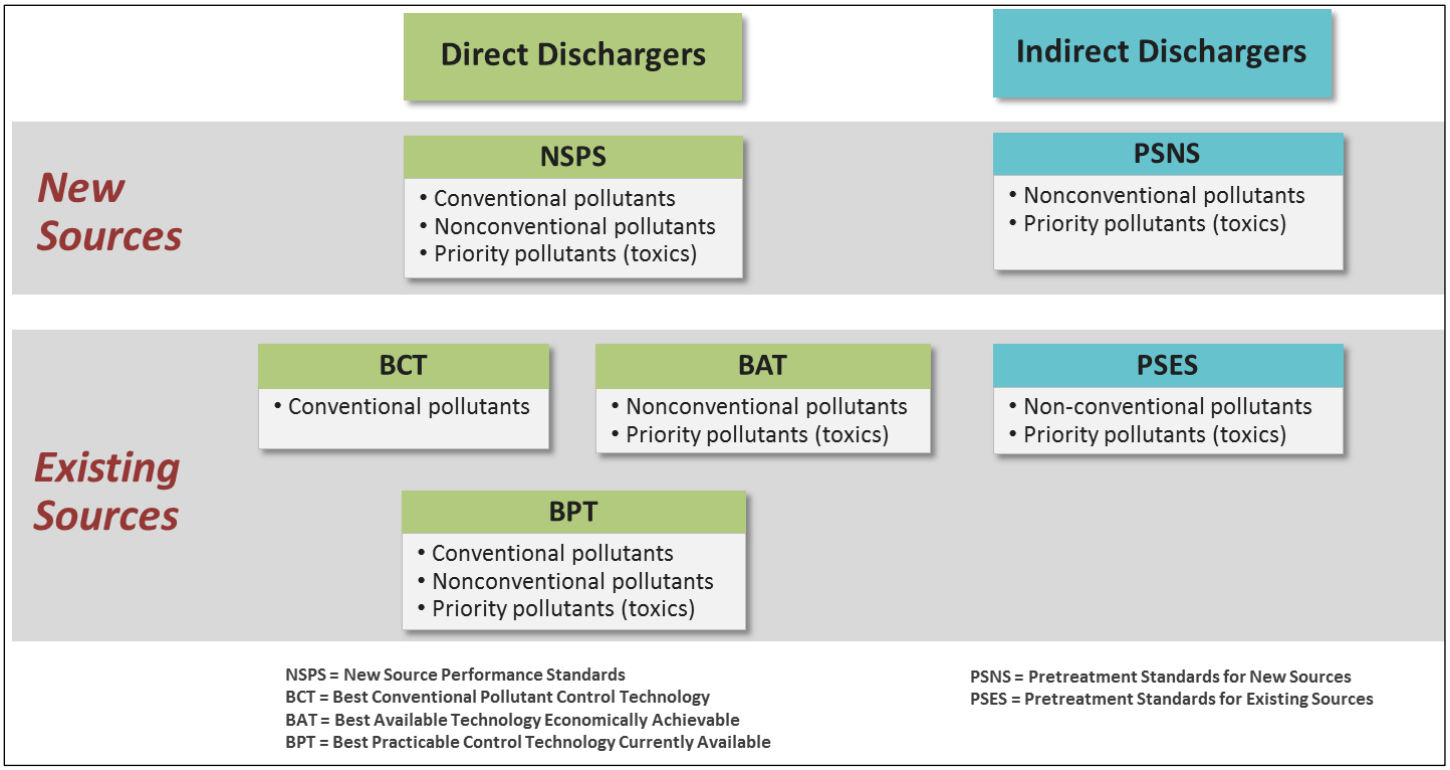
[22] Conventional pollutants include biochemical oxygen demand, total suspended solids, fecal coliform, pH, and oil and grease. CWA Section 304(a)(4) designates biological oxygen demand, suspended solids, fecal coliform, and pH as conventional pollutants. It also authorizes EPA to revise the list of conventional pollutants from time to time. EPA designated oil and grease as an additional conventional pollutant in 1979 (EPA, "Identification of Conventional Pollutants," 44 *Federal Register* 44501, 1979). The list of conventional pollutants is codified at 40 C.F.R. §401.16.

[23] *Toxic pollutant* includes the 65 pollutants and classes of pollutants on EPA's Toxic Pollutant List. Section 307(a)(1) (33 U.S.C. §1317(a)(1)) directed EPA to adopt an initial list of toxic pollutants presented in Committee Print 95-30 of the House Committee on Public Works and Transportation (U.S. Congress, House Committee on Public Works and Transportation, *Data Relating to H.R. 3199 (Clean Water Act of 1977)*, committee print, 95th Cong., November 1977, H.Prt. 95-30 [Washington: GPO, 1977], pp. 3-4). This list included both individual chemicals and categories of chemical compounds. As presented in the legislative history, this initial list was negotiated between EPA and the Natural Resources Defense Council in *Natural Resources Defense Council v Train* (U.S. Congress, House Committee on Public Works and Transportation, Subcommittee on Investigations and Review, *Water Contamination by Toxic Pollutants: An Assessment of Regulation*, committee print, 95th Cong., September 1977, 95-26, p. 6). The Toxic Pollutant List is codified at 40 C.F.R. §401.15. In 1977, EPA developed the Priority Pollutant List to make Toxic Pollutant List implementation more practical for water testing and regulatory purposes. The Priority Pollutant List includes individual chemicals, rather than groups of pollutants, for which EPA has published analytical test methods. Originally, the list included 129 pollutants. In 1981, when three pollutants were removed from the Toxic Pollutant List, they were also removed from the Priority Pollutant List. Accordingly, the Priority Pollutant List, codified at 40 C.F.R. §423, Appendix A, currently contains 126 pollutants.

[24] *Nonconventional pollutant* includes any pollutants other than those identified as conventional or toxic pollutants.

[25] CWA §301(b); 33 U.S.C. §1311(b); CWA §304(b); 33 U.S.C. §1314(b); CWA §306; 33 U.S.C. §1316; CWA §307; 33 U.S.C. §1317.

Figure 1. Clean Water Act Technology Levels of Control Required for Non-POTW Dischargers by Pollutant Category



Source: CRS, based on CWA §§301, 304, 306, and 307.

Notes: EPA regulations define *new source* as "any building, structure, facility, or installation from which there is or may be a 'discharge of pollutants,' the construction of which commenced: (a) after promulgation of standards of performance under CWA section 306 which are applicable to such source, or (b) after proposal of standards of performance in accordance with section 306 of CWA which are applicable to such source, but only if the standards are promulgated in accordance with section 306 within 120 days of their proposal" (40 C.F.R. §122.2).

An *existing source* is any source that is not a new source or a new discharger (40 C.F.R. §122.29 (a)(3)).

Effluent Limitation Guidelines and Standards (ELGs)

The CWA requires EPA to publish national regulations for non-POTW dischargers—called Effluent Limitation Guidelines and Standards (ELGs)—which set minimum standards for specific pollutants in industrial wastewater discharges based on the specified levels of control.[26] Since 1972, EPA has developed ELGs for 59 industrial categories.[27] For direct dischargers, states or EPA incorporate the limits established in ELGs into the NPDES permits they issue. For indirect dischargers, pretreatment standards established in ELGs to prevent pass through and interference at the POTW apply.[28]

[26] CWA §304(b); 33 U.S.C. §1314(b); CWA §306(b); 33 U.S.C. §1316(b); CWA §307(b)-(c); 33 U.S.C. §1317(b)-(c).

[27] 40 C.F.R. Chapter 1, Subchapter N, "Effluent Guidelines and Standards." See also EPA, "Industrial Effluent Guidelines," https://www.epa.gov/eg/industrial-effluent-guidelines.

[28] The national pretreatment program is a component of the NPDES program, which involves federal, state, and local regulatory agencies. Local municipalities are mostly responsible for implementing and enforcing pretreatment requirements. EPA and states authorized to act as the approval authority for POTWs in their states may approve a POTW's pretreatment program. If approved, the POTW is the control authority responsible for ensuring compliance

The CWA requires EPA to annually review all existing ELGs to determine whether revisions are appropriate.[29] In addition, CWA Section 304(m) requires EPA to publish a plan every two years that includes a schedule for review and revision of promulgated ELGs, identifies categories of sources discharging toxic or nonconventional pollutants that do not have ELGs, and establishes a schedule for promulgating ELGs for any newly identified categories.[30]

In its 2002 draft *Strategy for National Clean Water Industrial Regulations*, EPA described a process for identifying existing ELGs that the agency should consider revising as well as industrial categories that may warrant development of new ELGs.[31] As outlined in the strategy, EPA considers four main factors when prioritizing existing ELGs for possible revision: (1) the amount and type of pollutants in an industrial category's discharge and the relative hazard to human health or the environment, (2) the availability of an applicable and demonstrated wastewater treatment technology, process change, or pollution prevention measure that can reduce pollutants in the discharge and the associated risk to human health or the environment; (3) the cost, performance, and affordability or economic achievability of the wastewater treatment technology, process change, or pollution prevention measure; and (4) the opportunity to eliminate inefficiencies or impediments to pollution prevention or technological innovation or promote innovative approaches.[32] EPA considers nearly identical factors in deciding whether to develop new ELGs.[33]

EPA uses a variety of screening-level analyses to address these factors. These analyses evaluate discharge monitoring reports and EPA's Toxic Release Inventory to rank industrial categories according to the total toxicity of their wastewater.[34] In 2012, the Government Accountability Office recommended that the annual review include additional industrial hazard data sources to augment its screening-level reviews.[35] In response, EPA has begun to use additional data sources that provide information about CECs or new pollutant discharges, industrial process changes, and new and more sensitive analytical methods, among other things. For example, EPA has reviewed data from the agency's Office of Pollution Prevention and Toxics to identify potential CECs.[36]

If EPA identifies an industrial discharge category warranting further review, it conducts a more detailed review, which may lead to a new or revised guideline.[37]

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with pretreatment standards. If a POTW does not have an approved pretreatment program, the control authority is the approved state authorized to act as the approval authority or, in unapproved states, the EPA. See 40 C.F.R. §403, "General Pretreatment Regulations for Existing and New Sources of Pollution."

[29] CWA §304(b); 33 U.S.C. §1314(b); CWA §304(g); 33 U.S.C. §1314(g); CWA §304(m)(1)(A); 33 U.S.C. §1314(m)(1)(A). Also, per CWA Section 301(d) (33 U.S.C. §1311(d)), EPA is required to review effluent limitations required by CWA Section 301(b)(2) at least every five years. EPA issues regulations that simultaneously address both of these.

[30] 33 U.S.C. §1314(m).

[31] EPA, *A Strategy for National Clean Water Industrial Regulations (Draft)*, November 2002.

[32] EPA, *Final 2016 Effluent Guidelines Program Plan*, April 2018, https://www.epa.gov/eg/2016-effluent-guidelines-plan-documents. See also EPA, *A Strategy for National Clean Water Industrial Regulations*, pp. 20-25.

[33] EPA, *A Strategy for National Clean Water Industrial Regulations*, p. 23.

[34] EPA, *Final 2016 Effluent Guidelines Program Plan*, pp. 2-3–2-11.

[35] U.S. Government Accountability Office, Water Pollution: EPA Has Improved Its Review of Effluent Guidelines but Could Benefit from More Information on Treatment Technologies, GAO-12-845, September 2012, https://www.gao.gov/products/GAO-12-845.

[36] EPA, *Final 2016 Effluent Guidelines Program Plan*, p. 2-4.

[37] EPA, *Final 2016 Effluent Guidelines Program Plan*, p. 2-5.

EPA published its most recent effluent guidelines program plan—the *Final 2016 Effluent Guidelines Program Plan*—in April 2018. It identified one new rulemaking to revise the Steam Electric Power Generating Point Source Category ELG but concluded that no other industries warrant new ELGs at this time. In its plan, EPA also announced that it is initiating three new studies: a holistic look at the management of oil and gas extraction wastewater from onshore facilities, an industry-wide study of nutrients, and an industry-wide study of PFAS.[38]

Options to Address CECs through Technology-Based Requirements

Both EPA and states have authority under the CWA to address CECs through technology-based effluent limitations using ELGs or by setting technology-based effluent limits in NPDES permits on a case-by-case basis. In addition, the CWA authorizes EPA to add contaminants to the Toxic Pollutant List.

ELGs

When EPA develops an ELG for a new industrial category or revises an existing ELG, it is for the industrial category—not a specific pollutant. However, as evidenced in the agency's most recent effluent guidelines program plan, EPA may initiate a cross-industry review of particular pollutants (such as the agency is doing with PFAS and nutrients). EPA uses such reviews to prioritize further study of the industrial categories that may be candidates for ELG development or revision to control the discharges of those particular pollutants.[39] If EPA were to determine that new or revised ELGs are warranted to control discharges of those pollutants, and the agency had the necessary data to support the development or revision, the agency could initiate a rulemaking process to do so.

Establishing Technology-Based Effluent Limits in NPDES Permits on a Case-by-Case Basis

The CWA also authorizes EPA and states to impose technology-based effluent limits in NPDES permits on a case-by-case basis when "EPA-promulgated effluent limitations are inapplicable."[40] This includes when EPA has not developed ELGs for the industry or type of facility being permitted or pollutants or processes are present that were not considered when the ELG was developed.[41] This provides a means for the permitting authority to restrict pollutants in a facility's discharge even when an ELG is not available. CWA regulations require best professional judgment to set case-by-case technology-based effluent limits, applying criteria that are similar to the analysis EPA uses to develop ELGs but are performed by the permit writer for a single facility.[42]

Toxic Pollutant List

The CWA also authorizes EPA to designate contaminants as toxic pollutants, which can trigger other actions under the CWA and CERCLA. (For a discussion of the effect of designating a

[38] EPA, *Final 2016 Effluent Guidelines Program Plan*, p. 1-1.

[39] EPA, *Final 2016 Effluent Guidelines Program Plan*, p. 7-1.

[40] CWA §402(a)(1)(B); 33 U.S.C. §1342(a)(1)(B); 40 C.F.R. §125.3(c).

[41] EPA, *NPDES Permit Writers' Manual*, September 2010, pp. 5-45–5-46, https://www.epa.gov/npdes/npdes-permit-writers-manual.

[42] 40 C.F.R. §125.3(d).

contaminant as a toxic pollutant on the treatment of that contaminant under CERCLA, see "Designating CECs as Toxic Pollutants or Hazardous Substances.") CWA Section 307 authorizes EPA to designate toxic pollutants and promulgate ELGs that establish requirements for those toxic pollutants.[43] Section 307(a)(1) directed EPA to publish a specified list of individual toxic pollutants or combination of pollutants and, from time to time, add or remove any pollutant that possesses certain properties.[44] EPA adopted the initial list of 65 toxic pollutants in 1978, as directed by Congress.[45] Since that time, the list of 65 toxic pollutants has generally not changed.[46]

Section 307(a)(1) directs EPA to "take into account the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms, and the nature and extent of the effect of the toxic pollutant on such organisms" when revising the Toxic Pollutant List.[47] Section 307(a)(2) authorizes EPA to develop effluent limitations for any pollutant on the Toxic Pollutant List based on best available technology.[48] Notably, however, EPA has the authority to develop effluent limitations for any pollutant regardless of whether it is on the Toxic Pollutant List.

Adding a pollutant to the Toxic Pollutant List would trigger an additional requirement for states. Section 303(c)(2)(B) of the CWA[49] requires states, whenever reviewing, revising, or adopting water quality standards, to adopt numeric criteria for all toxic pollutants listed pursuant to Section 307, for which EPA has published water quality criteria under Section 304(a).[50] EPA and states use both the ELGs for industrial categories and state water quality standards in establishing pollutant limits in permits under Section 402.[51] (See **Figure 1**.)

Challenges to Addressing CECs through Technology-Based Requirements

EPA and states face a number of challenges in addressing CECs through technology-based effluent limitations. In particular, EPA officials stated that in developing a new ELG or updating

[43] 33 U.S.C. §1317.

[44] 33 U.S.C. §1317(a)(1). Section 307(a)(1) directed EPA to adopt an initial list of 65 toxic pollutants presented in Committee Print 95-30 of the House Committee on Public Works and Transportation. (U.S. Congress, House Committee on Public Works and Transportation, *Data Relating to H.R. 3199 (Clean Water Act of 1977)*, committee print, 95th Cong., November 1977, H.Prt. 95-30 [Washington: GPO, 1977], pp. 3-4.) These pollutants included both individual chemicals and categories of chemical compounds. As presented in the legislative history, this initial list was negotiated among parties to a 1976 settlement agreement between EPA and the Natural Resources Defense Council in the case of *Natural Resources Defense Council v Train* (U.S. Congress, House Committee on Public Works and Transportation, Subcommittee on Investigations and Review, *Water Contamination by Toxic Pollutants: An Assessment of Regulation*, committee print, 95th Cong., September 1977, 95-26, p. 6).

[45] EPA, "Publication of Toxic Pollutant List," 43 *Federal Register* 4108, January 31, 1978.

[46] EPA removed three pollutants from the list in 1981 after determining that the chemical properties of the pollutants are such that they do not pose a risk to human health or the environment by exposure through water. However, delisting these three pollutants did not change the 65 entries on the Toxic Pollutant List because they were specific compounds listed within two broader categories of listed compounds—halomethanes and haloethers. (See EPA, "Removal of Dichlorodifluoromethane and Trichlorofluoromethane from the Toxic Pollutant List Under Section 307(a)(1) of the Clean Water Act," 46 *Federal Register* 2266, January 8, 1981; EPA, "Removal of Bis-(Chloromethyl) Ether (BCME) from the Toxic Pollutant List Under Section 307(a)(1) of the Clean Water Act," 46 *Federal Register* 10723, February 4, 1981.) The Toxic Pollutant List is codified in federal regulation at 40 C.F.R. §401.15.

[47] 33 U.S.C. §1317(a)(1).

[48] 33 U.S.C. §1317(a)(2).

[49] 33 U.S.C. §1313(c)(2)(B).

[50] 33 U.S.C. §1314(a).

[51] 33 U.S.C. §1342.

an existing ELG, the agency needs to gather extensive supporting information.[52] This effort includes identifying the pollutants of concern; evaluating the levels, prevalence, and sources of those pollutants of concern; determining whether the pollutants are in treatable quantities and whether effective treatment technologies are available; and developing economic data to project the cost of treatment, among other things.[53]

Also, EPA and state officials have asserted that it is difficult for the agency and its CWA programs to keep pace with the growth of new chemicals in commerce.[54] Accordingly, the agency is generally reactive rather than proactive in addressing CECs. EPA officials stated that identifying demonstrated treatment technologies and documenting their efficiency is especially challenging.[55] The officials further stated that the most difficult task is showing that any technology selected as the basis for an ELG is economically achievable for the industry.[56]

In addition, EPA and states often lack analytical methods to measure an emerging contaminant.[57] Even where analytical methods are available, there is still often a lack of data on the levels of the contaminant in dischargers' effluent and/or in the receiving surface waters. The two sources of data most readily available to EPA—discharge monitoring report data and toxic release inventory data—are limited to specific contaminants on which industry is required to report.[58] EPA stated that the agency's capacity to collect data—including obtaining clearance to request and collect the data and undertaking the extensive effort to do so—is limited in light of their staffing levels and resources.[59]

Should EPA have enough data to determine that a new or revised ELG is warranted and announce its intent to do so in an effluent guidelines program plan, the time it takes to issue the regulation varies, according to EPA officials. CWA Section 304(m) establishes a three-year time limit for

[52] Personal communication between CRS and EPA staff, August 6, 2019.

[53] Personal communication between CRS and EPA staff, August 6, 2019. See also CWA §304(b); 33 U.S.C. §1314(b); and EPA, *Final 2016 Effluent Guidelines Program Plan*, p. 2-2.

[54] Personal communication between CRS and EPA staff, August 6, 2019. See also ACWA, ASDWA, *Recommendations Report*.

[55] Personal communication between CRS and EPA staff, August 6, 2019.

[56] Personal communication between CRS and EPA staff, August 6, 2019.

[57] For example, in EPA's *PFAS Action Plan*, the agency commits in the short term to developing analytical methods to "detect, identify, and quantify" known PFAS of concern in media, including wastewater and groundwater. EPA also commits to developing analytical methods for new, unknown PFAS in the long term. See EPA, *Per- and Polyfluoroalkyl Substances (PFAS) Action Plan*, February 2019, https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf, p. 34. As another example, in 2017, EPA convened a Microplastics Expert Workshop to identify and prioritize the scientific information needed to understand the risks posed by microplastics. In its report summarizing experts' recommendations, EPA concluded that "development of reliable, reproducible, and high-quality methods for microplastics is fundamental and of utmost importance for understanding microplastics risks." See EPA, *Microplastics Expert Workshop Report*. Also, in its *Final 2016 Effluent Guidelines Program Plan*, EPA describes its ongoing investigation looking at engineered nanomaterials and states that it will continue to look for opportunities to inform current data gaps, including development of analytical methods to detect and quantify engineered nanomaterials.

[58] Personal communication between CRS and EPA staff, August 6, 2019. See also EPA, *Final 2016 Effluent Guidelines Program Plan*, pp. 2-4 and 3-5.

[59] Personal communication between CRS and EPA staff, August 6, 2019. Note that under the Paperwork Reduction Act (44 U.S.C. §3501 *et seq.*), EPA can contact—with a survey or questionnaire—up to nine entities without first obtaining approval from the Office of Management and Budget. If EPA decides to contact 10 or more entities, the act requires the agency to prepare an Information Collection Request. In November 2018, EPA's Assistant Administrator for the Office of Water issued a memorandum clarifying its processes for collecting information from nine or fewer individuals or entities under CWA Section 308. The memorandum is available at https://www.epa.gov/sites/production/files/2018-11/documents/policy-use-of-cwa-308-letters.pdf.

new ELGs.[60] For revised ELGs, the EPA officials stated that the time can vary depending upon the availability of data and the level of complexity—some may be very technical and involve many wastestreams.[61] Two of the more recently issued ELGs—revisions of the oil and gas extraction and steam electric power generating categories—took five and six years, respectively.[62]

Water-Quality-Based Requirements

Under the CWA, water quality standards translate the goals of the act (e.g., fishable and swimmable waters, no toxic pollutants in toxic amounts) into measurable objectives to protect or improve water quality.[63] States, territories, and authorized tribes (hereinafter referred to collectively as states) are required to adopt water quality standards for waters of the United States, subject to EPA approval.[64] They may also adopt standards for additional surface waters if their own state laws allow them to do so.[65]

Water quality standards consist of three key required components:[66]

1. *Designated uses* for each water body—for example, recreation (swimming or boating), aquatic life support, fish consumption, public water supply, agriculture;
2. *Criteria*, which describe the conditions in a water body necessary to support the designated uses—expressed as concentrations of pollutants or other quantitative measures or narrative statements; and
3. *An antidegradation policy* for maintaining existing water quality.

States have the primary authority to adopt, review, and revise their water quality standards and implementation procedures. The CWA requires states to review their water quality standards at least once every three years.[67] EPA is required to review the states' water quality standards.[68]

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[60] 33 U.S.C. §1314(m).

[61] Personal communication between CRS and EPA staff, August 6, 2019.

[62] Note that these time frames include notice-and-comment requirements under the Administrative Procedure Act. EPA announced its intent to revise the Oil and Gas Extraction ELG to develop pretreatment standards for discharges from unconventional oil and gas facilities to POTWs in 2011 (76 *Federal Register* 66286) and published its final rule for the Oil and Gas Extraction ELG in 2016 (81 *Federal Register* 41845). EPA announced its intent to revise the Steam Electric Power Generating ELG in 2009 (74 *Federal Register* 68603) and issued its final rule in 2015 (80 *Federal Register* 67838). Note that on November 4, 2019, EPA announced a proposed rule to revise the Steam Electric Power Generating ELG applicable to two of the six wastestreams covered in the 2015 rule. For more information on the Steam Electric Power Generating ELG, see CRS In Focus IF10778, *Overview and Status of the Steam Electric Power Generating Effluent Limitation Guidelines (ELGs) and Standards*, by Laura Gatz.

[63] Section 101(a) of the CWA (33 U.S.C. §1251(a)) includes the objective and goals of the act. One of the goals—"water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water"—is often referred to in shorthand as "fishable and swimmable waters."

[64] CWA §303(c); 33 U.S.C. §1313(c). Per Section 502(3) of the CWA (33 U.S.C. §1362(3)), *state* is defined to include a state, the District of Columbia, or any of the U.S. territories. Per Section 518 of the CWA (33 U.S.C. §1377), EPA is authorized to treat an Indian tribe as a state for certain sections of the CWA, including the sections pertaining to water quality standards. EPA regulations at 40 C.F.R. §131.8 lay out the requirements and process by which a tribe may request and be approved to administer its own water quality standards program.

[65] CWA §510; 33 U.S.C. §1370.

[66] See CWA Section 303(c)(2)(A) for designated uses and criteria and CWA Sections 101(a) and 303(d)(4)(B) for antidegradation. Also see EPA's implementing regulations at 40 C.F.R. §131.

[67] CWA §303(c); 33 U.S.C. §1313(c).

[68] If EPA approves the water quality standards, they become effective. If EPA disapproves the water quality standards, the state has 90 days to revise them. If the state does not do so, EPA is required to promulgate standards that meet

Water Quality Criteria

Water quality criteria prescribe limits on specific contaminants or conditions in a water body that protect particular designated uses of the water body. Both the EPA and states have roles in establishing water quality criteria under CWA Section 304(a) and 303(c)(2), respectively.

EPA Role

CWA Section 304(a) requires EPA to develop and publish and "from time to time thereafter revise" criteria for water quality that accurately reflect the latest scientific knowledge.[69] These criteria are recommendations to states for use in developing their own water quality standards. EPA has developed several different types of criteria, including human health criteria, aquatic life criteria, and recreational criteria.[70] EPA has also published guidelines for deriving water quality criteria, which the agency uses to develop new criteria under Section 304(a). These guidelines also serve as guidance to states as they adjust water quality criteria developed under Section 304(a) to reflect local conditions or develop their own scientifically defensible water quality criteria.[71]

EPA most recently updated its human health criteria in 2015, revising 94 of the 122 existing human health criteria.[72] EPA last updated its methodology for deriving human health criteria in 2000,[73] incorporating "significant scientific advances in key areas such as cancer and non-cancer risk assessments, exposure assessments, and bioaccumulation in fish."[74]

EPA's national recommended aquatic life criteria table currently includes 58 criteria.[75] Many of these criteria were published prior to 1990. In the past 10 years, EPA has published two new criteria.[76] EPA has not updated its guidelines for deriving aquatic life criteria since 1985.[77] According to EPA, however, the guidelines allow for best professional judgment, which they have used in more recent criteria development and updates.[78] The agency recognizes that since 1985,

CWA requirements. CWA §303(c)(3); 33 U.S.C. §1313(c)(3).

[69] CWA §304(a)(1); 33 U.S.C. §1314(a)(1).

[70] EPA, "Basic Information on Water Quality Criteria," https://www.epa.gov/wqc/basic-information-water-quality-criteria.

[71] EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, October 2000, p. iii, https://www.epa.gov/sites/production/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf; EPA, *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses*, 1985, pp. 2-3, https://www.epa.gov/sites/production/files/2016-02/documents/guidelines-water-quality-criteria.pdf.

[72] EPA, "Final Updated Ambient Water Quality Criteria for the Protection of Human Health," 80 *Federal Register* 36986, June 29, 2015; EPA, "National Recommended Water Quality Criteria—Human Health Criteria Table," https://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria-table.

[73] EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*.

[74] EPA, *Fact Sheet: Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health—Revised Methodology*, 2000, https://www.epa.gov/wqc/fact-sheet-methodology-deriving-ambient-water-quality-criteria-protection-human-health-revised#copy.

[75] EPA, "National Recommended Water Quality Criteria—Aquatic Life Criteria Table," https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table.

[76] According to personal communication between CRS and EPA staff on May 29, 2019, in the past 10 years, EPA developed new criteria for two substances: carbaryl and acrolein.

[77] EPA, *Guidelines for Deriving Numerical National Water Quality Criteria*.

[78] Personal communication between CRS and EPA staff, May 29, 2019. Also see EPA, *Guidelines for Deriving Numerical National Water Quality Criteria*, p. 9.

there has been substantial scientific advancement that warrants updating these guidelines.[79] EPA formally initiated the guidelines revision process in 2015. However, according to EPA officials, the agency has shifted its focus from updating the guidelines to determining whether available data and research support development of human health criteria for PFAS.[80] In doing so, EPA officials indicated they plan to use information gathered for the guidelines revision and also noted that they are not tied to the 1985 guidelines due to the best professional judgment clause included therein.[81]

EPA's recreational water quality criteria are national recommendations for all inland and coastal waters that have a primary contact recreation (i.e., swimming) designated use. EPA establishes recreational water quality criteria to help protect against illness caused by organisms—such as viruses, bacteria, and their associated toxins—in water bodies.[82] In 2012, EPA updated its recreational water quality criteria, which it had last issued in 1986.[83] Additionally, in June 2019, EPA published final recreational water quality criteria for two algal toxins, which are commonly present in harmful algal blooms, to supplement the 2012 recreational water quality criteria.[84] In addition, EPA is currently developing recreational water quality criteria for coliphage, a viral indicator of fecal contamination.[85]

State Role

States use EPA's criteria as guidance in developing their own water quality standards. CWA Section 303(c)(2) requires states to adopt criteria to protect the designated uses of their water bodies and to also adopt criteria for all toxic pollutants listed pursuant to Section 307(a)(1), for which EPA has published criteria under Section 304(a). States' water quality criteria must be based on sound scientific rationale, contain sufficient parameters or constituents to protect the designated uses, and support the most sensitive use for water bodies with multiple designated uses.[86] EPA regulations further require that states should establish numeric criteria based on CWA Section 304(a) guidance, CWA Section 304(a) guidance modified to reflect site-specific conditions, or other scientifically defensible methods.[87] Where numeric criteria cannot be established, states are required to establish narrative criteria or criteria based on biomonitoring methods.[88] States may adopt more stringent criteria than what EPA recommends, including for pollutants or parameters for which EPA has not promulgated 304(a) criteria.[89]

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[79] EPA, "Aquatic Life Criteria and Methods for Toxics," https://www.epa.gov/wqc/aquatic-life-criteria-and-methods-toxics#sab.

[80] EPA anticipates completing the evaluation in 2021. See EPA, *Per- and Polyfluoroalkyl Substances (PFAS) Action Plan*.

[81] Personal communication between CRS and EPA staff, May 29, 2019.

[82] EPA, "Recreational Water Quality Criteria and Methods," https://www.epa.gov/wqc/recreational-water-quality-criteria-and-methods#rec.

[83] EPA, *2012 Recreational Water Quality Criteria*, December 2012, https://www.epa.gov/sites/production/files/2015-10/documents/rec-factsheet-2012.pdf.

[84] EPA, "Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin," 84 *Federal Register* 26413, June 6, 2019.

[85] EPA, "Recreational Water Quality Criteria and Methods," https://www.epa.gov/wqc/recreational-water-quality-criteria-and-methods#rec. See "Development of Recreational Water Quality Criteria for Coliphage" section.

[86] 40 C.F.R. §131.11.

[87] 40 C.F.R. §131.11(b).

[88] 40 C.F.R. §131.11(b).

[89] CWA §510; 33 U.S.C. §1370.

Options to Address CECs through Water-Quality-Based Requirements

EPA and states may establish water quality criteria for CECs. If EPA were to establish criteria under CWA Section 304(a) for a CEC, that action alone would not necessarily require states to adopt criteria for that contaminant. As explained above, the CWA requires that states adopt criteria to protect their designated uses into their water quality standards. EPA's regulations provide that if a state does not adopt new or revised criteria for parameters for which EPA has published new or updated recommendations, then the state shall provide an explanation.[90] States are explicitly required, as explained above, to adopt criteria for a contaminant if EPA designates it as a toxic pollutant under CWA Section 307 and publishes criteria for that contaminant under Section 304(a).[91]

Once a state has adopted water quality criteria for a contaminant as part of its state water quality standards and those standards have been approved, several CWA tools are available for achieving those standards. The primary tool is to limit or prohibit discharges of the contaminant in NPDES permits. In some cases, the technology-based effluent limits may already enable attainment of state water quality standards. In instances where they do not, the permit writer is required to establish water-quality-based effluent limitations.[92] If a water body is not attaining its designated use (i.e., is "impaired" for that use), the Total Maximum Daily Load (TMDL) may also be used.[93] A TMDL, essentially a "pollution diet" for a water body, is the maximum amount of a pollutant that a water body can receive and still meet water quality standards and an allocation of that amount to the pollutant's sources (including a margin of safety).[94] TMDLs consider point sources, which can be addressed through permits, as well as nonpoint (diffuse) sources, which are more often addressed through best management practices and related efforts under CWA Section 319 nonpoint source management programs.[95]

Challenges to Addressing CECs through Water-Quality-Based Requirements

A key challenge is often a lack of data about the occurrence, concentration, and persistence of CECs in the environment, as well as the effects on human health and aquatic life. Detection of a contaminant does not necessarily trigger regulatory measures. Information on the potential for the contaminant to adversely affect human health and aquatic life, potential exposure pathways, and other data would also be needed to inform such decisions.

Developing new water quality criteria or updating existing criteria can often be time intensive, particularly in cases where data are limited. The general process for developing criteria involves a number of steps, including problem formulation and developing an analysis plan; gathering data and analyzing relevant studies; drafting the criteria document; a rigorous review process (e.g., branch level, office level, interagency, and independent external peer review); public notice and comment, and revising and publishing the criteria.[96] According to EPA officials, the time it takes

[90] 40 C.F.R. §131.20(a).

[91] CWA §303(c)(2)(B); 33 U.S.C. §1313(c)(2)(B).

[92] Per 40 C.F.R. §122.44(d)(1)(i), limitations must be established in permits to "control all pollutants or pollutant parameters (either conventional, nonconventional, or toxic pollutants) which the Director determines are or may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any State water quality standard, including State narrative criteria for water quality."

[93] CWA §303(d); 33 U.S.C. §1313(d).

[94] 40 C.F.R. §130.2.

[95] 33 U.S.C. §1329.

[96] Personal communication between CRS and EPA staff, May 29, 2019.

to develop or update criteria is often a function of the data that are available.[97] EPA officials noted that developing criteria can take several years or longer. For example, the 2016 update for the aquatic life water quality criteria for selenium—an effort characterized by EPA as complicated, in part because of the contaminant's bioaccumulative properties—took 10 years to complete.[98] In other cases, such as when a contaminant has an existing EPA Integrated Risk Information System value, developing or updating the human health water quality criteria for that contaminant may take less time, according to EPA officials.[99]

In May 2019, a report from the Contaminants of Emerging Concern Workgroup, convened by the Association of State Drinking Water Administrators and the Association of Clean Water Administrators, provided recommendations from state regulators regarding the ways state and federal agencies could improve the management of CECs.[100] The report stated the following:

> The use of existing authorities and processes under the CWA and [Safe Drinking Water Act] to establish new criteria or standards is onerous, can take decades to implement, and does not meet public expectations for timely identification and prioritization of CECs…. However slow these federal processes are, many state agencies do not have the infrastructure (i.e., sufficient funds and/or staffing levels), regulatory authority, or technical expertise to derive their own criteria or set their own standards for drinking water, surface water, groundwater, and fish tissue.

Among numerous other recommendations provided in the report, the CEC workgroup recommended that EPA work with states to generate a list of priority CECs. To that end, EPA officials stated that they are developing a more formalized prioritization process for determining which contaminants warrant criteria development that will incorporate input from multiple stakeholders (including states), leverage information collected under the Safe Drinking Water Act, and incorporate monitoring and other data (e.g., ambient water concentrations).[101]

Designating CECs as Toxic Pollutants or Hazardous Substances

Two sections of the CWA—Sections 307 and 311—authorize EPA to designate contaminants as toxic pollutants and hazardous substances, respectively. Designating a contaminant under Section 307 or Section 311 of the CWA has implications for how the contaminant is treated under CERCLA. CERCLA defines the term *hazardous substance* to include toxic pollutants designated under CWA Section 307 and hazardous substances designated under CWA Section 311 (as well as substances designated under certain other statutes and other chemicals that EPA may designate as hazardous substances).[102]

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[97] Personal communication between CRS and EPA staff, May 29, 2019.

[98] Personal communication between CRS and EPA staff, May 29, 2019. See also EPA, *Aquatic Life Ambient Water Quality Criterion for Selenium—Freshwater 2016*, June 2016, pp. 1-3, https://www.epa.gov/sites/production/files/2016-07/documents/aquatic_life_awqc_for_selenium_-_freshwater_2016.pdf.

[99] Personal communication between CRS and EPA staff, May 29, 2019. EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates information on health effects of exposure to environmental contaminants. For more information on the IRIS program, see EPA, "Integrated Risk Information System," https://www.epa.gov/iris. According to EPA officials, because development of IRIS values requires a rigorous review process, EPA does not do a separate peer review in developing criteria using an IRIS value (personal communication between CRS and EPA staff, May 29, 2019).

[100] ACWA, ASDWA, *Recommendations Report*.

[101] Personal communication between CRS and EPA staff, May 29, 2019. EPA staff stated that, in the past, the agency has more informally determined the need for criteria through state and stakeholder input.

[102] Section 101(14) of CERCLA (42 U.S.C. §9601(14)) generally defines the term *hazardous substance* to include

Toxic Pollutants—CWA Section 307

EPA's authority to designate contaminants under CWA Section 307 as toxic pollutants and the CWA-related implications of that designation are discussed above under "Toxic Pollutant List."

Hazardous Substances—CWA Section 311

CWA Section 311(b)(2)(A) authorizes EPA to promulgate a rule designating as a "hazardous substance" any element or compound that, when discharged as specified under the section, would present an imminent and substantial danger to public health or welfare, including but not limited to fish, shellfish, wildlife, shorelines, and beaches.[103] EPA is authorized to revise the list of hazardous substances subject to these criteria as may be appropriate. EPA finalized the initial list of hazardous substances in 1978 and thereafter revised the list in 1979, 1989, and 2011.[104]

Pursuant to Section 311(b)(4), EPA established "harmful" quantities for these substances that are subject to the reporting of discharges prohibited under Section 311(b)(3).[105] Section 311(b)(5) requires a person in charge of a vessel or facility to notify the National Response Center, administered by the U.S. Coast Guard, as soon as that person has knowledge of a discharge.[106] Discharges permitted under other provisions of the CWA or otherwise allowable under certain other federal, state, and local regulations are excluded from reporting under CWA Section 311.[107]

CWA Section 311(c) authorizes federal actions to remove a prohibited discharge of a hazardous substance (or oil).[108] CWA Section 311(f) establishes liability for the recovery of removal costs, including restoration of damaged natural resources.[109] Section 311(e) authorizes enforcement orders to require a responsible party to abate an imminent and substantial threat to public health or welfare from a prohibited discharge, or threat of a harmful discharge, of a hazardous substance (or oil).[110]

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hazardous substances designated under Section 311(b)(2)(A) of the CWA; toxic pollutants listed under Section 307(a) of the CWA; hazardous waste with characteristics identified or listed under Section 3001 of the Solid Waste Disposal Act (with the exception of wastes excluded from regulation); hazardous air pollutants listed under Section 112 of the Clean Air Act; any imminently hazardous chemical substance or mixture for which EPA has taken action under Section 7 of TSCA; and other elements, compounds, mixtures, solutions, and substances designated pursuant to Section 102 of CERCLA.

[103] 33 U.S.C. §1321(b)(2)(A). CWA Section 311(b)(3) generally prohibits the discharge of a hazardous substance (or oil) in "harmful" quantities into or upon the navigable waters of the United States, adjoining shorelines, or the waters of the contiguous zone or in connection with activities under the Outer Continental Shelf Lands Act or the Deepwater Port Act of 1974 or that may affect natural resources belonging to, appertaining to, or under the exclusive management authority of the United States. However, Section 311(a)(2) of the CWA (33 U.S.C. §1321(a)(2)) defines the term *discharge* to exclude discharges in compliance with a permit issued under CWA Section 402, making such compliant discharges not prohibited.

[104] The list of hazardous substances designated under CWA Section 311 is codified at 40 C.F.R. §116.4. The original list published by EPA in 1978 included 271 hazardous substances. While 28 substances were added the following year, the list has changed slightly since that time and currently includes 296 substances.

[105] 33 U.S.C. §1321(b)(4).

[106] 33 U.S.C. §1321(b)(5).

[107] Quantities of "harmful" discharges of hazardous substances subject to reporting under CWA Section 311 are codified at 40 C.F.R. §117.

[108] 33 U.S.C. §1321(c).

[109] 33 U.S.C. §1321(f).

[110] 33 U.S.C. §1321(e). Such threats may include threats to fish, shellfish, wildlife, public and private property, shorelines, beaches, habitat, and other living and nonliving natural resources under the jurisdiction or control of the

Implications of CWA Designations on CERCLA

If EPA were to designate a CEC, or any contaminant, as a toxic pollutant or hazardous substance under the CWA, that contaminant would, by statutory definition, be defined as a hazardous substance under CERCLA. CERCLA authorizes federal actions to respond to a release, or substantial threat of a release, of a hazardous substance into the environment in coordination with the states. CERCLA similarly authorizes response actions for releases of other pollutants or contaminants that may present an imminent and substantial danger to public health or welfare. CERCLA also establishes liability for response costs and natural resource damages but only for hazardous substances and not for other pollutants or contaminants.

CERCLA response authority is available for releases of pollutants or contaminants but without liability to require a potentially responsible party to perform or pay for response actions. Designating a CEC as a toxic pollutant or hazardous substance under the CWA would have the effect of establishing liability for their release as a hazardous substance under CERCLA. However, releases in compliance with a CWA permit would be exempt from liability under CERCLA as a "federally permitted release" based on the premise that the permit requirements would mitigate potential risks.[111]

CWA Section 311 also establishes liability for releases of hazardous substances, but CERCLA liability and enforcement mechanisms are broader than the CWA. In practice, CERCLA has been the principal federal authority used to respond to discharges of hazardous substances into surface waters and to enforce liability, although the enforcement authorities of CWA Section 311 remain available to EPA. For a broader discussion of CERCLA, see CRS Report R41039, *Comprehensive Environmental Response, Compensation, and Liability Act: A Summary of Superfund Cleanup Authorities and Related Provisions of the Act*, by David M. Bearden.

Legislation in the 116th Congress

Recent congressional interest in CECs has largely focused on addressing one particular group of CECs—PFAS—and addressing them through several statutes, such as the Safe Drinking Water Act.[112] However, legislation in the 116th Congress proposes to address PFAS using CWA authorities. H.R. 3616—the Clean Water Standards for PFAS Act of 2019—and Section 330A of H.R. 2500, the House-passed version of the NDAA for FY2020, would direct EPA to add PFAS to the CWA Toxic Pollutant List and publish ELGs and pretreatment standards for PFAS within specified time frames. In addition, Section 330G of the House-passed version of the NDAA bill, Sections 6731-6736 of S. 1790 (the Senate NDAA bill), H.R. 1976, and S. 950 would direct the U.S. Geological Survey (USGS) to carry out nationwide sampling—in consultation with states and EPA—to determine the concentration of perfluorinated compounds in surface water, groundwater, and soil. These bills would also require USGS to prepare a report for Congress and provide the sampling data to the EPA as well as other federal and state regulatory agencies that request it. Additionally, the bills would require the data to be used to "inform and enhance

United States.

[111] Section 107(j) of CERCLA (42 U.S.C. §9607(j)) exempts federally permitted releases from liability under the statute. Section 101(10) of CERCLA (42 U.S.C. §9601(10)) defines the term *federally permitted release* to include discharges permitted under Sections 402 and 404 of the CWA and releases permitted under various other federal environmental laws.

[112] For a discussion of select PFAS legislation in the 116th Congress, see CRS Report R45986, *Federal Role in Responding to Potential Risks of Per- and Polyfluoroalkyl Substances (PFAS)*, coordinated by David M. Bearden.

assessments of exposure, likely health and environmental impacts, and remediation priorities." Some Members have also introduced legislation to require comprehensive PFAS toxicity testing (H.R. 2608).[113]

In addition to focusing on PFAS, several bills proposed in the 116th Congress look more broadly at how to address CECs. For example, some aim to improve federal coordination and research and support states in addressing emerging contaminants. S. 1507, S. 1251, and Sections 6741-6742 of S. 1790 would direct the White House Office of Science and Technology Policy to establish a National Emerging Contaminant Research Initiative. The bills would also direct EPA to develop a program to provide technical assistance and support to states for testing and analysis of emerging contaminants and establish a database of resources available through the program to assist states with testing for emerging contaminants. While these efforts are more focused on CECs in drinking water, the bill directs the EPA to ensure that the database is available to groups that have interest in emerging contaminants, including wastewater utilities.

Conclusion

While Congress is currently debating how to best address the concerns related to widespread detections of PFAS, attention to other emerging contaminants (e.g., microplastics and algal toxins) has also increased with the availability of new detection methods and increased monitoring. Observers note that in the coming years, other CECs will likely emerge and prompt similar calls for immediate action to protect public health and the environment. Many observers argue that federal actions to address CECs currently tend to be reactive rather than proactive. Many of these observers assert that more focus and attention is needed on assessing the toxicity of chemical substances before they are introduced into commerce. Congress is currently considering legislation to improve federal coordination and responses to CECs.

Specific to the CWA, some observers advocate for oversight to identify and address potential gaps or barriers in CWA authorities and processes that make it difficult for EPA and states to quickly respond when CECs are detected. Other observers assert that EPA could better use its existing authorities to address CECs. For example, EPA has not updated its ELGs for certain industrial categories in decades. Accordingly, some observers assert that various ELGs do not reflect advancements in science or technology that could lead to new effluent limitations for CECs. Similarly, some stakeholders assert that EPA could better prioritize which CECs warrant water quality criteria development. EPA's ability to address these and other recommendations depends on the availability of resources, treatment technologies, and scientific and economic data. Moving forward, Congress may be interested in evaluating EPA appropriations for the CWA programs that support EPA's efforts to address discharges of CECs. Congress may also be interested in overseeing the Administration's implementation of these programs.

[113] H.R. 2608 would amend TSCA to direct EPA, within 60 days of enactment, to require comprehensive toxicity testing of PFAS and to direct EPA, within 60 days of enactment, to require that PFAS manufacturers and processors submit certain records and studies to the agency.

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Helena Valley Ground Water: Pharmaceuticals, Personal Care Products, Endocrine Disruptors (PPCPs) and Microbial Indicators of Fecal Contamination

By Kathleen (Kate) J. Miller and Joseph Meek, both of the Montana Department of Environmental Quality

Abstract

The city of Helena, Montana and its surrounding valley (fig.1) are experiencing marked population growth with attendant proliferation of onsite wastewater disposal (septic tanks and drainfields) systems. Thirty eight public and private domestic water supplies deriving ground water from the Quaternary/Tertiary valley fill aquifer and various bedrock formations were sampled in the summer and fall of 2005 for pharmaceutically active compounds, personal care products, and endocrine disrupting compounds (PPCP as used here).

The two most frequently detected PPCPs are sulfamethoxazole (SMX) and the herbicide atrazine, with detection frequencies of 80% and 40%, respectively. Atrazine demonstrates a strong correlation with chloride and total dissolved solids (TDS). Because chloride and TDS are commonly used inorganic indicators of water-quality degradation from domestic wastewater discharge, the correlation suggests that atrazine could be occurring in domestic wastewater. This hypothesis should be verified in subsequent investigations

The wells were also sampled for microbial indicators of fecal contamination and for inorganic constituents. There is a poor correlation between the microbial indicators of fecal contamination and PPCP occurrence, with zero detections of either *E.coli* or the somatic or male specific coliphage. Total coliform was detected at only 8 sites.

Introduction

Twenty-two PPCPs have been detected in ground water used for drinking water for private and public water supplies in the Helena valley, Montana. PPCPs are a group of compounds that include antibiotics, hormones, and drugs. Results of several recent studies (Godfrey, 2004, Hinkle, 2005, Heberer, 2004) show that PPCPs are present in relatively low concentrations [nanogram per liter (ηg/L) to microgram per liter (μg/L ranges)] in municipal and domestic wastewater as well as in some surface and ground water. The presence of these compounds in ground water and surface water has drawn public attention not only because of potential health risks from exposure to one or a mixture of these chemicals, but also because the primary mode of entry into our environment is not from manufacturing discharge but from widespread and continual use in human and veterinary and clinical practice (Lancet, 2002) and discharge associated with domestic wastewater. Low levels of various PPCPs in ground water provide clear evidence that domestic wastewater is a source of contamination. In spite of a growing body of evidence describing their distribution in the environment, little is known about their mobility and persistence in ground water or surface water, nor are their effects on human health and aquatic ecosystems well understood.

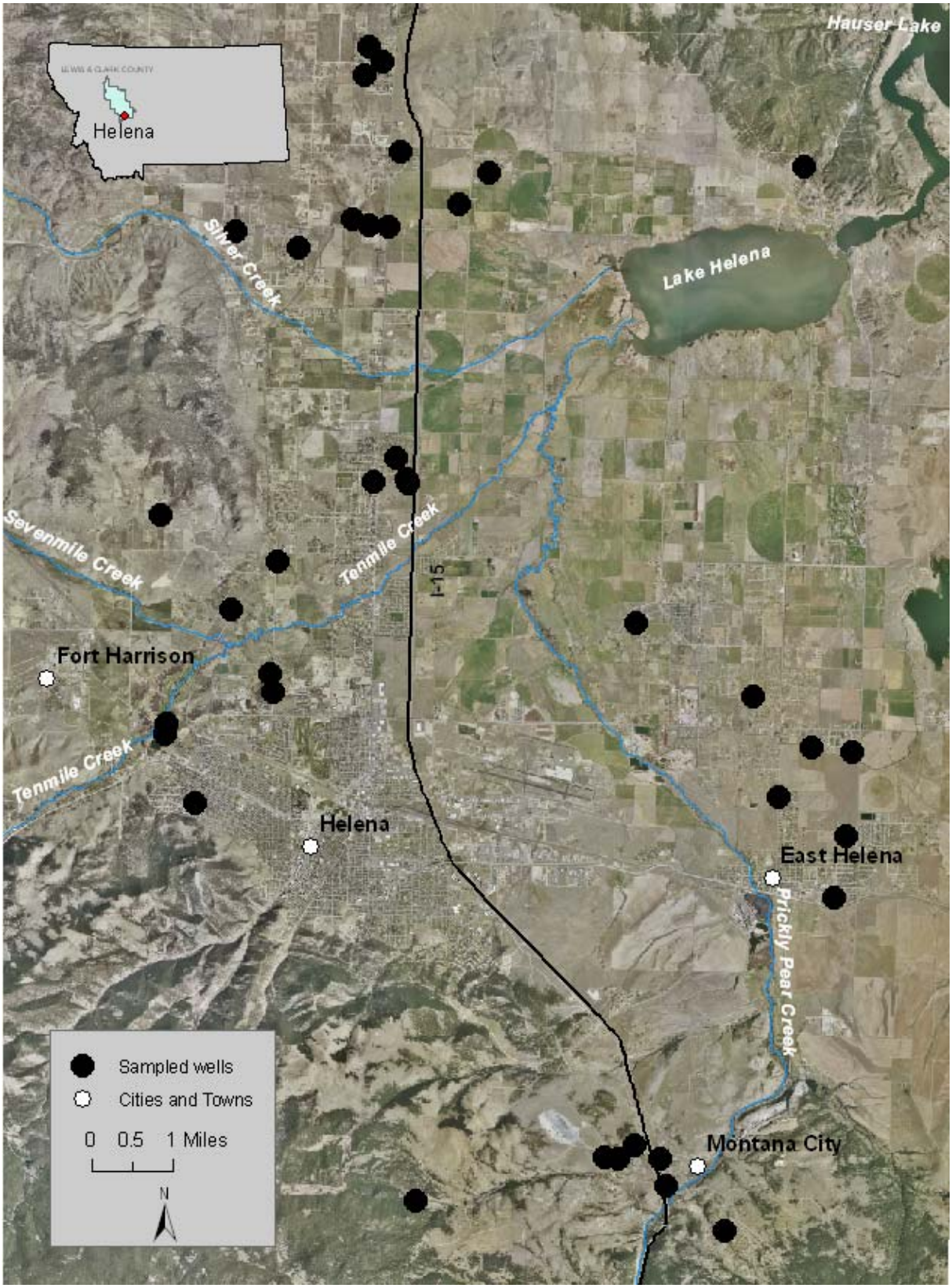

Figure 1. General location of the Helena valley, Montana

The proposed Ground Water Rule of the National Primary Drinking Water Regulations (40 CFR Parts 141 and 142, May 10, 2000) recognizes the need for a targeted risk-based regulatory strategy that identifies those systems with source-water contamination and systems deriving ground water from hydrogeologically "sensitive" aquifers. Among other stipulations of the proposed Ground Water Rule, public water supplies may be required to monitor ground-water sources for multiple indicators of fecal contamination; under the proposed rule both a bacterium (*E.coli* or enterococci) and a virus (male specific and somatic coliphage) could be used as indicators. Previous investigators have found coliphage, PPCPs, and other organic wastewater compounds in ground water and in septic tanks (onsite wastewater). In each study the types of analytes differ somewhat. In a shallow unconfined sandy aquifer near La Pine Oregon, the U.S. Geological Survey (Hinkle, 2005) found 45 organic wastewater compounds in onsite wastewater. In ground-water samples only 9 of the 45 wastewater compounds were found, along with sulfamethoxazole (SMX), acetaminophen, and caffeine. They found that the reactivity of this particular suite of organic wastewater compounds may limit their usefulness as tracers of onsite wastewater discharged into aquifers. In the same study coliphage was frequently detected in onsite wastewater but was only occasionally detected (8 occurrences) at low concentrations in wells, with a consistent absence in replicate or repeat samples. The authors speculate that coliphage was probably attenuated to less than 1 plaque forming unit (PFU)/100 mL before reaching the sampled wells.

Heberer (2004) noted that more than 60 pharmaceutical residues have been detected in surface water but only a very limited number of the compounds have been found in ground water and suggests that not only is there a small number of ground-water studies, but the compounds are likely removed or attenuated during transport into ground water. USGS investigators (2005) found that nitrate and chloride concentrations in onsite wastewater exhibited small variability among systems but that concentrations of individual organic wastewater compounds varied dramatically among different onsite wastewater treatment systems - not uncommonly by several orders of magnitude - suggesting that loading rates of wastewater compounds might be highly variable.

After the analysis of 42 septic tanks and influent to and effluent from the public wastewater treatment facility (WWTF) for Missoula, Montana, Godfrey and Woessner (2004) found 18 pharmaceutically active compounds in septic tanks, 12 in the WWTF influent and 9 in the WWTF effluent. The most frequently detected non-prescription drugs were acetaminophen, caffeine, and nicotine; frequently found prescription drugs were codeine, trimethroprim, and carbamazepine. In a similar evaluation of organic wastewater compounds in septic tanks at about 20 sites in New Jersey, Szabo (2004) found 4-nonylphenol, phenol, caffeine, cotinine, menthol, 3-beta-coprastanol, cholesterol, and β-sitosterol.

Background

The Helena valley in west-central Montana comprises about 330 square miles (207,400 acres) and is underlain by about 6,000 feet of valley fill composed of Tertiary sediments unconformably overlain by about 100 feet of Quaternary alluvium. Because of the

hydraulic interconnection of water-yielding zones, the valley fill deposits function as one complex aquifer system (Briar, 1992). Surface water enters the valley from Prickly Pear, Tenmile, Sevenmile, and Silver Creeks and from the Missouri River after it has been diverted into irrigation canals. Ground water and surface water discharges principally to Lake Helena and ultimately to the Missouri River. The Helena valley is bounded by folded and fractured sedimentary, metamorphic, and igneous bedrock of Precambrian to Cretaceous age (fig. 2). Figure 2 also shows ground-water level contours that depict flow from the south, west, and north margins of the valley toward Lake Helena.

Ground-water quality in the valley fill deposits is characterized as a calcium bicarbonate type with a median pH of 7.5. As shown on Table 1, arsenic, uranium and nitrate are elevated in ground-water samples at a few locations in the Helena Valley. The maximum values are17.1 µg/L for arsenic, [Maximum Contaminant Level (MCL) = 10 µg/L], 29.1µg/L for uranium (MCL=30 µg/L) and 12.4 mg/L for nitrate (MCL = 10 mg/L). Irrigation with arsenic-laden Missouri River water is a possible explanation for the elevated arsenic concentrations. Uraniferous rocks in surrounding bedrock are the probable source of elevated uranium. Elevated nitrate could be indicative of water-quality degradation from domestic wastewater; agricultural sources are possible but less numerous than those derived from domestic wastewater.

Historically a mining and agricultural area, the city of Helena and its surrounding valley is now experiencing dramatic increases in the density of individual onsite wastewater disposal facilities and residential wells. As shown on figure 3, the number of wells installed per year from 1973 through 1994 has averaged about 190. But in the period from 1995-2005 the average number of wells installed has escalated to 284 per year. It can be assumed that most of these wells are being installed to serve residences that are not served by city water or sewer services.

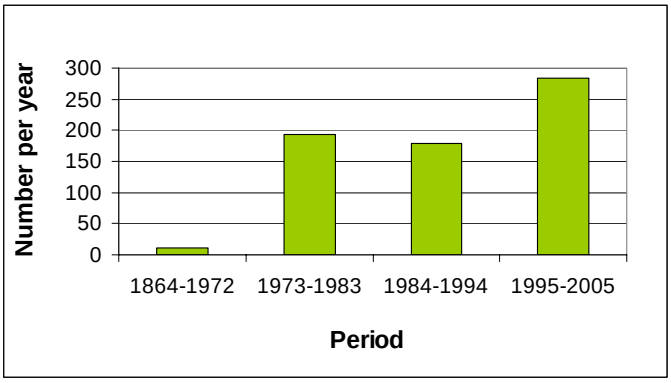

Figure 3. Annual number of new well installations in the Helena valley from 1864 – 2005.

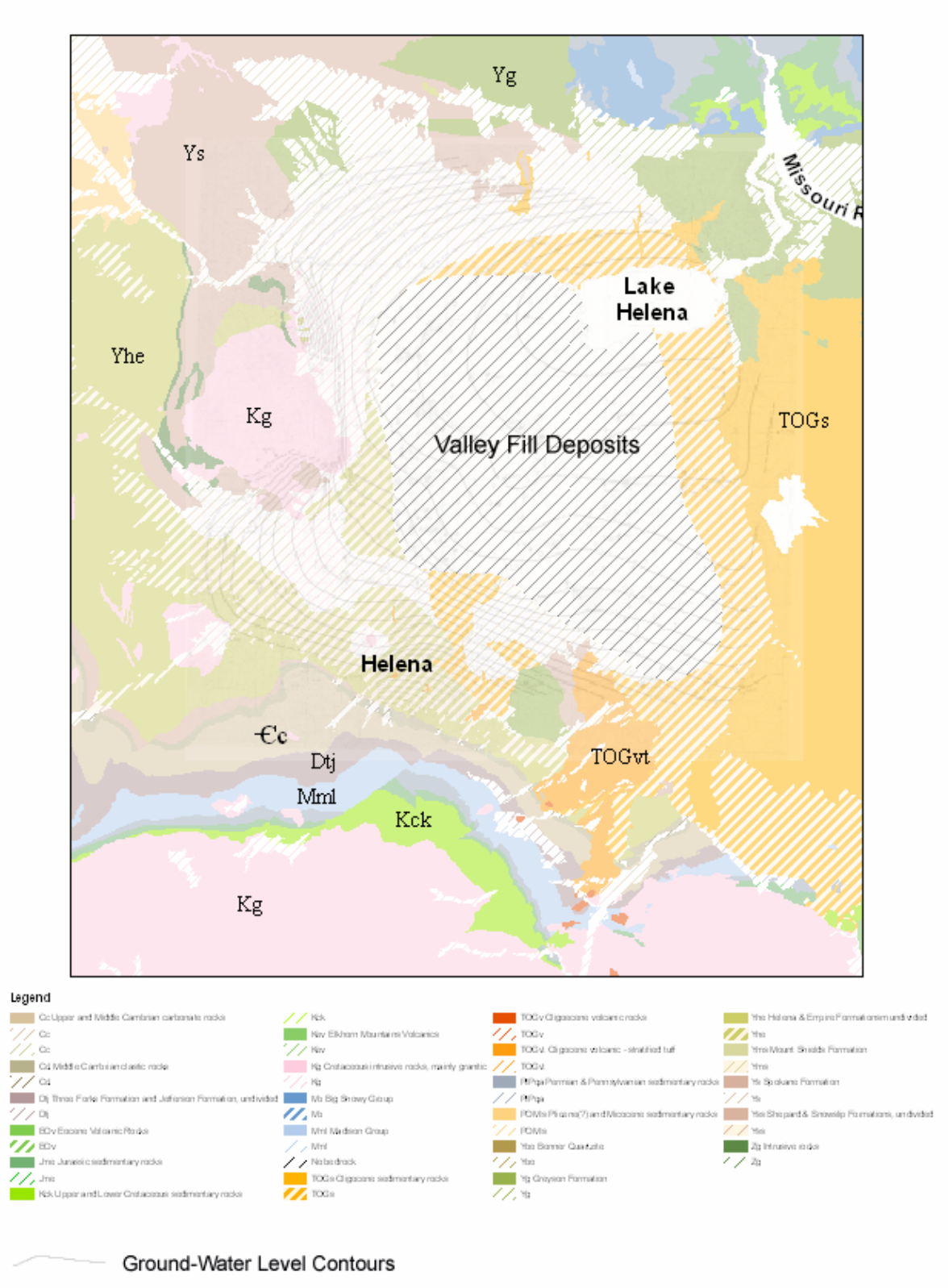

Figure 2. Bedrock geology and water-level contours for the Helena valley, Montana. Modified from Thamke and Reynolds (2002) and Briar and Madison (1992).

A microbial occurrence survey of the Helena valley was conducted in April 2004 by Steve Kilbreath and Joe Meek of the Montana Department of Environmental Quality (DEQ) and Kathy Moore of the Lewis and Clark County Water Quality Protection District (LCWQPD). Results of that survey showed positive male specific coliphage occurrence in 10 of 19 sampled wells in the Helena valley with no detections of either of *E.coli* or enterococci. Subsequent re-sampling in August 2004 produced negative results for all coliphage, *E.coli,* and enterococci (Steve Kilbreath, Kathy Moore, and Joe Meek, unpub. data, 2004).

Methods

Thirty-eight wells representing both bedrock- (n=12) and valley fill-(n=26) aquifers, were sampled for total coliform, E.coli, enterococci, male specific- and somatic coliphage in April, June and November 2005. During the same period, 35 wells were sampled for 28 PPCPs and inorganic constituents. Eighteen wells serve small public water supplies with the remainder serving private residences. Well depths range from 39 to 425 feet (Table 1).

Wells were flushed prior to sampling until the field parameters of pH, specific conductance and temperature were stable as per the Montana Bureau of Mines and Geology (MBMG) Standard Operating Procedure for Collection of Ground-Water Samples for Inorganic Analyses (2004).

Samples for the analysis of male specific and somatic coliphage were collected and analyzed in accordance with proposed EPA Method 1601: Male Specific (F+) and Somatic Coliphage in Water by Two-Step Enrichment Procedure (USEPA, 2000). Total coliform, *E.coli*, and enterococci samples were collected and analyzed using Autoanalysis Colilert (MDPHHS, 2004) and Enterolert systems (MDPHHS, 2004), respectively.

Samples for the analysis of PPCPs were collected as grab samples in 1-L amber bottles. After arrival at the lab, Columbia Analytical Services in Kelso, WA prepared the samples using EPA Method 3535 and analyzed the samples using LC/MS/MS (Columbia Analytical Services, 2005).

Samples to be analyzed for inorganic constituents were field-filtered and preserved prior to shipment to the MBMG Analytical Laboratory. The sampling procedures follow the MBMG Standard Operating Procedures for Collection of Ground-Water Samples for Inorganic Analyses (2004). The inorganic analytical methods follow those as published in the MBMG Analytical Division Fee Schedule (1999).

Each well site is assigned a unique identification number that can be cross-referenced to the Montana Ground-Water Information Center (GWIC ID). All pertinent well construction, site inventory and water-quality data may be found on the website, http://mbmggwic.mtech.edu.

Table 1. Results of dissolved inorganic analyses for 35 well sites in the Helena Valley with maximum, minimum and median values.

Gwic Id	Sample Date	Total Well Depth (ft)	Water Temp	Field pH	Field S.C.	Lab pH	Lab Specific Conductance (umhos/cm2)	Total Dissolved Solids (mg/l)	Ca (mg/l)	Mg (mg/l)	Na (mg/l)	K (mg/l)	Fe (mg/l)	Mn (mg/l)	SiO2 (mg/l)	HCO3 (mg/l)	CO3 (mg/l)	SO4 (mg/l)	Cl (mg/l)	NO3 (mg/l)	F (mg/l)	OPO4 (mg/l)
62523	5/24/05	50	10.3	7.3	376	7.85	510	315.2	70.7	20.6	10.9	2.3	0.0	<0.001	20.8	298.0	0.0	38.2	4.8	0.0	0.1	<0.05
64826	5/23/05	42	10.2	7.9	285	8.19	532	333.8	54.8	25.3	25.6	0.8	0.0	<0.001	26.4	264.0	0.0	53.4	15.1	1.9	0.4	<0.05
5756	5/23/05	66	10.1	7.8	625	7.92	840	790.2	83.7	34.9	56.9	3.5	0.0	0.0	274.0	386.0	0.0	111.0	29.5	5.4	0.4	0.7
62570	5/23/05	70	12.6	7.3	1667	7.57	2580	1810.8	221.0	119.0	235.0	6.9	0.0	<0.001	35.1	616.0	0.0	538.0	342.0	9.9	<1.0	<1.0
64806	5/23/05	41		7.8	611	7.42	846	528.7	47.4	21.6	115.0	1.1	0.0	<0.001	38.4	421.0	0.0	71.8	17.1	8.6	0.3	<0.05
194850	5/24/05	180	1	7.3	523	7.78	702	446.3	93.4	30.8	16.2	3.3	0.0	<0.001	19.6	353.0	0.0	90.8	17.6	0.7	<0.05	<0.05
62369	5/31/05	110	10.2	7.7	341	7.58	838	546.5	53.1	23.5	119.0	1.2	0.0	0.0	40.8	418.5	0.0	75.4	17.6	9.5	0.2	<0.05
62575	5/31/05	93	10.1	7.6	229	7.59	863	543.3	51.9	22.8	118.0	1.2	0.0	0.0	39.9	419.9	0.0	75.4	17.6	9.4	0.2	<0.05
65388	6/5/05	87	10.1	7.5	578	7.76	587	364.0	63.8	26.0	28.9	1.7	0.0	<0.001	19.3	201.1	0.0	76.1	45.2	3.9	0.0	0.0
170202	6/5/05	300	10.3	7.6	378	7.52	508	312.5	58.2	14.5	27.9	5.6	0.0	0.0	13.7	228.1	0.0	62.7	17.1	0.0	0.4	<0.05
187850	5/30/05	100	10.2	7.7	452	7.75	607	364.5	61.8	25.2	27.2	1.7	0.0	<0.001	19.0	199.3	0.0	83.9	43.5	3.8	0.2	<0.10
206394	5/30/05	200	10.1	7.8	943	7.68	1288	731.5	128.0	60.3	35.6	2.3	<0.005	0.0	16.2	160.1	0.0	159.0	240.0	11.2	<0.63	0.0
165085	7/15/05	201	10.8	7.3	252	7.77	273	199.0	29.7	6.5	14.1	3.3	0.0	0.0	45.7	130.8	0.0	29.2	4.9	0.9	0.3	<0.05
220274	7/14/05		12.4	7.3	617	7.64	607	397.4	80.3	24.3	19.3	3.5	<0.005	<0.001	27.0	255.9	0.0	87.4	27.1	2.0	0.4	<0.05
220272	7/15/05		12.7	7.6	689	7.94	729	425.7	67.2	34.8	26.7	1.8	0.0	<0.001	17.7	188.2	0.0	83.6	96.4	4.7	0.0	0.0
58685	7/15/05	310	17.4	7.5	504	7.78	462	268.8	44.5	22.6	13.9	2.9	<0.005	<0.001	19.8	215.0	0.0	51.5	7.1	0.0	0.5	0.1
58712	7/14/05	148	12.2	7.2	902	7.41	838	511.4	96.8	44.3	29.8	4.8	<0.005	<0.001	21.8	309.9	0.0	115.0	35.8	10.4	0.0	0.0
165017	7/19/05	94	12.3	7.4	444	7.85	462	288.9	51.9	12.4	34.6	2.1	0.0	<0.001	9.1	237.2	0.0	44.7	15.7	1.5	0.1	<0.05
65071	7/19/05	39	10.9	7.1	470	7.54	467	280.7	54.8	14.3	20.7	3.2	<0.005	<0.001	20.8	197.4	0.0	49.4	16.6	3.5	0.2	<0.05
61051	7/20/05	123				7.31	451	288.8	59.1	14.7	17.3	3.2	0.0	<0.001	23.1	195.4	0.0	59.6	13.4	2.0	0.2	<0.05
61055	7/19/05	145	11.2	7.0	351	7.34	395	261.9	51.6	13.2	14.8	3.1	0.0	<0.001	23.5	183.7	0.0	54.4	9.4	1.2	0.2	<0.05
62802	7/19/05	130	15.5	7.4	561	7.78	543	325.7	55.3	29.5	17.0	2.5	0.0	<0.001	14.7	230.6	0.0	66.4	22.4	4.2	0.1	<0.05
62779	7/19/05	50	11.3	7.3	461	7.67	438	271.4	47.8	16.1	21.0	3.9	0.2	0.1	22.0	205.2	0.0	42.7	15.8	0.0	0.6	0.1
58737	7/19/05	207	11.1	7.0	549	7.41	524	320.8	75.1	17.1	10.6	5.5	0.1	0.0	24.0	198.6	0.0	61.0	17.2	12.4	<0.05	<0.05
134497	7/19/05	145	16.3	7.3	661	7.61	649	398.1	67.6	30.6	24.7	5.5	0.1	0.0	24.0	255.9	0.0	116.0	1.1	1.0	1.1	0.4
220386	7/22/05		11.7	7.4	411	7.78	564	377.2	60.7	17.0	37.1	3.4	0.0	<0.001	31.0	147.9	0.0	126.0	26.1	2.5	0.6	<0.05
153703	7/22/05	257				8.27	377	243.5	43.2	11.4	20.6	3.0	<0.005	<0.001	23.5	145.4	0.0	57.1	11.4	1.3	0.4	<0.05
182549	7/22/05	100	13.9	7.3	299	7.85	379	241.1	46.2	10.0	20.7	3.2	<0.005	<0.001	19.9	177.9	0.0	39.5	12.9	0.8	0.3	<0.05
60800	7/22/05	100	13.2	7.4	444	7.91	445	287.0	52.9	12.7	28.3	3.3	<0.005	<0.001	19.9	204.7	0.0	50.8	15.6	2.3	0.3	<0.05
134635	7/29/05	120	13.9	7.6	402	8.08	486	271.1	41.5	17.2	24.8	1.2	0.0	<0.001	22.7	214.5	0.0	40.8	17.0	0.0	0.2	<0.05
130936	7/29/05	140	15	7.7	379	8.04	418	251.3	44.8	14.8	22.0	2.1	<0.005	<0.001	18.1	202.3	0.0	36.5	13.3	0.0	0.1	<0.05
64880	7/29/05	86	11.7	7.4	574	7.95	658	390.5	67.1	18.8	51.6	2.4	0.0	<0.001	19.9	274.2	0.0	67.4	19.9	8.4	<0.05	<0.05
177845	8/1/05	198	10.6	7.2	524	7.53	543	334.8	66.9	26.0	11.6	11.4	0.0	0.1	19.9	253.2	0.0	54.8	17.2	1.9	0.3	<0.05
61619	8/1/05	70	11.4	6.9	338	7.74	341	216.2	40.6	8.8	17.3	3.0	0.0	<0.001	22.3	128.1	0.0	50.8	9.2	0.8	0.2	<0.05
177799	8/2/05	425	19.1	7.3	746	8.01	795	577.5	86.4	22.0	69.5	4.2	0.3	0.0	35.7	206.5	0.0	210.0	44.8	0.5	2.4	<0.05
Maximum				7.9	1667	8.3	2580.0	1810.8	221.0	119.0	235.0	11.4	0.3	0.1	274.0	616.0	0.0	538.0	342.0	12.4	2.4	0.7
Minimum				6.9	229	7.3	273.0	199.0	29.7	6.5	10.6	0.8	0.0	0.0	9.1	128.1	0.0	29.2	1.1	0.0	0.0	0.0
Median				7.4	470	7.8	543.0	333.8	58.2	21.6	24.8	3.1	0.0	0.0	22.0	214.5	0.0	62.7	17.1	2.0	0.3	0.0

Table 1. Results of dissolved inorganic analyses for 35 well sites in the Helena Valley with maximum, minimum and median values, continued.

Gwic Id	Sample Date	As (ug/l)	B (ug/l)	Ba (ug/l)	Be (ug/l)	Br (ug/l)	Cd (ug/l)	Co (ug/l)	Cr (ug/l)	Cu (ug/l)	Li (ug/l)	Mo (ug/l)	Ni (ug/l)	Pb (ug/l)	Sb (ug/l)	Se (ug/l)	Sr (ug/l)	Ti (ug/l)	Tl (ug/l)	U (ug/l)	V (ug/l)	Zn (ug/l)	Zr (ug/l)
62523	5/24/05	0.0	<30	25.8	<2	<50	<1	<2	<2	4.2	6.4	10.7	<2	<2	<2	<1	385.0	<1	<5	6.3	<5	2.3	<2
64826	5/23/05	1.8	69.9	47.7	<2	<50	<1	<2	<2	<2	35.7	<10	<2	<2	<2	1.0	441.0	<1	<5	5.9	<5	4.4	<2
5756	5/23/05	2.7	88.9	68.0	<2	<100	<1	<2	<2	2.6	19.0	<10	<2	<2	<2	3.0	654.0	<1	<5	29.1	6.1	14.2	<5
62570	5/23/05	0.0	<150	33.6	<2	<100	<1	<2	<10	<5	25.6	<10	3.3	<10	<10	7.8	940.0	<1	<25	17.7	<10	522.0	<2
64806	5/23/05	2.0	<30	184.0	<2	<50	<1	<2	<2	<2	12.8	<10	<2	<2	<2	1.5	347.0	<1	<5	4.7	<5	8.5	<2
194850	5/24/05	2.0	<30	184.0	<2	<50	<1	<2	<2	<2	12.8	<10	<2	<2	<2	1.5	347.0	<1	<5	4.7	<5	8.5	<2
62369	5/31/05	3.2	188.0	35.6	<2	<50	<1	<2	2.2	44.7	30.3	<10	<2	<2	<2	1.7	502.0	1.1	<5	10.6	6.7	28.6	<2
62575	5/31/05	3.2	188.0	36.4	<2	<50	<1	<2	2.2	25.0	29.7	<10	<2	<2	<2	1.8	492.0	<1	<5	10.7	6.8	15.4	<2
65388	6/5/05	1.5	<30	61.3	<2	<500	<1	<2	<2	2.5	17.4	<10	<2	<2	<2	4.3	519.0	<1	<5	3.9	<5	14.5	<2
170202	6/5/05	1.7	31.8	33.0	<2	109.0	<1	<2	<2	3.9	48.4	<10	<2	3.6	<2	4.3	638.0	<1	<5	5.5	<5	58.0	<2
187850	5/30/05	1.6	<30	59.9	<2	203.0	<1	<2	3.2	<2	16.5	<10	<2	<2	<2	4.6	509.0	<1	<5	3.8	<5	7.9	<2
206394	5/30/05	3.0	<30	99.0	<2	642.0	<1	<2	<2	3.4	20.9	<10	<2	<2	<2	13.3	1107.0	1.7	<5	4.3	<5	23.1	<2
165085	7/15/05	1.0	<30	62.6	<2	<50	<1	<2	<2	<2	17.0	<10	<2	<2	<2	1.3	285.0	<1	<5	2.5	<5	10.5	<2
220274	7/14/05	7.4	37.6	24.5	<2	77.0	<1	<2	<2	2.3	16.2	<10	<2	<2	<2	3.5	389.0	<1	<5	7.5	<5	12.1	<2
220272	7/15/05	2.4	<30	72.5	<2		<1	<2	<2	<2	16.0	<10	<2	<2	<2	7.5	676.0	<1	<5	4.2	<5	28.3	<2
58685	7/15/05	5.3	31.3	21.4	<2	<50	<1	<2	<2	4.0	9.6	<10	<2	<2	<2	1.6	247.0	<1	<5	4.5	<5	92.7	<2
58712	7/14/05	4.0	77.7	86.0	<2	<500	<1	<2	<2	13.8	15.3	13.1	<2	6.3	<2	6.1	339.0	<1	<5	11.0	<5	10.5	<2
165017	7/19/05	1.9	90.4	45.4	<2	<50	<1	<2	<2	22.5	10.6	<10	<2	4.5	<2	<1	242.0	<1	<25	0.0	<25	9.7	<2
65071	7/19/05	2.7	<30	69.5	<2	<50	<1	<2	<2	2.1	22.6	<10	<2	<2	<2	<1	298.0	<1	<5	3.3	<5	<2	<2
61051	7/20/05	2.0	<30	61.6	<2	<50	<1	<2	<2	29.7	29.0	<10	3.4	<2	<2	<1	329.0	<1	<5	4.0	<5	19.3	<2
61055	7/19/05	2.1	<30	54.1	<2	<50	<1	<2	<2	<2	29.1	<10	<2	<2	<2	<1	295.0	<1	<5	3.4	<5	2.6	<2
62802	7/19/05	1.6	<30	29.1	<2	<50	<1	<2	2.1	8.5	10.2	<10	<2	<2	<2	2.0	226.0	<1	<20	2.2	<5	2.4	<2
62779	7/19/05	17.1	59.2	33.8	<2	<50	<1	<2	<2	<2	47.1	<10	<2	<2	<2	<1	314.0	<1	<5	6.5	<5	7.4	<2
58737	7/19/05	1.3	<30	4.0	<2	<50	<1	<2	<2	8.8	12.4	<10	<2	2.2	<2	<1	329.0	<1	<5	13.5	7.4	2.0	<2
134497	7/19/05	0.0	32.0	21.6	<2	<100	<1	<2	<2	<2	12.4	<10	<2	2.2	<2	3.1	333.0	<1	<5	8.4	<5	2.9	<2
220386	7/22/05	1.8	32.3	25.3	<2	178.0	<1	<2	<2	<2	20.0	<10	<2	<2	<2	7.1	503.0	<1	<5	7.3	<5	<2	<2
153703	7/22/05	1.8	<30	52.8	<2	83.0	<1	<2	<2	6.9	15.3	<10	<2	<2	<2	3.0	391.0	<1	<5	7.5	<5	2.9	<2
182549	7/22/05	1.1	69.8	43.5	<2	<50	<1	<2	<2	<2	16.6	10.6	<2	<2	<2	1.1	425.0	<1	<5	10.3	<5	14.5	<2
60800	7/22/05	1.8	62.7	51.0	<2	<50	<1	<2	<2	<2	18.2	18.4	<2	<2	<2	<1	494.0	<1	<5	20.1	<5	<2	<2
134635	7/29/05	2.1	90.4	59.6	<2	<50	<1	<2	<2	<2	18.9	<10	<2	<2	<2	1.4	272.0	<1	<5	2.6	<5	8.4	<2
130936	7/29/05	1.8	77.4	71.5	<2	<50	<1	<2	<2	3.0	8.0	<10	<2	<2	<2	<1	212.0	<1	<5	1.8	<5	<2	<2
64880	7/29/05	2.7	59.2	48.9	<2	<50	<1	<2	<2	18.4	10.3	<10	<2	<2	<2	2.4	201.0	<1	<5	2.6	<5	16.5	<2
177845	8/1/05	1.9	<30	14.5	<2	<50	<1	<2	<2	<2	18.6	<10	<2	<2	<2	2.4	201.0	<1	<5	2.6	<5	16.5	<2
61619	8/1/05	1.7	<30	49.5	<2	<50	<1	<2	<2	22.0	16.5	<10	<2	<2	<2	4.2	327.0	<1	<5	4.6	<5	89.2	<2
177799	8/2/05	11.4	315.0	15.9	<2	<50	<1	<2	<2	<2	85.8	<10	<2	<2	<2	2.8	708.0	<1	<5	2.2	<5	19.3	<2
Maximum		17.1	315.0	184.0	<2	642.0	<1	<2	3.2	44.7	85.8	18.4	3.4	6.3	<2	13.3	1107.0	1.7	<5	29.1	7.4	522.0	<2
Minimum		0.0	31.3	4.0	<2	77.0	<1	<2	2.1	2.1	6.4	10.6	3.3	2.2	<2	1.0	201.0	1.1	<5	0.0	6.1	2.0	<2
Median		1.9	69.9	48.9	<2	143.5	<1	<2	2.2	6.9	17.0	11.9	3.4	3.6	<2	2.9	347.0	1.4	<5	4.7	6.7	12.1	<2

Results and Discussion

As shown on figures 4 and 5 and in Table 2, out of 28 PPCP analytes sampled from 38 sites, only 6 were not detected in ground water. Detection frequencies, concentrations, and locations of the PPCPs in ground-water samples are shown in figures 4, 5, and 6, respectively. The most frequently detected PPCPs are sulfamethoxazole (SMX), atrazine, carbamazepine, dilantin, and diclofenac with detection frequencies of 78-, 41-, 31-, 24-, and 18 percent, respectively. Concentrations of SMX range from no detection (ND) to 490 ηg/L. Maximum concentrations of atrazine, carbamazepine, dilantin, and diclofenac are 130 ηg/L, 420 ηg/L, 22ηg/L, and 46 ηg/L respectively. Table 2 also shows that the occurrence and level of PPCP seems to have little or no correlation to the producing aquifer for each sampled well.

The locations of sites with samples containing SMX, atrazine and types of wastewater discharges in the Helena valley mapped on figure 7 indicate that although point-sources of wastewater discharges (municipal, storm water, industrial and a concentrated animal feeding operation) occur within the valley, onsite wastewater discharge appears to dominate water-quality samples. As used on figure 7, the definitions of high and moderate density are greater

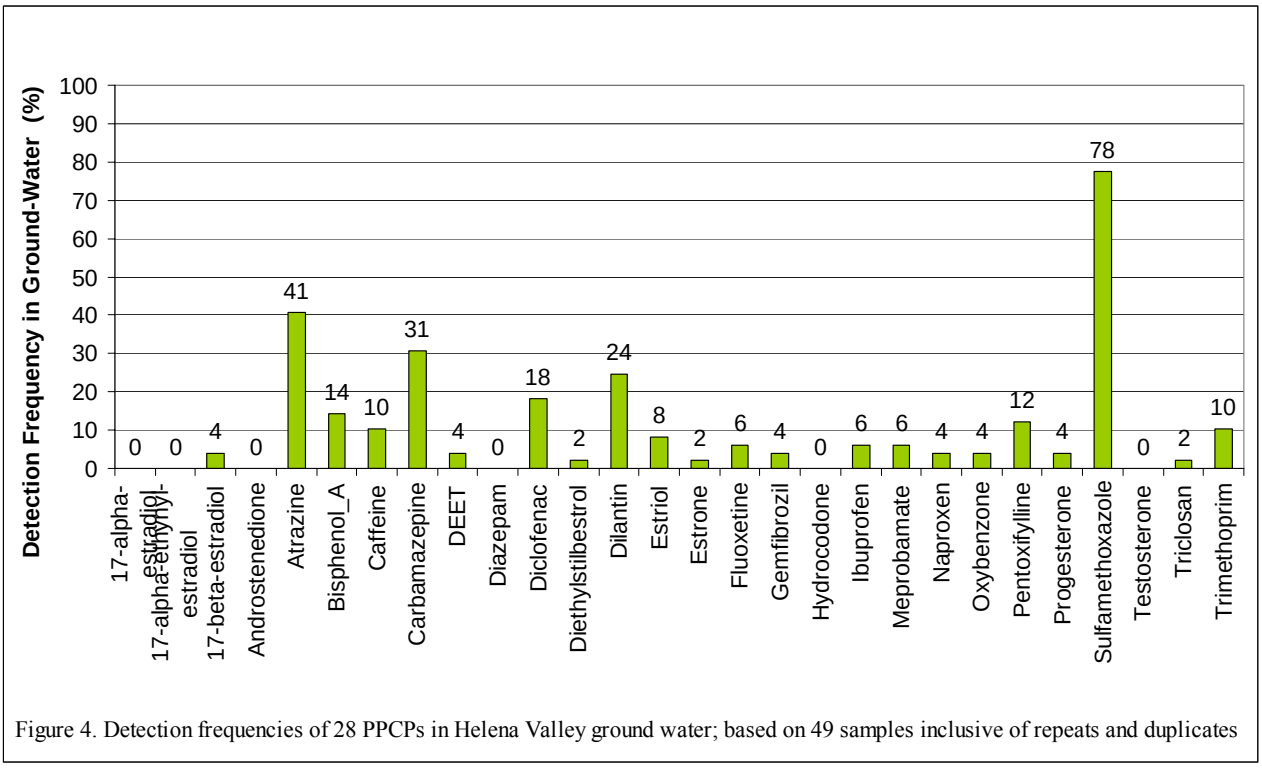

Figure 4. Detection frequencies of 28 PPCPs in Helena Valley ground water; based on 49 samples inclusive of repeats and duplicates

Table 2. Pharmaceuticals, personal care products and endrocrine disrupting compounds in ground-water samples from the Helena Valley, ng/L.

GWIC ID	Aquifer*	Date Sampled	Lab Code	MRL=2.0 Hydrocodone	MRL=1.0 Trimethoprim	MRL=5.0 Caffeine	MRL=1.0 Pentoxifylline	MRL =1.0 Fluoxetine	MRL=5.0 Meprobamate	MRL= 0.5 Sulfamethoxazole	MRL=0.5 Carbamazepine	MRL=2.0 DEET	MRL=0.5 Atrazine	MRL=2.0 Testosterone	MRL=0.5 Diazepam	MRL=1.0 Androstenedione	MRL=0.5 Progesterone	MRL=2.0 Oxybenzone	MRL=0.5 Naproxen	MRL=0.5 Gemfibrozil	MRL=10.0 Ibuprofen	MRL=2.0 Diclofenac	MRL=1.0 Dilantin	MRL=2.0 Estriol	MRL=10.0 Bisphenol_A	MRL=2.0 17-beta-estradiol	MRL=0.5 17-alpha-estradiol	MRL=1.0 Estrone	MRL=5.0 Triclosan	MRL=2.0 17-alpha-ethynyl-estradiol	MRL=0.5 Diethylstilbestrol
60800	vf	04/26/05	K0500046-005	NA	ND	ND	ND	ND	ND	34.0	80.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	23[B]	23.0	5.7	ND	ND	ND	ND	ND	ND	ND	ND
		11/01/05	K0505535-033	ND	ND	ND	ND	ND	ND	6.1	39.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	2.5	ND	ND	ND	ND	ND	ND	ND	ND
177845	Kg	11/01/05	K0505535-024	ND	ND	11.0	ND	ND	ND	1.5	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
165017	vf	11/01/05	K0505535-007	ND	ND	8.2	ND	ND	ND	15.0	4.3	ND	0.5	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
64826	vf	11/01/05	K0505535-031	ND	ND	ND	ND	ND	ND	1.8	ND	ND	0.9	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	1.2	ND	ND	ND	ND	ND	ND	ND
65388	vf	11/01/05	K0505535-008	ND	1.1	14.0	ND	ND	ND	490.0	170.0	ND	0.6	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
60987	vf	04/26/05	K0500046-003	NA	ND	ND	1.1	ND	ND	ND	ND	ND	0.5	ND	ND	ND	ND	ND	ND	ND	ND	24[B]	15.0	1.5	2.5	ND	ND	ND	1.0	ND	ND	ND
		11/01/05	K0505535-036	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		04/26/05	K0500046-004	NA	ND	ND	34.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	22[B]	15.0	ND	3.0	ND	ND	ND	ND	ND	ND	ND	ND
153703	vf	11/01/05	K0505535-015	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
65071	vf	11/02/05	K0505535-003	ND	ND	ND	ND	ND	ND	95.0	ND	ND	0.8	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
186800	vf	11/08/05	K0505535-039	ND	ND	ND	ND	ND	ND	2.4	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
194850	Ys	11/01/05	K0505535-005	ND	ND	ND	ND	ND	ND	1.6	1.6	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
62369	Kg	11/01/05	K0505535-021	ND	ND	ND	ND	ND	ND	61.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	2.2	ND	ND	ND	ND	ND	ND	ND	ND
62575	vf	11/02/05	K0505535-019	ND	ND	ND	ND	ND	ND	0.6	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
62570	vf	04/27/05	K0500046-002	NA	ND	ND	5.1	1.1	7.1	110.0	5.5	ND	130.0	ND	ND	ND	ND	4.1	ND	ND[I]	78[B]	46.0	ND	6.4	470.0	ND	ND	ND	ND	ND	0.6
		11/02/05	K0505535-017	ND	3.1	8.8	5.0	21.0	5.1	73.0	5.6	2.2	68.0	ND	ND	ND	0.6	ND	ND	ND	ND	ND	2.1	ND	ND	ND	ND	ND	ND	ND	ND	ND
		11/02/05	K0505535-018	ND	2.6	21.0	1.6	ND	ND	62.0	6.0	2.4	78.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	1.9	ND	ND	ND	ND	ND	ND	ND	ND
62597	vf	11/08/05	K0505535-037	ND	ND	ND	ND	ND	ND	46.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
58712	Ovt	06/07/05	K0500969-002	NA	ND	ND	ND	ND	ND	ND	ND	ND	1.2	ND	ND	ND	ND	ND	0.7	ND[I]	92.0	41.0	ND	ND	21.0	ND	ND	ND	ND	ND	ND	ND
		06/07/05	K0500969-002	NA	ND	ND	ND	ND	ND	ND	ND	ND	0.7	ND	ND	ND	ND	ND	0.6	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		11/01/05	K0505535-029	ND	ND	ND	ND	ND	ND	3.1	ND	ND	0.7	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
170202	OGs	11/01/05	K0505535-032	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		11/01/05	K0505535-012	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
220274	Dtj	06/07/05	K0500969-001	NA	ND	ND	ND	ND	ND	3.2	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	20.0	16.0	1.6	ND	14.0	ND	ND	ND	ND	ND	ND
		11/01/05	K0505535-023	ND	ND	ND	ND	ND	ND	4.6	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
64880	vf	11/01/05	K0505535-009	ND	ND	ND	ND	ND	ND	5.7	1.4	ND	1.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
165085	vf	11/01/05	K0505535-013	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	140.0	ND	ND	ND	ND	ND
		11/01/05	K0505535-014	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	190.0	ND	ND	ND	ND	ND
137172	vf	11/01/05	K0505535-011	ND	ND	ND	ND	ND	ND	2.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
5756	vf	11/01/05	K0505535-020	ND	1.2	ND	ND	ND	ND	12.0	3.5	ND	3.5	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	2.9	ND	ND	ND	ND	ND
177799	Cc	11/01/05	K0505535-027	ND	ND	ND	ND	ND	ND	2.7	ND	ND	12.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
182549	vf	04/26/05	K0500046-001	NA	ND	ND	ND	ND	ND	2.2	ND	ND	0.7	ND	ND	ND	ND	7.5	ND	ND	13[B]	10.0	2.2	4.3	440.0	ND	ND	ND	5.5	ND	ND
		11/01/05	K0505535-016	ND	ND	ND	ND	ND	ND	1.5	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	2.5	ND	ND	ND	ND	ND
134497	Ovt	11/01/05	K0505535-026	NA	ND	ND	ND	ND	ND	13.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
62802	Yhe	11/08/05	K0505535-038	ND	ND	ND	ND	ND	ND	6.1	ND	ND	2.6	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
58685	Ovt	11/01/05	K0505535-028	ND	ND	ND	ND	ND	ND	0.6	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
206394	Ys	11/01/05	K0505535-006	ND	ND	ND	1.7	1.1	ND	340.0	82.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	21.0	ND	ND	ND	ND	ND
64806	vf	11/01/05	K0505535-030	ND	1.4	ND	ND	ND	ND	3.1	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
134632	vf	06/07/05	K0500969-003	NA	ND	ND	ND	ND	ND	1.6	ND	ND	0.7	ND	ND	ND	ND	ND	ND	ND	ND	15.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		11/02/05	K0505535-001	ND	ND	ND	ND	ND	ND	14.0	0.5	ND	0.5	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		11/02/05	K0505535-002	ND	ND	ND	ND	ND	ND	11.0	0.5	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
61051	vf	11/01/05	K0505535-035	ND	ND	ND	ND	ND	ND	11.0	ND	ND	1.3	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
58737	Kck	11/01/05	K0505535-025	ND	ND	ND	ND	ND	ND	41.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
220272	vf	06/08/05	K0500969-004	NA	ND	ND	ND	ND	ND	23.0	26.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	3.8	ND	2.9	12.0	ND	ND	ND	ND	ND	ND	ND	ND
		11/02/05	K0505535-004	ND	ND	ND	ND	ND	8.6	270.0	420.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	1.7	ND	ND	22.0	ND	ND	ND	ND	ND	ND	ND	ND
62523	vf	11/01/05	K0505535-022	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
61619	vf	11/01/05	K0505535-034	ND	ND	ND	ND	ND	ND	1.9	ND	ND	0.8	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
187850	vf	11/01/05	K0505535-010	ND	ND	ND	ND	ND	ND	20.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	7.6	ND	ND	ND	ND	ND	ND	ND	ND
Method Blank		4/26-27/05	KWG0507179-3	NA	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	0.6	ND	ND	ND	11.0	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Method Blank		11/1/-11/02/05	KWG0521724-3	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Method Blank		11/1/-11/02/06	KWG0521725-3	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND

Explanation:

[B] The analyte was found in the associated method blank at a level that is significant relative to the sample result; MRL = Method Reporting Limit, ng/L; ND = Not Detected; NA = Not Analyzed

Aquifer Designation:

vf	unconsolidated valley fill of Quarternary or Tertiary age
TOvt	Oligocene (Tertiary) volcanic rocks
TOGs	Oligocene (Tertiary) sedimentary rocks
Kg	Cretaceous intrusive rocks, mainly granitic
Kck	Upper and Lower Cretaceous rocks
Dtj	Devonian Three Forks and Jefferson Fms, dolomitic limestone
Cc	Upper and Middle Cambrian carbonate rocks
Yhe	Middle Proterozoic Helena and Empire Fms, dolomitic
Ys	Middle Proterozoic Spokane Fm

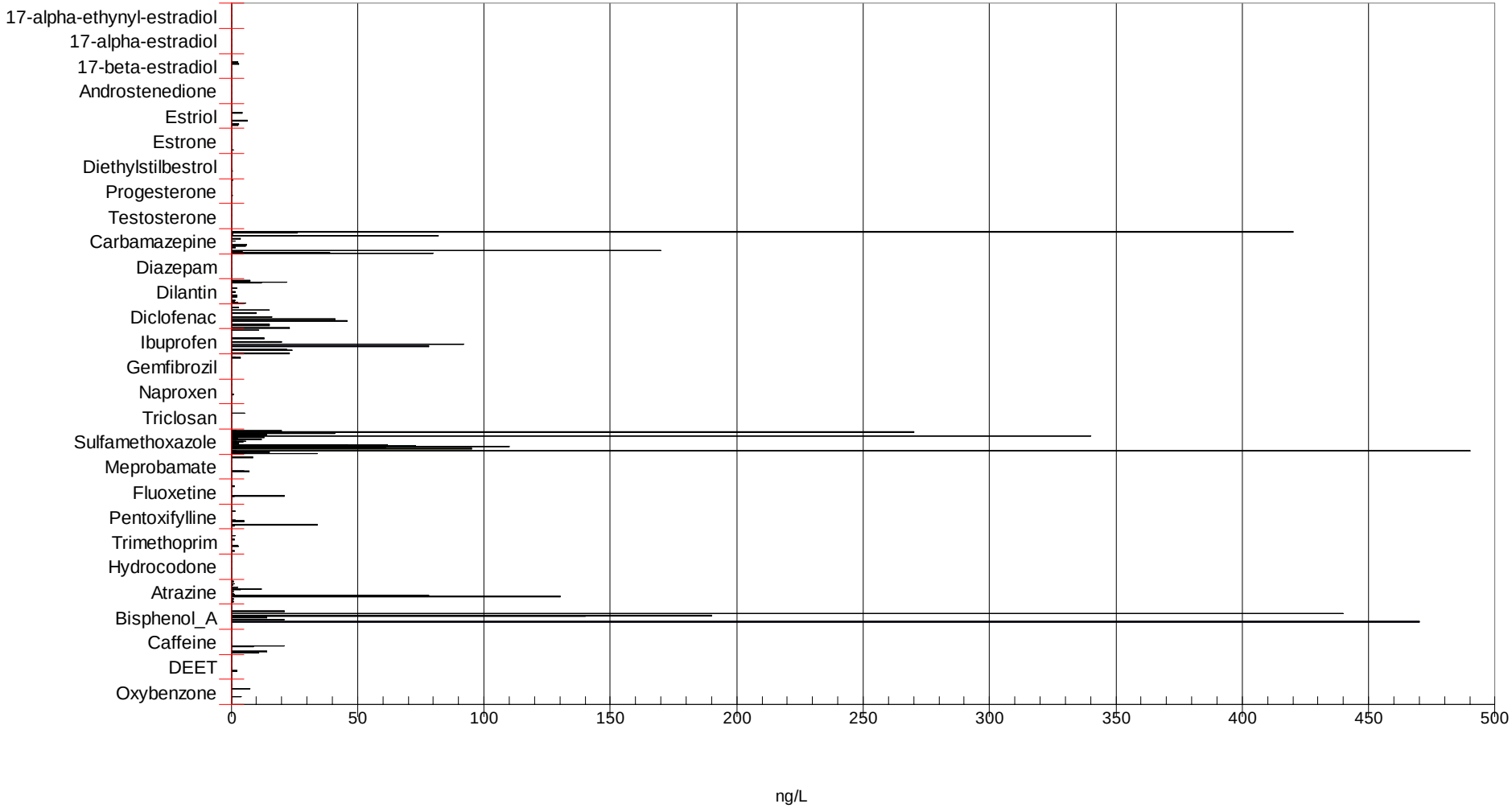

Figure 5. PPCP concentrations.

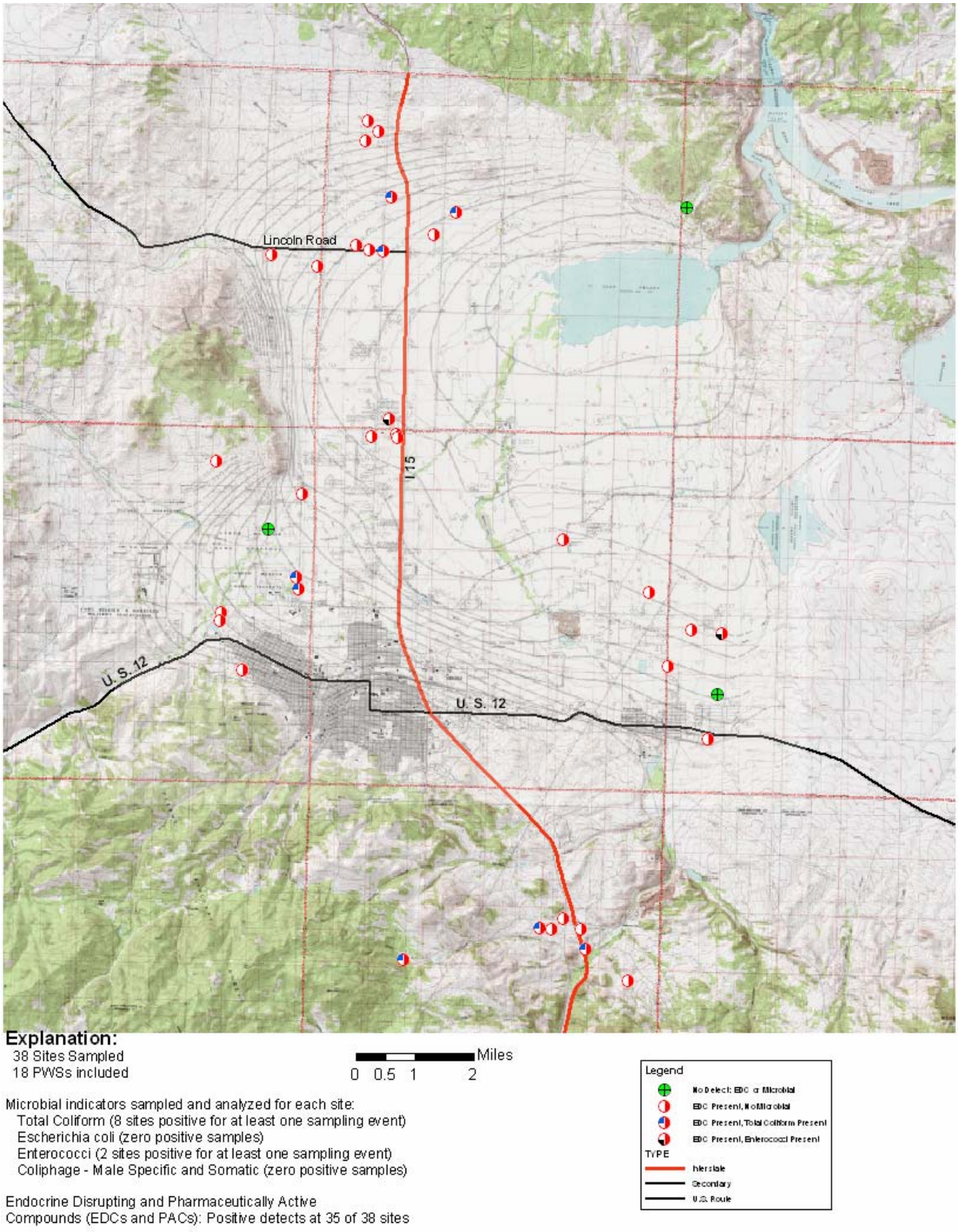

Figure 6. Locations and results of PPCPs and microbial indicators.

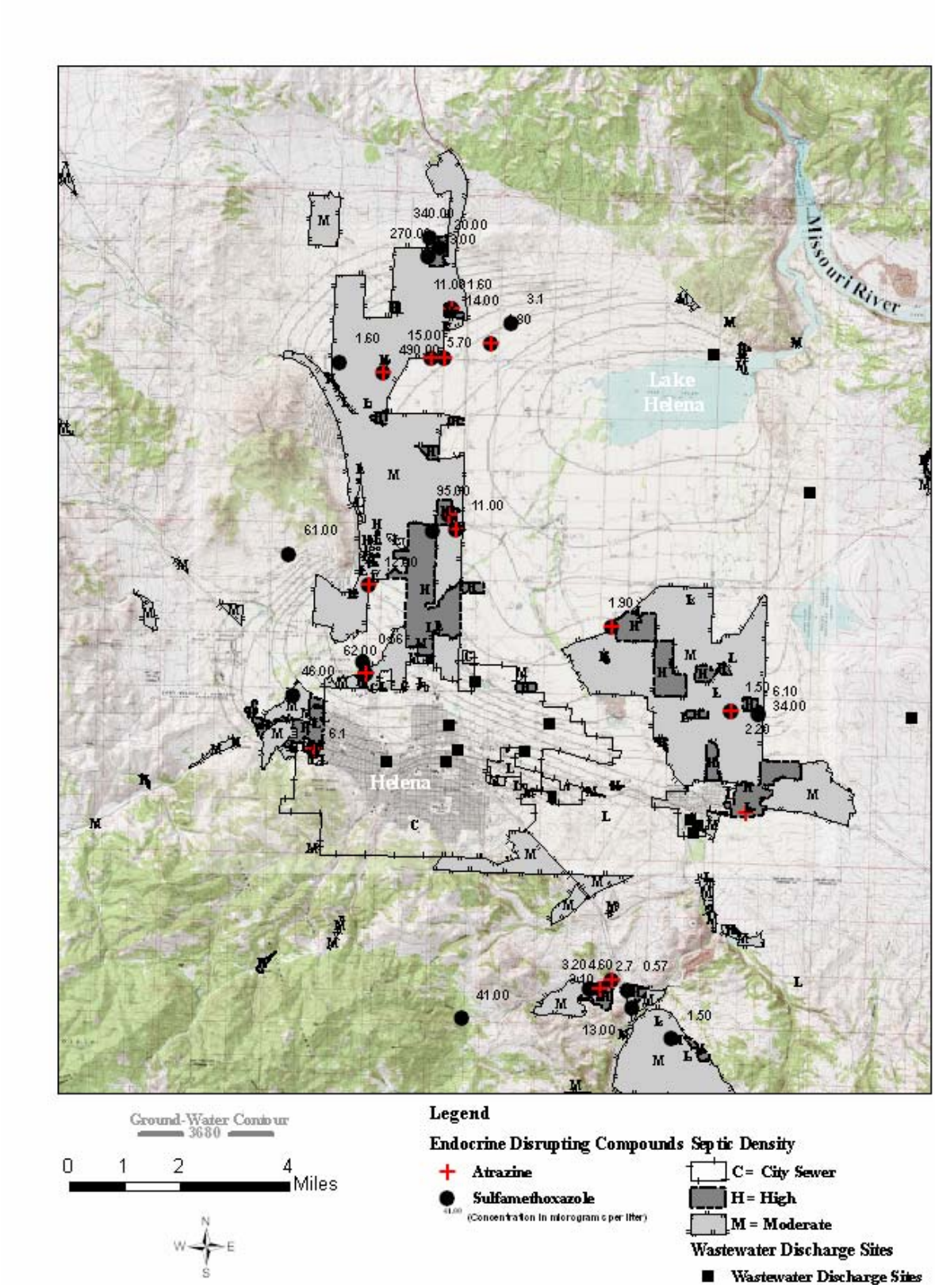

Figure 7. Wastewater discharges, SMX, and atrazine in the Helena valley.

than 300 septic systems (750 persons) per square mile and between 50 (125 persons) and 300 septic systems per square miles, respectively. Figure 8 and Table 3 correlate and compare the occurrence of chloride, nitrate, and total dissolved solids (TDS) with SMX and atrazine, the two most frequently detected PPCPs. Chloride, nitrate, and TDS are commonly used inorganic surrogate "indicators" of contamination from domestic wastewater systems. SMX showed no correlation (coefficient < 50%) to chloride, nitrate, or TDS. But atrazine demonstrated 80% correlation with chloride and almost 90% correlation with TDS, suggesting that atrazine may be occurring in domestic wastewater. Atrazine is a triazine herbicide used for the control of broadleaf and grassy weeds so its presence in domestic wastewater is not expected. SMX is undoubtedly also occurring in domestic wastewater, but it may not be conservative in its flow through septic tanks, perhaps being oxidized by chlorine or other compounds that may be found in wastewater (Dodd, 2004). Complete results of the inorganic analyses can be found at the website, http://mbmggwic.mtech.edu.

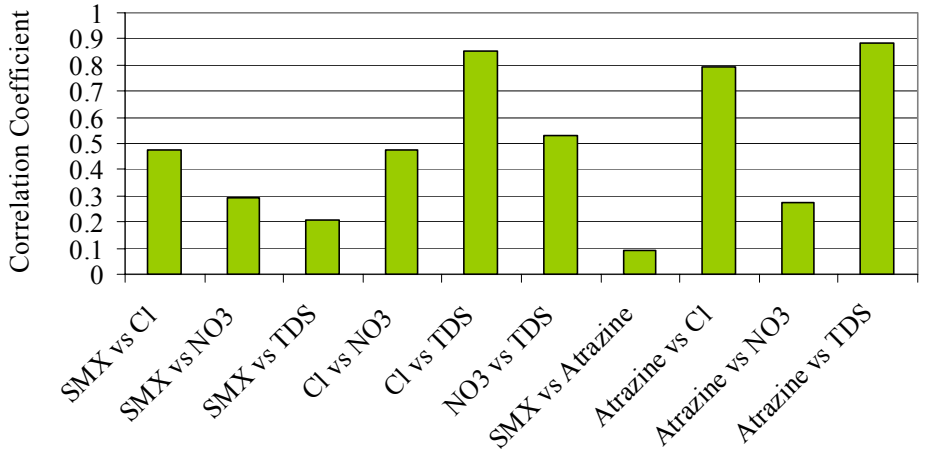

Figure 8. Correlation coefficients for SMX, atrazine, chloride, nitrate and TDS.

Table 4 presents the results of microbiological analyses of samples collected simultaneously with PPCP samples. As shown on Table 4 and on figure 6, there were no positive detections of male specific coliphage, somatic coliphage, or *E.coli* at any of the 38 sites. Yet PPCPs were detected at 32 of the 35 sites. Enterococci were present at 2 different sites at 3 different times of the year (April, July, and November). Ten positive total coliform samples were detected at 8 different sites. Although the 19 sites used by Kilbreath and others in 2004 were included in the sampling network for this project, his findings were not substantiated in this work. Sample site location within the valley (figure 6) does not appear to affect the presence or absence of PPCPs or microbial indicators of fecal contamination.

Table 3. Sulfamethoxazole (SMX), atrazine, total dissolved solids (TDS), chloride and nitrate in ground-water samples.

GWIC ID	SMX (ng/L)	Atrazine (ng/L)	TDS (mg/l)	Cl (mg/l)	NO3 (mg/l)
5756	12.00	3.50	790.2	29.5	5.4
58685	0.57	0.00	268.8	7.1	0.0
58712	3.10	1.20	511.4	35.8	10.4
58737	41.00	0.00	320.8	17.2	12.4
60800	34.00	0.00	287.0	15.6	2.3
60987	0.00	0.54	377.2	26.1	2.5
61051	11.00	1.30	288.8	13.4	2.0
61619	1.90	0.79	216.2	9.2	0.8
62369	61.00	0.00	546.5	17.6	9.5
62523	0.00	0.00	315.2	4.8	0.0
62570	110.00	130.00	1810.8	342.0	9.9
62575	0.56	0.00	543.3	17.6	9.4
62802	6.1	2.6	325.7	22.4	4.2
64806	3.1	0.00	528.7	17.1	8.6
64826	1.80	0.91	333.8	15.1	1.9
64880	5.70	0.96	390.5	19.9	8.4
65071	95.00	0.82	280.7	16.6	3.5
65388	490.00	0.59	364.0	45.2	3.9
134497	13.00	0.00	398.1	1.1	1.0
134635	14.00	0.66	271.1	17.0	0.0
137172	2.00	0.00	251.3	13.3	0.0
153703	0.00	0.00	243.5	11.4	1.3
165017	15.00	0.54	288.9	15.7	1.5
165085	0.00	0.00	199.0	4.9	0.9
170202	0.00	0.00	312.5	17.1	0.0
177799	2.7	12.00	577.5	44.8	0.5
177845	1.50	0.00	334.8	17.2	1.9
182549	2.20	0.68	241.1	12.9	0.8
187850	20.00	0.00	364.5	43.5	3.8
194850	1.60	0.00	446.3	17.6	0.7
206394	340.00	0.00	731.5	240.0	11.2
220272	270.00	0.00	425.7	96.4	4.7
220274	4.60	0.00	397.4	27.1	2.0

Table 4. Total coliform, *E.coli* , enterococcus and coliphage in ground-water samples.

GWIC ID	DPHHS Lab ID#	Sample Collection Date	Total Coliform, cfu**/100 ml	E. Coli, cfu/100 ml	Enterococci, cfu/100 ml	Coliphage, Male Specific	Coliphage, Somatic
60800	W0504-1598	04/27/05	<1	<1	1	Neg	Neg
	W0511-4702	11/02/05	<1	<1	<1	Neg	Neg
177845	W0511-4670	11/02/05	<1	<1	<1	Neg	Neg
165017	W0507-2958	07/19/05	4	<1	<1	Neg	Neg
	W0511-4686	11/02/05	<1	<1	<1	Neg	Neg
64826	W0504-1577	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4678	11/02/05	<1	<1	<1	Neg	Neg
65388	W0505-1674	05/04/05	<1	<1	<1	Neg	Neg
	W0511-4687	11/02/05	<1	<1	<1	Neg	Neg
60987	W0504-1597	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4705	11/02/05	<1	<1	<1	Neg	Neg
	W0504-1582	04/27/05	<1	<1	<1	Neg	Neg
153703	W0505-1677	05/04/05	<1	<1	<1	Neg	Neg
	W0511--4694	11/02/05	<1	<1	<1	Neg	Neg
65071	W0507-2959	07/19/05	<1	<1	2	Neg	Neg
	W0511-4682	11/02/05	<1	<1	<1	Neg	Neg
186800	W0511-4851	11/09/05	<1	<1	<1	Neg	Neg
194850	W0504-1580	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4684	11/02/05	<1	<1	<1	Neg	Neg
62369	W0505-1675	05/04/05	<1	<1	<1	Neg	Neg
	W0511-4700	11/02/05	<1	<1	<1	Neg	Neg
62575	W0505-1676	05/04/05	9	<1	<1	Neg	Neg
	W0511-4698	11/020/05	12	<1	<1	Neg	Neg
62570	W0504-1601	04/27/05	1	<1	<1	Neg	Neg
	W0511-4696	11/02/05	<1	<1	<1*	Neg	Neg
	W0511-4697	11/02/05	<1	<1	1*	Neg	Neg
62597	W0511-4849	11/09/05	<1	<1	<1	Neg	Neg
58712	W0506-2233	06/07/05	<1	<1	<1	Neg	Neg
	W0511-4675	11/02/05	<1	<1	<1	Neg	Neg
	W0511-4676	11/02/05	<1	<1	<1	Neg	Neg
170202	W0504-1575	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4679	11/01/05	<1	<1	<1	Neg	Neg
	W0511-4691	11/01/05	<1	<1	<1	Neg	Neg
220274	W0506-2234	06/07/05	<1	<1	<1	Neg	Neg
	W0511-4669	11/02/05	2	<1	<1	Neg	Neg
64880	W0504-1579	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4688	11/02/05	<1	<1	<1	Neg	Neg
165085	W0507-2957	07/19/05	<1	<1	<1	Neg	Neg
	W-511-4692	11/02/05	<1	<1	<1	Neg	Neg
	W0511-4693	11/02/05	<1	<1	<1	Neg	Neg
137172	W0504-1581	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4690	11/02/05	<1	<1	<1	Neg	Neg
160324	W0504-1599	04/27/05	<1	<1	<1	Neg	Neg
5756	W0504-1602	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4699	11/02/05	<1	<1	<1	Neg	Neg
177799	W0506-2231	06/07/05	<1	<1	<1	Neg	Neg
	W0511-4673	11/02/05	<1	<1	<1	Neg	Neg
182549	W0504-1574	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4695	11/02/05	<1	<1	<1	Neg	Neg
134497	W0507-2963	07/19/05	16	<1	<1	Neg	Neg
	W0511-4672	11/02/05	165	<1	<1	Neg	Neg
62802	W0507-2960	07/19/05	<1	<1	<1	Neg	Neg
	W0511-4850	11/09/05	<1	<1	<1	Neg	Neg
58685	W0506-2232	06/07/05	<1	<1	<1	Neg	Neg
	W0511-4674	11/02/05	<1	<1	<1	Neg	Neg
206394	W0505-1673	05/04/05	<1	<1	<1	Neg	Neg
	W-511-4685	11/02/05	<1	<1	<1	Neg	Neg
64806	W0504-1576	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4677	11/02/05	4	<1	<1	Neg	Neg
134632	W0506-2235	06/07/05	1	<1	<1	Neg	Neg
	W0511-4680	11/02/05	<1	<1	<1	Neg	Neg
	W0511-4681	11/02/05	<1	<1	<1	Neg	Neg
61051	W0507-2955	07/19/05	<1	<1	<1	Neg	Neg
	W0511-4704	11/02/05	<1	<1	<1	Neg	Neg
61055	W0507-2956	07/19/05	<1	<1	<1	Neg	Neg
58737	W0507-2962	07/19/05	4	<1	<1	Neg	Neg
	W0511-4671	11/02/05	<1	<1	<1	Neg	Neg
220272	W0506-2230	06/08/05	<1	<1	<1	Neg	Neg
	W0511-4683	11/02/05	<1	<1	<1	Neg	Neg
62779	W0507-2961	07/19/05	<1	<1	<1	Neg	Neg
62523	W0504-1603	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4701	11/02/05	<1	<1	<1	Neg	Neg
61619	W0504-1600	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4703	11/02/05	<1	<1	<1	Neg	Neg
187850	W0504-1578	04/27/05	<1	<1	<1	Neg	Neg
	W0511-4689	11/02/05	<1	<1	<1	Neg	Neg

***** Growth in Enterococcus media

****** cfu = colony forming units

The lack of positive coliphage detections in the presence of PPCPs point to its unsuitability as an indicator of fecal contamination in ground water. Whether coliphage is being attenuated in the subsurface as suggested by USGS (2005) or whether the poor reproducibility of results is attributable to laboratory or sampling error, the argument can be made that coliphage results are difficult to reproduce in the field, casting its utility as an indicator organism into question. Based on Table 4, it appears that of the five microorganisms, total coliform is the most reliable indicator of fecal contamination. Both *E.coli* and enterococci are associated with fresh sewage. A drawback to using these two indicators in regional ground-water settings is that they may die out more quickly or be less mobile in the subsurface than some waterborne pathogens, thereby rendering them even less suitable as indicator organisms than coliphage.

Conclusions

The Helena Valley in west-central Montana is experiencing rapid growth into previously un-sewered areas that rely on septic tanks and drainfields for onsite wastewater treatment and disposal. Detections of PPCPs in drinking water derived from wells is consistent with the findings of other investigators who are evaluating the occurrence of these compounds in ground-water and septic systems.

SMX and atrazine, the two most frequently detected compounds, were found at frequencies of 80% and 40% of samples, respectively. A comparison of SMX and atrazine with chloride, TDS and nitrate shows that atrazine demonstrates a strong correlation with chloride and TDS, two typical inorganic indicators of ground-water degradation from domestic wastewater. Further sampling and analysis of septic tank effluent should be conducted to verify whether atrazine is occurring in domestic wastewater.

While there are limited detections of total coliform and enterococci, PPCPs are consistently detected in the absence of both male specific and somatic coliphage as well as *E.coli*. These results present implications for the suitability of coliphage and *E.coli* as indicators of fecal contamination in ground water. Total coliform, though detected at only 8 sites, was superior to coliphage as an indicator organism in this ground-water setting.

The human and aquatic effects from chronic exposure and ingestion of PPCPs at μg/L or sub-ηg/L concentrations are mostly unknown as are potential synergistic or additive effects of exposure and ingestion of PPCP mixtures such as those found in the Helena valley. Since the ground water ultimately discharges to the Missouri River, it is hoped that effects on human health and aquatic ecosystems become better understood.

Future investigations should include fate and transport studies that evaluate the role of various aquifer properties and water-quality parameters in controlling PPCP sorption and degradation and coliphage survival and attenuation in the subsurface. PPCP fate in advanced onsite wastewater treatment systems should also be further evaluated.

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