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Role of Detection Limits in Drinking Water Regulation

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Some commentators on environmental science and policy have claimed that advances in analytical chemistry, reflected by an ability to detect contaminants at ever-decreasing concentrations, lead to regulations stricter than justified by available toxicological data. We evaluate this claim in the context of drinking water regulation, with respect to contaminants regulated under the Safe Drinking Water Act (SDWA). We examine the relationships between historical and present maximum contaminant levels and goals in the greater context of detection capability and evaluate the extent to which different aspects of the regulatory apparatus (i.e., analytical capability, cost-benefit analysis, analysis of competing risks, and available toxicological data) influence the regulatory process. Our findings do not support the claim that decreases in detection limit lead to more stringent regulation in the context of drinking water regulation in the United States. Further, based on our analysis of the National Primary Drinking Water Regulation and existing United States Environmental Protection Agency approaches to establishing the practical quantifiable level, we conclude that in the absence of changes to the underlying toxicological model, regulatory revision is unlikely.

Introduction

The phenomenon of improved detection capabilities precipitating more stringent regulations is sometimes termed "the vanishing zero effect" or "detection limit creep" (*1*) and is the subject of a recurring claim by some commentators on environmental science and policy. However, this claim does not appear to have been the subject of scholarly research; we have identified only two editorials addressing this issue in the scientific literature (*1, 2*). More commonly, the concept is addressed in research articles assessing risk in regulatory decision making (*3*) or discussed at conferences (see refs *3* and *4* for respective examples). At least one article in an industry trade journal predicts that detection limits would be the 'dominating force' of environmental regulations in the 1990s and beyond (*5*). In some cases, the articles we reviewed suggest that improved detection capability can itself motivate regulation at levels departing from available toxicological data (*1, 3*). This phenomenon has been compared to the Delaney Clause, summarizing the mind-set, "If you can detect it to that limit, you should regulate it to that limit." (*6*). Although this study is, to the best of our knowledge, the first comprehensive analysis of the role that improved detection capabilities play in drinking water regulation, it is important to note that previous research has been directed at this question from a technical perspective on a case-by-case basis; Ferguson et al. demonstrate the technical feasibility of lowering the practical quantitation limit (PQL) of arsenic, based on the detection ability afforded by a variety of commercially available technologies (*7*). Otherwise, researchers have commented tangentially that the detection limits USEPA requires are in fact below the associated health standards it sets, suggesting that, in some contexts, analytical capability is playing a decreasingly important role (*8*). Whatever the relationship to regulation, advances in analytical chemistry are a documented concern to stakeholders in environmental policy; Johns writes that it is necessary to consider the added costs of more advanced analytical procedures that would be borne by industries and small municipalities in the event that state regulators require them (*9*).

Relevant toxicological models are generally understood to be the dominant influence on environmental exposure standards, including drinking water quality criteria. However, minimum detection capability serves as the lower limit below which regulation is not possible. In this way, ability to regulate is dependent on ability to detect, and advances in analytical chemistry allow for more stringent regulations.

We evaluate the vanishing zero claim with respect to drinking water regulation through the following steps:

1. **Establishing a reregulation mechanism:** We outline a regulatory mechanism based on the relationships between analytical capability, toxicological models, and cost benefit analysis and delineate the mechanism by which increased detection ability would bring about more stringent regulations;

2. **Grouping currently regulated contaminants:** We organize a subset of relevant contaminants, as outlined by the mechanism established in ref *1*, according to relationships between final regulations, analytical capability, and toxicological goals to identify which regulated contaminants are theoretically most susceptible to reregulation on the basis of improved detection ability;

3. **Assessment of the significance of detection capability in reregulation mechanism:** We describe the ongoing regulation and reregulation assessment process at USEPA and evaluate the extent to which improved detection ability is influencing the regulatory apparatus, in terms of the delineated contaminant groups and mechanisms;

4. **Review of real past regulatory changes:** We document previous regulatory revisions against a timeline of analytical capability and establish the role analytical advances have historically played in triggering regulatory revisions; and

5. **Significance of detection capability in emerging contaminants:** We examine the process by which USEPA identifies new regulatory opportunities and assess the limitations imposed by, and overall significance of, detection ability.

To our knowledge, this study is the only policy analysis to date focusing on the mechanism by which changes are made in contaminant regulation, or the significance of analytical advances in triggering reregulation, targeted at a

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specific regulatory apparatus. This study considers drinking water regulation only in the United States, the only country whose regulatory apparatus our research has found to be the subject of documented claims of 'the vanishing zero effect' or 'detection limit creep'. Indeed, a comparison of drinking water standards for 67 chemical contaminants promulgated variously by the USEPA, the World Health Organization, and the governments of Australia and Canada show that there is much room for drinking water standards in the U.S. to 'creep' downward: only 28 of the 67 contaminants targeted by this international comparison are currently regulated by the USEPA, and of these 28 contaminants, the standard enforced by the USEPA is greater than the smallest value in the comparison by at least 1 order of magnitude for 15 of them (*10*). Augmenting the findings of this study with the remaining contaminants whose regulations are currently limited in the U.S. by detection ability (a total of 24), we find that nine of them are greater by at least an order of magnitude than the guideline value of at least one other country in the comparison.

Much of our analysis was carried out on the basis of USEPA's six-year reviews of existing drinking water standards, for which it performed studies on the technical feasibility of lowering existing regulations. These studies were carried out in 2003 and 2009 both for contaminants regulated down to the detection limit recognized by USEPA as well as for contaminants with detection levels already more sensitive than the regulation or public health goal. The supporting documentation explained USEPA's approach of tying the regulation to the detection limit in instances where the detection limit is greater than the public health goal, signaling a mechanism that may facilitate detection limit creep as described above (*11, 12*).

Background. The Safe Drinking Water Act (SDWA) empowers USEPA to regulate drinking water quality in the context of cost-benefit analysis and available treatment technology and toxicological data (*13*). It should be noted that the role of cost-benefit analysis in the many statutes administered by USEPA is not uniform: economic analysis weighing benefits against cost-related factors is specifically limited for a number of statutes under USEPA's jurisdiction (*14*). In contrast, the standards USEPA sets within the framework of the SDWA are the result of economic analysis that balances cost of compliance and expected benefits in the greater context of analytical and treatment feasibility (*13*).

The National Primary Drinking Water Regulations (NPDWR) are the end results of toxicological, technical, and economic assessment and constitute the list of legally enforceable standards promulgated under the SDWA. The NPDWR target a total of 84 water contaminants as well as three indicators. Since 1998, USEPA has published contaminant candidate lists (CCL) every five years to track potential targets for regulation under NPDWR (*15*). From the CCLs, USEPA is required to make a regulatory determination on five contaminants every five years, on the basis of the danger posed by different chemical contaminants, the frequency and extent of their occurrence in public water systems, and the potential of a regulation to protect public health (*16*).

USEPA relies on two parameters to communicate the recognized detection capabilities for each of the contaminants it regulates: the method detection limit (MDL) and the practical quantification limit (PQL). For a thorough discussion of the operational definitions of each of these parameters, the reader is referred to Gibbons's analysis (*17*). However, we summarize MDL as the lowest concentration at which the presence of a given analyte can be confirmed (differentiated from a zero concentration) with a given analytical method to 99% certainty and the PQL as the lowest concentration of an analyte that can be reliably measured and differentiated from other, nonzero concentrations. The PQL can be determined in two ways. First, by real laboratory performance, where data are available, the PQL corresponds to the lowest concentration accurately measured by 75% of USEPA regional and state laboratories (*18*). Alternatively, the PQL can be calculated by multiplying the MDL by 5 or 10, according to the uncertainty or level of conservativeness required (*18*); whereas the MDL is determined experimentally and is specific to the operator and instrument at the time of analysis, the PQL is calculated by USEPA as a measure of typical expected lab performance (*19*). USEPA therefore considers the PQL, rather than the MDL, the lowest level to which it is technically feasible to regulate. USEPA specifies the MDL required of tests performed on drinking water contaminants (*20*) but uses the PQL as a measure of regulatory feasibility. Hamilton et al. compare drinking water standards to the MDL data, but not to PQL data, as a comment on of the role of analytical capability in pesticide regulation (*8*).

The third quantity of interest for this analysis is the maximum contaminant level goals (MCLG). MCLGs are the concentrations of contaminants in drinking water that are not expected to have an adverse effect on human health (*13*). USEPA sets MCLG values based on the available evidence of carcinogenicity, according to weight of evidence categories (*21*). For known or probable human carcinogens, the MCLG is zero, because USEPA considers that no dose of carcinogenic contaminants will present zero risk, unless there is specific evidence to the contrary for a given contaminant (*22*). The fourth quantity of interest is the maximum contaminant level (MCL), which is the numerical value of the regulation USEPA sets for drinking water contaminants. The MCL must be set as close to the MCLG as feasible, taking into account cost and technical factors.

A 1996 amendment to the SDWA requires USEPA to review existing NPDWR and make revisions, where appropriate (*11*). An integral part of this process is an analytical feasibility review to identify where USEPA is technically able to revise the PQL and, in some cases, the MCL. Reviews conducted in 2003 and 2009 assessed all but three chemical contaminants on the NPDWR in terms of the feasibility of lowering their PQL. The 2003 review did not target all the contaminants on the NPDWR but rather two subsets: 1) those whose MCL is limited by analytical feasibility (MCLG < PQL = MCL) and 2) those contaminants considered by USEPA as being likely or possible targets of toxicological review determining the appropriateness of lowering the MCLG (another component of the six-year review). The 2003 review targeted a total of 40 chemical contaminants, including 22 of the 24 contaminants where MCLG < PQL = MCL, and 18 contaminants regulated less stringently than technically possible but that were likely to undergo a toxicological review of the MCLG. The 2009 review re-examined all but one of these 40 contaminants along with 27 others, including the two remaining contaminants where MCLG < PQL = MCL. The 2003 Review targeted almost all of the contaminants of immediate relevance to our analysis and presented more detailed information on improvements in analytical sensitivity and so is more relevant to our study than the 2009 Review.

Findings.

1. Establishing a Mechanism. We inferred the limiting effect of different parts of the regulatory apparatus by organizing contaminants listed in the NPDWR according to the relationships between the public health goal (MCLG), regulation (MCL), and detection capability (PQL), as illustrated in Figure 1. Figure 1 shows the two main possible cases: either the regulation equals the public health goal (Relationship 1) or the regulation is less protective than the public health goal. A regulation can be less protective than the public health goal where it is limited by detection ability

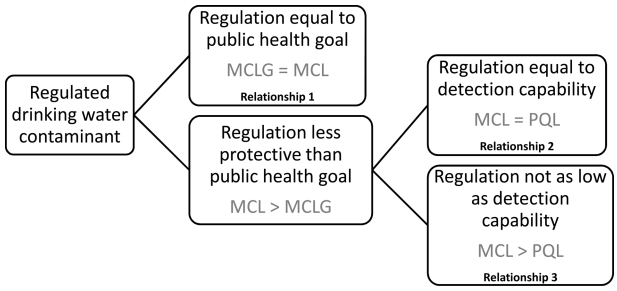

FIGURE 1. Relationships between public health goal (MCLG), regulation (MCL), and detection capability (PQL) in NPDWR contaminants.

(Relationship 2) **or** where limited by cost-benefit analysis at some point above detection capability (Relationship 3).

If the regulation is fully protective of public health (Relationship 1), it is only likely to be revised if there is a change to the underlying toxicological model, not as a result of increased detection ability, because no public health motivation exists for a stricter regulation. If limited by cost-benefit analysis (Relationship 3), improved detection ability reflected by a lowered PQL would not be immediately relevant. USEPA would already have decided that it is not economically feasible to regulate to the level technically possible. If, however, the regulation is limited by analytical capability (Relationship 2), a change to the PQL *could* precipitate a change to the regulation promulgated by USEPA. Therefore, Relationship 2 is the most relevant to our analysis as it includes the contaminants susceptible to reregulation as a result of improved detection capability.

Ferguson et al. identified all regulated drinking water contaminants where MCLG < PQL, including arsenic, the subject of their study. They used the observation that MCLG < PQL to conclude that lowered detection ability may facilitate a lowered MCL (*7*). However, the authors did not comment on the relationship between the PQL and the MCL itself: the current PQL for arsenic is lower than the MCL, meaning that the regulation is limited not by technical feasibility but by cost-benefit analysis. While the PQL may stand to be lowered, we cannot conclude that it is likely to have an impact on the regulation set by USEPA (*11*). Indeed, USEPA stated specifically that the arsenic rule protects public health to the extent that the benefits justify the costs (*23*).

Recall that USEPA's study evaluated the technical feasibility of lowering regulations for 1) those contaminants currently regulated to the limit of detection (MCL = PQL, Relationship 2) and 2) where a possible revision to the toxicological model might change the MCLG, hence perhaps the MCL. While advances in analytical capability could facilitate a lower MCL (more stringent regulation) for either group, these advances can actively influence a change in MCL only where detection capabilities are the dominant factor (Relationship 2). We previously identified Relationship 2 contaminants to be the most sensitive to reregulation on the basis of improved detection capabilities. Assuming that such reregulation occurs, the resulting relationship between the new regulation (MCL'), the new detection limit (PQL'), and the public health goal (MCLG) would imply reclassification of the contaminant under Relationship 2, or 3, as illustrated in Figure 2. The new MCL (MCL') could be set equal to the new PQL (PQL') if it is economical to do so (Relationship 2 remains). If USEPA decides it is not economical to regulate to this level, whether PQL' is higher or lower than the public health goal (MCLG), MCL' would only be regulated to that cost-effective level (Relationship 3 takes over). If PQL' is lower than or equal to the public health goal **and** it is economical to regulate to that level, MCL' will only be set as low as the public health goal, as there would be no

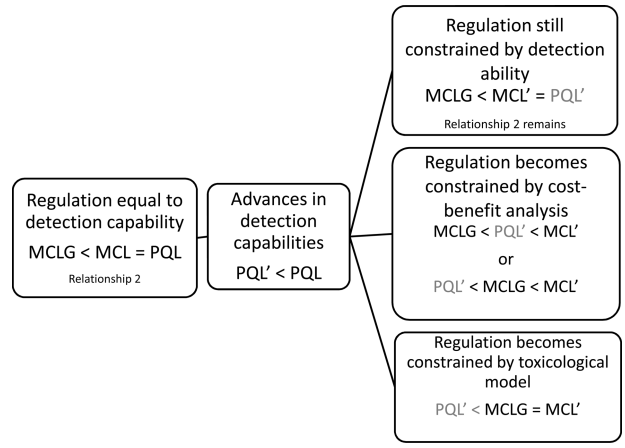

FIGURE 2. The three possible outcomes of a regulation revision triggered by advances in detection abilities.

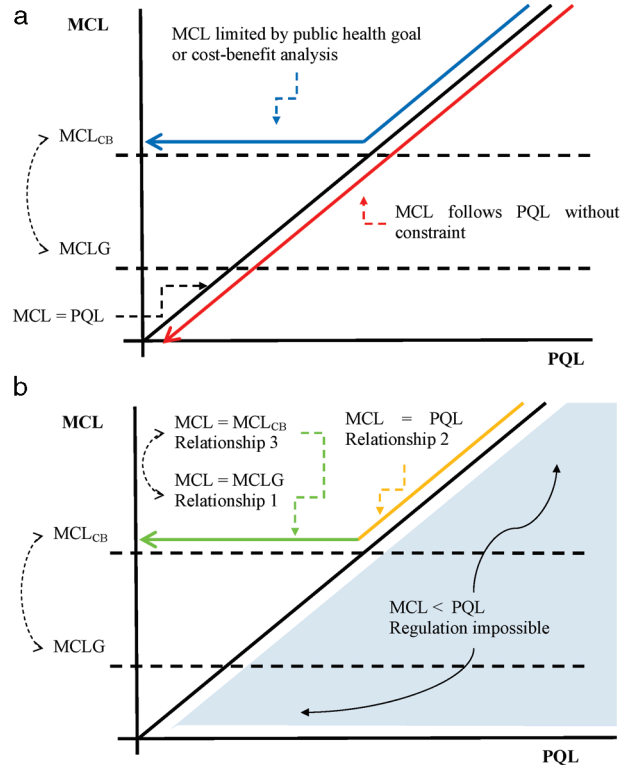

FIGURE 3. a: Two competing conceptions of how regulations follow detection ability. b: Two competing conceptions of how regulations follow detection ability.

toxicological need to regulate to a lower level (Relationship 1 takes over).

We should note that many of the contaminants currently classified under Relationship 2 are carcinogenic compounds, with an MCLG = 0. For these contaminants, it would not be possible for Relationship 1 to take over, since it is impossible to detect and therefore regulate to zero.

For all contaminants, detection capability (PQL), cost-benefit analysis, and toxicological knowledge (MCLG) all represent some value below which the MCL will not be set.

Figure 3 maps two conceptions of how drinking water regulations (MCL) change in response to improved detection capability (lower PQL) for contaminants whose regulatory levels are constrained by detection capability (Relationship 2). The blue line illustrates the mechanism we have outlined, whereby the MCL may be revised to follow the PQL until it reaches the strictest MCL justified by cost-benefit analysis, which we have represented in the figure as MCL_{CB} (Relation-

ship 3 takes over), or until it reaches the public health goal (MCLG) beyond which there would be no need to regulate (Relationship 1 takes over). This contrasts with the red line that represents unconstrained regulation along with the detection capabilities at levels closer and closer to zero as might be suggested by the 'vanishing zero' effect. Depending on the contaminant, MCL_{CB} may be greater, less than, or equal to the MCLG (the variable relationship between MCL_{CB} and MCLG is represented in Figure 3a,b by double-headed arrows). For most carcinogenic contaminants, the MCLG is equal to zero (in the absence of evidence that indicates the existence of a safe nonzero concentration). For contaminants that are the subject of competing risk analysis, such as between risk of illness from waterborne pathogens and cancer risk from disinfection byproducts, the MCL is calculated in consideration of these competing risks.

Figure 3b reproduces the graph of the mechanism we outlined above, identifying where Relationships 1, 2, and 3 fit in. For a given contaminant, the MCL_{CB} may be greater or lower than the MCLG. If $MCL_{CB} > MCLG$, as depicted in Figure 3a,b, we would expect cost-benefit analysis to limit further regulation (Relationship 3 takes over) before the public health goal. If that relationship is reversed ($MCLG > MCL_{CB}$), as indicated by the hashed arrows, then we would expect the public health goal to limit further regulation (Relationship 1 takes over) before cost-benefit analysis.

2. Grouping Currently Regulated Contaminants. In the 2003 and 2009 analytical feasibility reviews, USEPA identified a total of 24 contaminants where the MCL is currently tied to the PQL, representing a regulatory mechanism that directly connects detection capability with drinking water standard (*11, 12*). Generally speaking, these are the known or probable human carcinogens to which USEPA considers there to be no safe exposure. According to the regulatory mechanism outlined above, the MCLs of these 24 are not limited by cost-benefit analysis but by current detection abilities. This is also the case for two contaminants to which USEPA *does* consider there to be a safe nonzero exposure, that is, for which $MCLG \neq 0$ (thallium and 1,1,2-trichloroethane). The remaining contaminants regulated to a value higher (less stringent) than the value possible with current analytical methods are regulated to the limit deemed necessary by available toxicological data. Thus, improvements in detection ability (decreases in PQL) would not necessarily lead to more stringent regulation. Rather, cost-benefit analysis could then prevent further strengthening of the regulation. A similar mechanism could facilitate the reregulation to a higher (less stringent) level of contaminants currently regulated to their MCLG if found not to be accurately represented by a linear dose−response profile (i.e., whose MCLG is re-evaluated above the PQL as the result of a toxicological or health review).

However, for contaminants where the MCL is currently tied to the PQL and for which improved detection capability facilitates a lower PQL, there is room for reregulation on the basis of improved analytical methods.

3. Assessment of the Significance of Detection Capability in Reregulation Mechanism. Since the 2003 analytical feasibility review aimed to determine whether data on laboratory performance can be used to reassess the PQL of different contaminants (hence creating the possibility of a reassessment of the MCL), we assessed correlation between an overall improvement of detection capabilities and a call to reassess the PQL for two subgroups of contaminants: $MCLG < PQL = MCL$ (Relationship 2) and $PQL < MCL$, where the MCLG might be subject to revision (a subset of Relationships 1 or 3) (*11*). Therefore, USEPA assessed the practical feasibility of lowering the PQL of a large group of contaminants, some of which are classified under Relationship 2. Recall that this is the group for which the PQL is most relevant, and for which a revised PQL could logically lead to a revised MCL if cost-benefit analysis does not stop this from happening. The 2009 analytical feasibility review examined the same contaminants, plus two more whose regulation is contingent on detection ability (Relationship 2), and most of the remaining chemical contaminants not likely to undergo an MCLG revision and therefore not targeted by the 2003 review.

We organized the 67 chemical contaminants targeted by the 2003 and 2009 analytical feasibility reviews according to the relationship between overall improvement in the sensitivity of methods since promulgation and the conclusion that a PQL re-evaluation is in order (*11, 12*). This categorization was facilitated for contaminants targeted by the 2003 review by the detailed information available on the improvement of analytical methods since time of promulgation. For the 27 contaminants targeted by the 2009 review and not targeted by the 2003 review, only improvements in analytical sensitivity having occurred between 2000 and 2007 were considered in the supporting documentation. It was therefore not possible to perform a parallel classification for these contaminants. Readers interested in the classification of each contaminant are referred to Table S1 in the Supporting Information. For the 40 contaminants targeted by the 2003 review, we compared the distribution of conclusions as to the appropriateness of a PQL readjustment between two main groups of contaminants: those whose regulations are currently limited by detection capability (Relationship 2) and those currently limited by toxicological model or cost-benefit analysis (Relationships 1 or 3). For each of these two groups, we consider the four permutations of two yes/no possibilities whether there has been an overall improvement in detection abilities since promulgation by USEPA, and whether USEPA concluded that a PQL reassessment may be appropriate. The distribution of contaminants within these four cases for the different Relationships will be discussed below. With these two groups and four cases, we can assess the correlation between advances in analytical capabilities and the PQL reassessment conclusion both for the group whose MCLs were identified as potentially susceptible to the influence of improved detection abilities (Relationship 2) and the group whose MCLs should be a function only of MCLG and cost-benefit analysis (Relationship 1 or 3, respectively). Contaminants targeted by the 2003 analytical feasibility study are about evenly distributed between Relationship 2 (total of 22) and Relationships 1 or 3 (total of 18). Also, the distribution of contaminants among the four cases is roughly equal between Relationships 2 and Relationships 1 or 3. For both groups of contaminants, USEPA's conclusion that a PQL re-evaluation is likely necessary was more common for those contaminants where no real improvement in sensitivity had occurred since promulgation: for Relationship 2 (MCL controlled by PQL), 15 contaminants were identified as candidates for a PQL revision. Out of these, 12 had had no overall improvement in the sensitivity of methods, while only three had had such an improvement. Similarly, 10 contaminants in the Relationship 1 or 3 group were identified as PQL re-evaluation candidates, with 8 having seen no improvement in detection capabilities. Examining specifically those contaminants having seen an improvement in detection ability, we see that for Relationship 2, three were identified as PQL re-evaluation candidates, and two were not. Similarly, under Relationship 1 or 3, two contaminants having seen improvements in detection abilities were identified as PQL re-evaluation candidates and two were not. Improvement in detection capability is therefore not a useful indicator for predictions of PQL reassessment. An identical analysis based on the 2009 review was limited by the fact that only information on improvements in analytical sensitivity between 2000 and 2007 was available. For these contaminants, we also found that improvement in detection ability was not

a useful indicator for predictions of PQL reassessment, but our sample of contaminants having undergone improvements in analytical ability was likely underrepresented. These comparisons are tabulated in Table S2.

USEPA identified a reason why it has so far been unsuccessful at establishing lower PQLs for contaminants targeted by the Six-Year Reviews (*11, 12*). USEPA determines the PQL by sending samples spiked with different concentrations of different contaminants to real laboratories and plotting the percentage of laboratories 'passing' vs concentration tested. Laboratories that pass are those that accurately quantify the spike sample within specified acceptance limits. USEPA defines PQL as the concentration at which 75% of laboratories successfully detect the concentration in the spike sample. USEPA refers to these as its 'Water Studies'. Where laboratory performance testing yielded consistently high results, determining the concentration at which 75% of laboratories would pass was not possible, limiting USEPA's ability to make an assessment of what might be a more accurate PQL. The analytical feasibility support document relied on real laboratory performance data to evaluate the possibility of revising the PQL for different contaminants. In several instances, the water studies tested the detection capabilities of laboratories at concentrations higher than the concentrations of interest and thus were of limited use. This could represent a significant practical barrier to the mechanism connecting advances in detection capabilities with PQL revisions. If the Water Study data USEPA used to reassess PQLs reflected performance at concentrations closer to the real detection limits, there may have been greater basis for PQL re-evaluation.

4. Review of Real Past Regulatory Changes. We compiled the previous regulatory revisions made to the NPDWR and assessed the role of detection capability in facilitating or precipitating the change for each regulatory revision. A total of 15 drinking water standards have been revised since they were first promulgated by USEPA or its predecessors (*24*). Out of these, six have been lowered while seven have been raised. Additionally, the nickel regulation was remanded, and the lead regulation was changed from an MCL to a required treatment technique (in addition to other requirements of the broader Lead and Copper Rule). Out of the 15 contaminants whose numerical standards were changed (including consideration of standards that predate the SDWA), seven have actually increased (become less stringent) since originally promulgated, while one other has been remanded. The arsenic standard was lowered, not to the PQL, but rather, to the MCL_{CB}, as discussed earlier; this is also the case for cadmium, methoxychlor, and 2,4-D. The MCL for lead was replaced with a required treatment technique. Available data on historical detection capabilities for these 12 contaminants suggest that regulation to a lower value is possible but that incomplete toxicological data or economic realities have resulted in a higher value. For the remaining two (lindane and toxaphene), a thorough search through regulatory support documents identified no evidence explicitly tying the changes to advances in detection capabilities, although we notice that their MCLs are both equal to their PQLs. Table S3, in the Supporting Information, presents a summary of previous regulatory revisions with comments on historical detection capabilities.

5. Significance of Detection Capability in Emerging Contaminants. Turning our attention from revisions to existing standards, we can examine the role detection ability plays in the implementation of new regulations.

USEPA uses frequency of detections and concentrations detected to make a judgment on whether regulation would protect public health for regulatory determinations (*25*). We discussed the practice of regulating to the detection limit when this is the lowest level obtainable. However, if a candidate contaminant is only present in drinking water samples below the detection limit, a regulation would have limited potential to protect public health, likely precluding promulgation of an MCL. Advances in detection abilities could change this assessment. For potential targets of regulation, common occurrence of nondetects, or very low median concentrations of contaminants suggest detection ability might play a crucial role in the regulatory process. Contaminants not regulated today may be regulated when we become able to detect them.

We reviewed the screening support document used to filter potential contaminants on the third contaminant candidate list (CCL3) to assess the significance of limitations attributable to detection capabilities. To assemble a preliminary CCL, USEPA starts by assigning the contaminants to "toxicity categories" 1 (most toxic) to 5 (least toxic), on the basis of toxicological data and weight of evidence narratives (*25*). It then considers the median concentrations found of the contaminants in representative finished drinking water samples. The more toxic a contaminant, the lower the median concentration detected needs to be before it is considered a potential regulatory target. Out of the 107 chemicals arrayed in terms of toxicity category and median concentration, only one was in the lowest concentration range (0 to <0.1 μg), although, this chemical is in toxicity category 1 (most toxic). The bulk of potentially regulated contaminants are present in concentrations substantially higher than the detection limit. Thus, USEPA is already able to promulgate MCLs that would have a measurable effect on the concentrations found in finished drinking water. We cannot therefore conclude that detection capabilities are preventing promulgation of new drinking water regulations.

Future improved detection capabilities are unlikely to lead to regulation of currently unregulated contaminants. Where detection ability prevents regulation of contaminants down to the level fully protective of public health or down to the lowest level that would be cost-effective, USEPA would presumably resort to its practice of setting the MCL to the PQL (Relationship 2). Candidate contaminants are as constrained by detection ability as the large number of currently regulated contaminants already classified under Relationship 2.

Discussion

We outlined a mechanism by which improved detection capabilities would lead to lower regulations but found little evidence showing that this mechanism has had or will have a significant effect on the overall trend of regulation revisions as compared to the other factors USEPA considers in its regulatory determinations.

Drinking water contaminants can be grouped according to the relationship between the associated public health goal (MCLG), recognized detection capability (PQL), and regulatory limit (MCL) in order to identify which are most susceptible to reregulation on the basis of improved detection, which are limited by cost-benefit analysis, and which are limited by the public health goal. Drinking water contaminants whose regulations are now equal to the recognized detection capability (MCL = PQL) are the most vulnerable to reregulation on the basis of the mechanism we identified, but there are several reasons this does not tend to occur.

USEPA is required to demonstrate that the costs of regulation will be justified by the benefits of new or strengthened regulation; this severely limits the likelihood of regulations departing from justifiable levels. Additionally, the mechanism we identified by which lower MDLs would lead to lower recognized PQLs and potentially stricter MCLs is short-circuited by the lack of widespread implementation

of more sensitive methods at individual laboratories. Laboratory freedom to choose among approved methods and their predominant tendency not to use the most sensitive available seems to suggest that laboratory performance falls short of what is technically possible.

Both laboratory underperformance, in terms of adopting more sensitive methods, and laboratory overperformance, with respect to the Water Studies, limit USEPA's ability to take a position on the feasibility of lowering PQLs and hence possibly lowering MCLs. However, it is hard to predict how the conclusions regarding PQL adjustment feasibility would change as a function of improved assessment methods on the part of USEPA.

Indeed, the difficulties associated with reregulating as a function of improved detection capabilities and/or assessing the real improvement of detection capabilities over time is echoed by the lack of precedent for this kind of revision.

Within the data set we studied, we found no historical evidence for the claim that improvements in analytical capability alone lead to decreases in regulatory limits. Although we identify a mechanism making this possible, we note that USEPA's methods for enforcing laboratory standards and determining the PQL seriously limit the extent to which this would occur. As a consequence, there is good reason to believe that reductions in regulatory levels of contaminants will continue to be driven by improvements in toxicological understanding of contaminant effect or by improvements in economic feasibility of contaminant removal.

We further conclude that the process by which new regulatory opportunities are explored is not limited by current detection capability, based on the high median concentrations of the bulk of the universe of drinking water contaminants relative to their limits of detection. USEPA is technically able to pass new regulations that are at least as protective as existing regulations with respect to the constraints imposed by limits of detection. Although we do not find the vanishing zero concept within the regulatory apparatus per se, we must note that increased detection capability undeniably facilitates regulatory debate of increasing numbers of contaminants. This distinction is well illustrated by perchlorate regulation efforts: an improved ability to detect contaminants triggered calls to regulate, but ongoing cost-benefit and other analysis has so far stalled those efforts. When regulation results from this circuitous but more plausible version of vanishing zero, this indicates that cost-benefit analysis has identified a meaningful opportunity for protection of public health. Although the concentrations of contaminants are venturing into the imperceptible, we can be confident the anticipated benefits would not be.

Finally, this study only evaluates the claim that improved detection limits in and of themselves can lead to more stringent regulation. In the context of environmentally regulated industry, the vanishing zero claim would be more directly linked to the regulatory apparatus underlying the Clean Water Act or the Clean Air Act, which impose more hotly contested emissions controls.

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Supporting Information Available

Table S1, contaminants sorted by improvement in method sensitivity, PQL re-evaluation, and relationship between MCL and MCLG;

Table S2, tabulation of contaminants sorted by improvement in method sensitivity, PQL re-evaluation, and relationship between MCL and MCLG; and

Table S3, summary of NPDWR regulation revisions with motivations and commentary on the possible influence of analytical capability.

This material is available free of charge via the Internet at http://pubs.acs.org.

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Supporting Information for

The Role of Detection Limits in Drinking Water Regulation

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Summary of supporting information

Number of pages	3
Number of tables	3

TABLE S1: Contaminants sorted by improvement in method sensitivity, PQL re-evaluation and relationship between MCL and MCLG

SDWA Chemical Contaminant	MCLG (mg/L)	MCL (mg/L)	Current PQL (mg/L)	MCL = PQL?	PQL > MCLG?	MCL > MCLG?	Improvement in sensitivity of methods since promulgation	Improvement in sensitivity of methods 2000-2007	PQL reevaluation? Review 1	PQL reevaluation? Review 2
Original contaminants targeted by first Six-Year Review (2003) [22]										
Alachlor	zero	0.002	0.002	yes	yes	yes	no	no	(1)	(2)
Benzene	zero	0.005	0.005	yes	yes	yes	no	no	(2)	(2)
Benzo(a)pyrene	zero	0.0002	0.0002	yes	yes	yes	yes	no	(1)	(1)
Beryllium	0.004	0.004	0.001	no	no	no	yes	no	(1)	(1)
Bis(2-ethylhexyl)phthalate	zero	0.006	0.006	yes	yes	yes	yes	no	(1)	(1)
Cadmium	0.005	0.005	0.002	no	no	no	no	no	(2)	(1)
Carbofuran	0.04	0.04	0.007	no	no	no	yes	yes	(2)	(2)
Carbon tetrachloride	zero	0.005	0.005	yes	yes	yes	no	no	(2)	(2)
Chlordane	zero	0.002	0.002	yes	yes	yes	yes	no	(2)	(2)
Chromium (Cr III and VI)	0.1	0.1	0.1	yes	no	no	no	no	(1)	(1)
1,2-Dibromo-3-chloropropane (DBCP)	zero	0.0002	0.0002	yes	yes	yes	no	no	(2)	(2)
1,4-Dichlorobenzene (para)	0.075	0.075	0.005	no	no	no	no	no	(2)	(2)
1,2-Dichloroethane	zero	0.005	0.005	yes	yes	yes	no	no	(2)	(2)
1,1-Dichloroethylene	0.007	0.007	0.005	no	no	no	no	no	(2)	(2)
Dichloromethane (methylene chloride)	zero	0.005	0.005	yes	yes	yes	no	no	(2)	(1)
1,2-Dichloropropane	zero	0.005	0.005	yes	yes	yes	no	no	(2)	(2)
Dioxin (2,3,7,8-TCDD)	zero	3	0.00000003	no	yes	yes	no	no	(1)	N/A
Diquat	0.02	0.02	0.004	no	no	no	yes	no	(1)	(1)
Ethylene dibromide	zero	0.00005	0.00005	yes	yes	yes	no	no	(1)	(1)
Fluoride	4	4	0.5	no	no	no	no	no	(1)	(1)
Glyphosate	0.7	0.7	0.06	no	no	no	no	no	(1)	(1)
Heptachlor	zero	0.0004	0.0004	yes	yes	yes	yes	no	(2)	(2)
Heptachlor epoxide	zero	0.0002	0.0002	yes	yes	yes	no	no	(2)	(2)
Hexachlorobenzene	zero	0.001	0.001	yes	yes	yes	no	no	(2)	(2)
Hexachlorocyclopentadiene	0.05	0.05	0.001	no	no	no	no	no	(2)	(2)
Mercury	0.002	0.002	0.0005	no	no	no	no	no	(1)	(1)
Methoxychlor	0.04	0.04	0.01	no	no	no	no	no	(2)	(2)
Oxamyl (Vydate)	0.2	0.2	0.02	no	no	no	no	no	(2)	(1)
PCBs (as decachlorobiphenyl)	zero	0.0005	0.0005	yes	yes	yes	no	no	(1)	(1)
Pentachlorophenol	zero	0.001	0.001	yes	yes	yes	no	yes	(1)	(1)
Picloram	0.5	0.5	0.001	no	no	no	no	no	(1)	(1)
Tetrachloroethylene	zero	0.005	0.005	yes	yes	yes	no	no	(2)	(2)
Thallium	0.0005	0.002	0.002	yes	yes	yes	no	no	(2)	(1)
Toluene	1	1	0.005	no	no	no	no	no	(2)	(2)
Toxaphene	zero	0.003	0.003	yes	yes	yes	yes	no	(2)	(2)
1,1,1-Trichloroethane	0.2	0.2	0.005	no	no	no	yes	yes	(2)	(2)
1,1,2-Trichloroethane	0.0003	0.005	0.005	yes	yes	yes	yes	no	(2)	(2)
Trichloroethylene	zero	0.005	0.005	yes	yes	yes	no	no	(2)	(2)
Vinyl chloride	zero	0.002	0.002	yes	yes	yes	no	no	(1)	(2)
Xylene (total)	10	10	0.005	no	no	no	no	no	(2)	(1)
Additional contaminants targeted by second Six-Year Review (2009) [26]										
Antimony	0.006	0.006	0.006	yes	no	no		no	N/A	(2)
Arsenic	zero	0.01	0.003	no	yes	yes		no	N/A	(1)
Atrazine	0.003	0.003	0.001	no	no	no		yes	N/A	(2)
Barium	2	2	0.15	no	no	no		no	N/A	(2)
Bromate	zero	0.01	0.01	yes	yes	yes		yes	N/A	(1)
Copper	1.3	TT	0.05	no	no	N/A		no	N/A	(1)
Chlorobenzene	0.1	0.1		no	no	no		no	N/A	(2)
Cyanide	0.2	0.2	0.1	no	no	no		no	N/A	(1)
2,4-D	0.07	0.07	0.005	no	no	no		yes	N/A	(1)
Dalapon	0.2	0.2	0.01	no	no	no		no	N/A	(1)
Dichlorobenzene (ortho)	0.6	0.6	0.005	no	no	no		no	N/A	(1)
cis-1,2-Dichloroethylene	0.07	0.07	0.005	no	no	no		no	N/A	(2)
trans-1,2-Dichloroethylene	0.1	0.1	0.005	no	no	no		no	N/A	(2)
Di(2-ethylhexyl) adipate	0.4	0.4	0.006	no	no	no		no	N/A	(1)
Dinoseb	0.02	0.02	0.002	no	no	no		yes	N/A	(1)
Endothall	0.1	0.1	0.09	no	no	no		no	N/A	(1)
Endrin	0.002	0.002	0.0001	no	no	no		no	N/A	(1)
Ethylbenzene	0.7	0.7	0.005	no	no	no		no	N/A	(2)
Lead	zero	TT	0.005	no	yes	N/A		yes	N/A	(1)
Lindane	0.0002	0.0002	0.0002	yes	no	no		no	N/A	(2)
Nitrate	10	10	0.4	no	no	no		no	N/A	(1)
Nitrite	1	1	0.4	no	no	no		yes	N/A	(2)
Selenium	0.05	0.05	0.01	no	no	no		no	N/A	(1)
Simazine	0.004	0.004	0.01	no	yes	no		no	N/A	(1)
Styrene	0.1	0.1	0.005	no	no	no		no	N/A	(2)
2,4,5-TP (Silvex)	0.05	0.05	0.005	no	no	no		yes	N/A	(2)
1,2,4-Trichlorobenzene	0.07	0.07	0.005	no	no	no		no	N/A	(2)

(1) Current PQL still appropriate or insufficient data to reach conclusion
(2) Conclusions of Six-Year Review support change or may support change of PQL

MCLG < MCL = PQL

TABLE S2: Tabulation of contaminants sorted by improvement in method sensitivity, PQL re-evaluation and relationship between MCL and MCLG for first and second Six-Year Reviews (2003 and 2009), as presented in table S1

Contaminants targeted by both Six-Year Reviews (2003 and 2009) as presented in Review 1 (2003)*

Improvement in sensitivity of methods since promulgation	PQL reevaluation indicated by Six-Year Review?	Count MCLG < MCL = PQL (Relationship 2)	% of total count	Count PQL < MCL (Relationships 1 or 3)	% of total count
yes	yes	3	14	2	11
yes	no	2	9	2	11
no	yes	12	55	8	44
no	no	5	23	6	33

Contaminants targeted by both Six-Year Reviews (2003 and 2009) as presented in Review 2 (2009)

Improvement in sensitivity of methods 2000-2007	PQL reevaluation indicated by Six-Year Review?	Count MCLG < MCL = PQL (Relationship 2)	% of total count	Count PQL < MCL (Relationships 1 or 3)	% of total count
yes	yes	3	14	2	12
yes	no	3	14	2	12
no	yes	12	55	5	29
no	no	4	18	8	47

Additional contaminants targeted by second Six-Year Review (2009) as discussed in Review 2 (2009)

Improvement in sensitivity of methods 2000-2007	PQL reevaluation indicated by Six-Year Review?	Count MCLG < MCL = PQL (Relationship 2)	% of total count	Count PQL < MCL** (Relationships 1 or 3)	% of total count
yes	yes	0	0	3	12
yes	no	1	50	3	12
no	yes	1	50	7	28
no	no	0	0	12	48

* Includes dioxin, which was not targeted by Review 2 (2009)

** Includes copper and lead, two contaminants that have prescribed treatment efficacies instead of MCLs but that are not limited by detection ability

Table S3: Historical Regulatory Revisions of Chemical Contaminants [23]

SDWA Chemical Contaminant	Initial standard (year)	MCL (year)	MCLG (current)	PQL (current)	Notes
2,4,5-TP	0.01 mg/L (1975); Proposed MCL = MCLG = 0.05 mg/L (1989)	0.05 mg/L (1992)	0.05 mg/L	0.05 mg/L	Value of standard **increased** between 1975 and 1989. 1989 value adopted in 1992.Not identified as possibly subject to a toxicological review.
2,4-D	0.1 mg/L (1975)	0.07 mg/L (1991)	0.07 mg/L	0.05 mg/L	Not identified as possibly subject to a toxicological review.
Arsenic	NIPDWR: 0.05 mg/L	0.01 mg/L (2001)	zero	0.03 mg/L	Regulation lowered from 0.05 to 0.01 mg/L on account of growing body of evidence suggesting old standard was inadequate to protect health. Note that reg > PQL. Question of cost/benefit.
Barium	USPHS: 1.0 mg/L (1962) NIPDWR: 1.0 mg/L; Proposed MCL = MCLG = 5 mg/L (1989);	2 mg/L (1991)	2 mg/L	0.15 mg/L	Value of standard has **increased** since 1962. Not identified as possibly subject to a toxicological review.
Cadmium	0.01 mg/L (1975)	0.005 mg/L (1991)	0.005 mg/L	0.002 mg/L	Standard lowered, but this followed a revision to the concentration considered to be protective of public health, not a significant improvement in detection ability
Chromium	0.05 mg/L (1975)	0.1 mg/L (1991)	0.1 mg/L	0.1 mg/L	Value of standard has **increased**.
Endrin	0.0002 mg/L (1975)	0.002 mg/L	0.002 mg/L	0.0001 mg/L	Value of standard has **increased**.
Fluoride	1.4 to 2.4 mg/L (1975)	4 (1986)	4	0.5 mg/L	Standards have been decided upon based on various health studies with variable importance being ascribed to sensitive populations and "cosmetic" impacts. Value of standard has
Lead	0.05 mg/L (1975)	(Treatment technology)	zero	0.005 mg/L	Lead regulation has changed from a maximum concentration to a mandatory removal efficiency
Lindane	0.004 mg/L (1975)	0.0002 mg/L	0.0002 mg/L	0.0002 mg/L	Value of standard has **decreased**. No information found tying re-regulation to detection capabilities
Methoxychlor	0.1 mg/L (1975)	0.04 mg/L (1992)	0.04 mg/L	0.01 mg/L	Regulation has been lowered, but not to PQL. Therefore, toxicological model or cost-benefit analysis dominates the regulation.
Nickel	0.1 mg/L (1992)	N/A (1995)	0.1	N/A	Regulation **remanded**
Selenium	0.01 mg/L (1975)	0.05 mg/L (1991)	0.05 mg/L	0.001 mg/L	Value of standard has **increased**.
THMs	0.1 mg/L (1979)	0.8 (1998)	N/A	N/A	Value of standard has **increased**.THMs are regulated only to the extent to which implementation would not result in exceedences to microbiological drinking water standards. Regulations are function of competing risk models.
Toxaphene	0.005 mg/L (1975)	0.003 mg/L (1991)	zero	0.003 mg/L (1991)	Toxaphene MCL is tied to PQL.

USPHS : United States Public Health Service
NPIDWR: National Interim Primary Drinking Water Regulations