The Price of Confidence: Choosing Water Quality Goals Under Uncertainty

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Introduction

Risk assessment has become a central tool in regulatory and other environmental decisions, both as the primary basis for establishing limits on environmental pollutants and as a part of cost-benefit analyses used to justify the cost-effectiveness of solutions that inevitably involve risk tradeoffs. Regulatory agencies and other environmental managers work under a mandate to protect the public health against unacceptable risks. Risk-based regulatory decisions generally apply a margin of safety to guard against underestimation of risk in the face of inter-subject variability and uncertainty.

Uncertainty and variability, however, often are vaguely characterized, and so a default process based on conservative assumptions and uncertainty factors has been used to build a degree of protectiveness into a standard. As a result, it rarely is possible to specify the fraction of population protected, or the confidence with which this protection can be assured, under a published MCL. It is possible that an MCL (or other regulatory limit) may be established based on a significantly larger margin of safety than is necessary, reasonable or consistent with that applied to other contaminants. Since the size of the margin of safety usually determines regulatory costs, it is further possible that the use of default processes to reflect concern for uncertainty and inter-subject variability may result in ineffective expenditures of limited financial resources.

In the traditional approach in risk-based decision making, the best estimate of the risk (i.e. probability of getting cancer, Pc) is obtained for a representative individual in the

exposed population. As the MCL is lowered, this reduces the risk to this representative individual, and so increased cost associated with a lower MCL may be viewed as "purchasing" a reduction in health effects in the affected population. At the same time, lowering the MCL increases the fraction of the population whose risk is below a target risk level. The increased cost associated with a lower MCL may be viewed as "purchasing" an addition in the fraction of individuals whose risk is below the target level of risk. Finally, lowering the MCL raises the confidence that a given fraction of the population is protected against the target risk. The increased cost associated with a lower MCL may then be viewed as "purchasing" increased confidence that the policy goal has been reached.

The above discussion suggests that each potential MCL can be described by three values: (Pc, F, C), where Pc is the probability of getting cancer (replaced by the Hazard Quotient, HQ, for non-cancer effects), F is the fraction of the population whose risk is below this value of Pc or HQ, and C is the confidence with which the assessor can state that at least this fraction of the population is protected from a risk with the value of Pc or HQ. Policies based on such a triplet of values are based on the answer to the question: *What is the MCL for which it can be said with at least C (%) confidence that at least F (%) of the population will be protected from target risks of Pc (or HQ)?*

Methods

To address this question, both uncertainty and inter-subject variability of risk (Pc or HQ) must be quantified using methods of probabilistic risk assessment. The structure of such an assessment, used in the present paper, is shown in Figure 1. The core equation is that for Average Daily Rate of Intake (ADRI):

Equation 1 $$ADRI = C \times IR / BW$$

where C is the concentration of a contaminant in water (here, arsenic or perchlorate); IR is the intake rate of water (L/day); and BW is the body mass (kilograms). The values of IR and BW are variable (and correlated, so we use the inter-subject variability distribution of IR/BW rather than having these as separate random variables). The value

of C is fixed and equal to the proposed MCL. The probability of cancer is given by the product of ADRI and the cancer slope factor, and the value of HQ is given by the ratio of ADRI divided by the RfD.

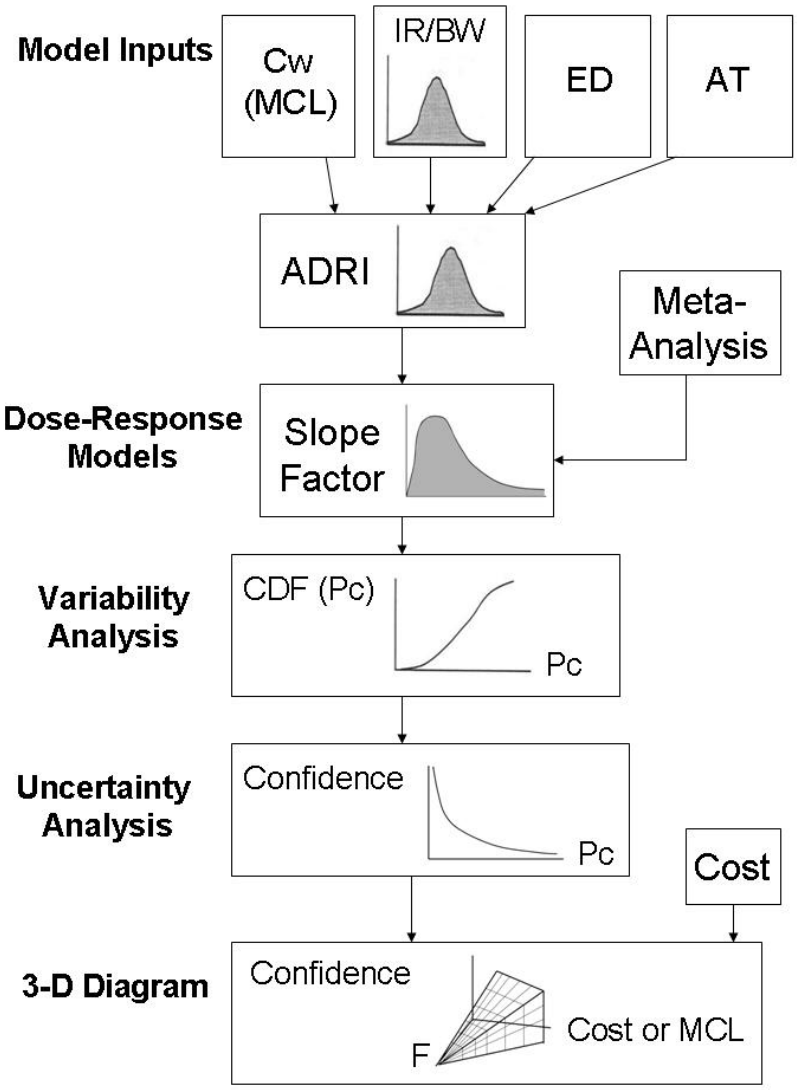

Figure 1. The nested variability-uncertainty analysis used in the present study.

Variability of the terms in Equation 1 is determined from information in the EPA Exposure Factors Handbook (EPA 1997). Uncertainty in the case of arsenic is considered here by five models of dose-response (see Table 1): a model in which arsenic increases mitosis; one in which arsenic decreases repair effectiveness for DNA damage; a linear model based on the National Research Council's cancer slope factor (NRC 1999); and a

linear model and upper-bound model considered in an analysis by Morales et al (2000). Uncertainty for perchlorate is developed from the uncertainty factors employed in developing the RfD, with the median value of the uncertainty distribution for the hazard quotients developed here determined from the NOAEL identified by the NRC (2005) and the geometric standard deviation (GSD) being 3 (to represent an overall 95% uncertainty bound within a factor of 10 of the median value). For both arsenic and perchlorate, the variability analysis is nested within the uncertainty analysis outer loop.

MODELS	Pc ([As]= 10 µg/L)	EQUIVALENT SLOPE FACTORS	SUBJECTIVE CONFIDENCE
Mitosis	1.00E-06	4.42E-06	0.2
Repair	9.60E-05	4.25E-04	0.2
NAS	2.00E-04	8.85E-04	0.2
Linear New	3.50E-04	1.55E-03	0.2
Upper Morales	6.00E-04	2.65E-03	0.2

Table 1. The five models for arsenic dose-response used here. Models are given equal weight.

Results

The surfaces showing Pc, F and C for arsenic are provided in Figures 2 through 5 for MCLs of 50, 20, 10 and 1 µg/L (ppb), respectively. The surfaces show the increasing confidence in protectiveness (Pc and F) with lowered MCL. Figure 6 shows the increasing cost of this confidence, represented here by additional cost per percentile of confidence increase.

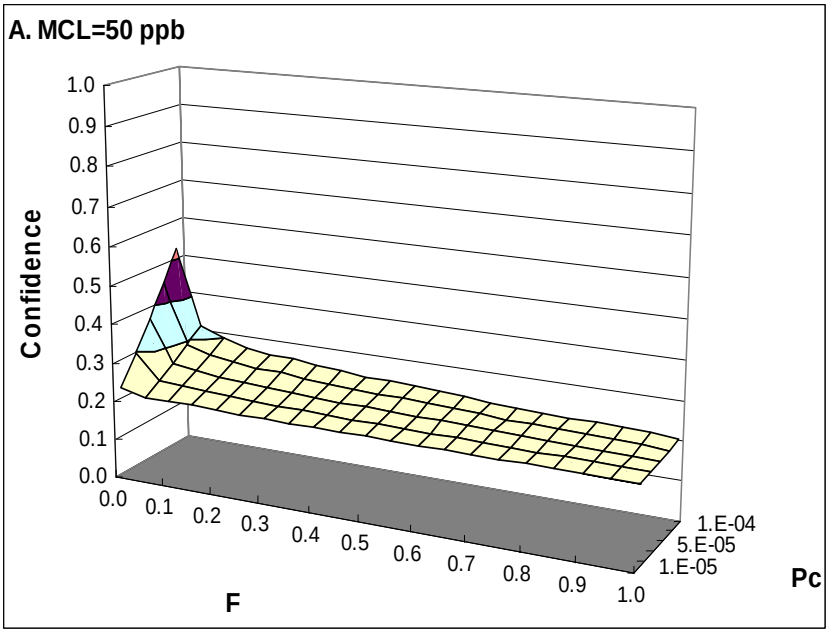

Figure 2. The (Pc, F, C) surface at an arsenic MCL of 50 µg/L (ppb).

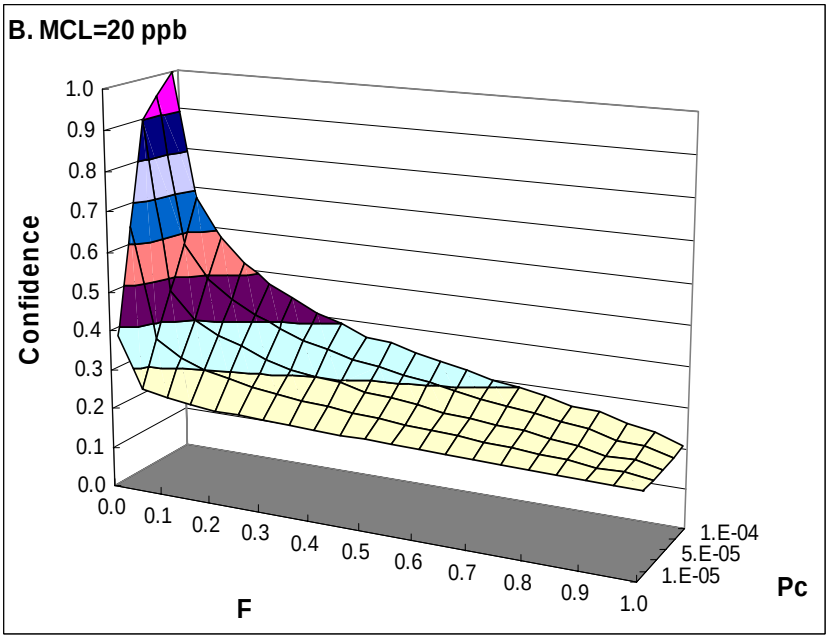

Figure 3. The (Pc, F, C) surface at an arsenic MCL of 20 µg/L (ppb).

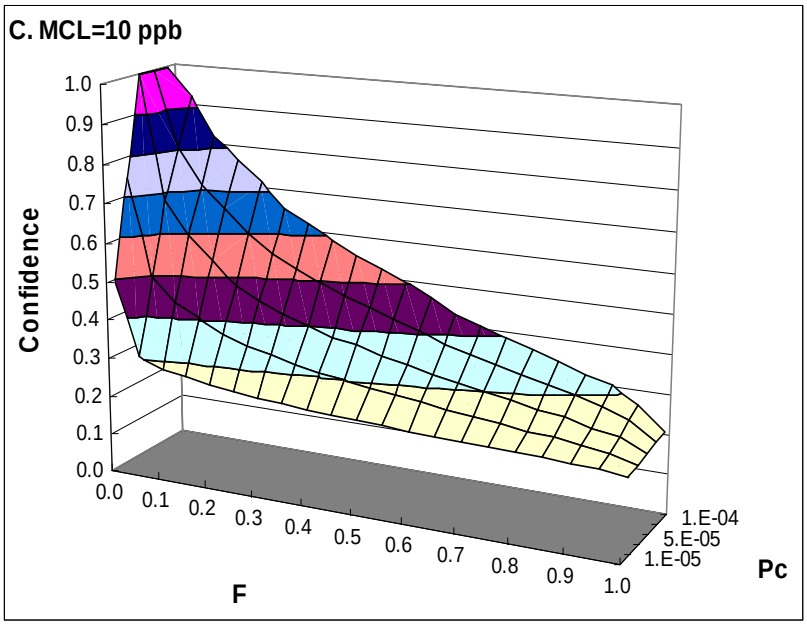

Figure 4. The (Pc, F, C) surface at an arsenic MCL of 10 µg/L (ppb).

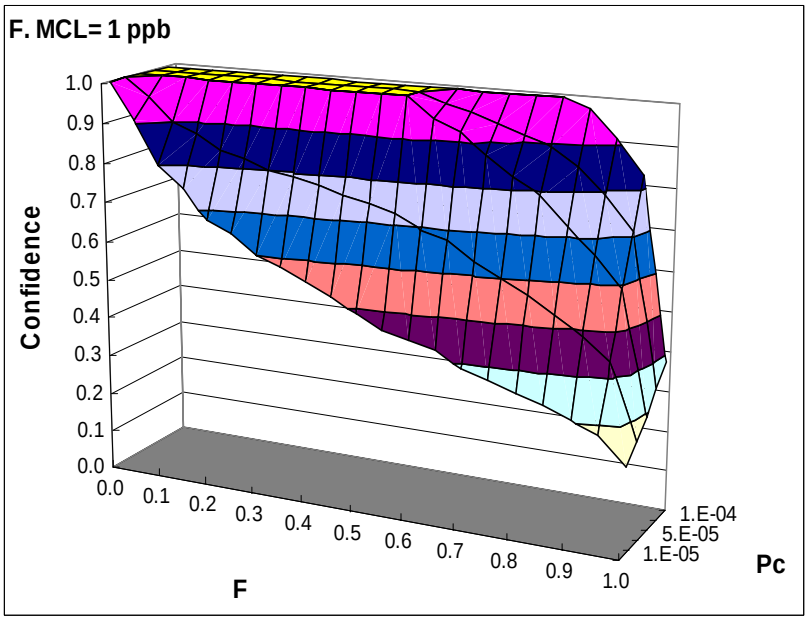

Figure 5. The (Pc, F, C) surface at an arsenic MCL of 1 µg/L (ppb).

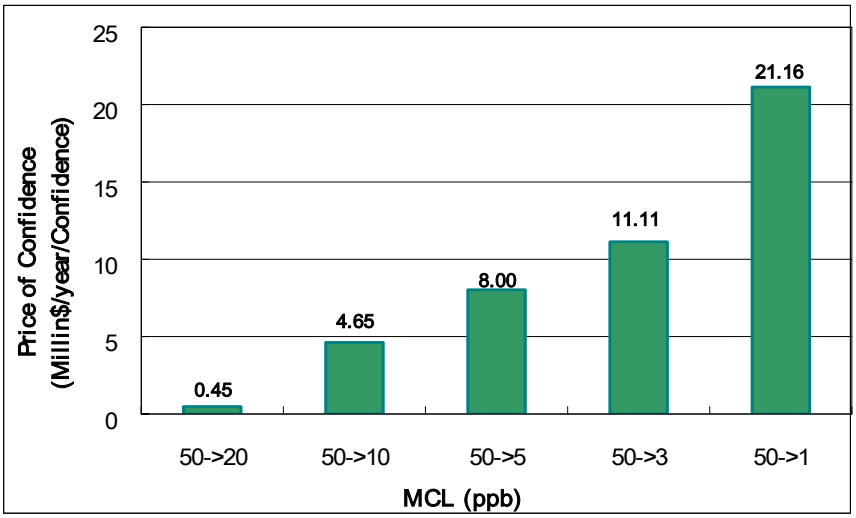

Figure 6. The additional expenditure in regulatory controls per percent increase in confidence associated with different MCLs. Cost data are from Gurian et al (2001).

The inter-subject variability of hazard quotient for perchlorate is displayed in Table 2 below. Note that the upper percentiles of this distribution begin to exceed 1 at MCLs of above 10 µg/L (ppb)

MCL	Median	90%	95%
1	0.02	0.05	0.06
2	0.04	0.09	0.11
5	0.11	0.23	0.29
10	0.22	0.47	0.57
20	0.44	0.93	1.14
50	1.08	2.27	2.81

Table 2. The percentiles of the inter-subject variability distribution for HQ values in individuals exposed to perchlorate in water at different MCLs.

Finally, the surface of HQ, F and C for perchlorate at different proposed MCLs is shown in Figure 7. The data needed to calculate costs per increased unit of confidence are not available at present for perchlorate, so the analogue of Figure 6 cannot be produced.

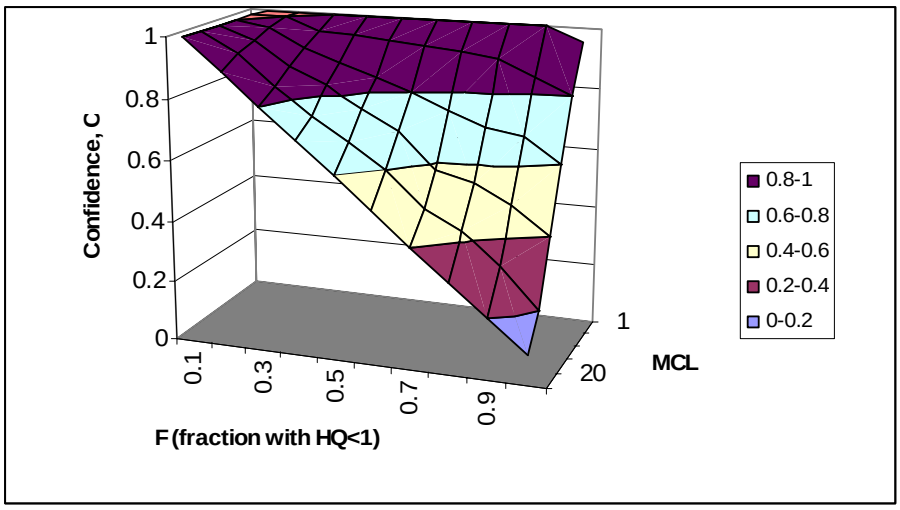

Figure 7. The (F, C) surface at different perchlorate MCLs. Here, the risk-based target is an HQ value of 1 or below, so the axis related to Pc is not applicable.

Conclusions

Probabilistic methods of risk assessment are becoming increasingly sophisticated, allowing risk managers to better understand the degree of protectiveness built into proposed regulatory limits. In the case of arsenic and perchlorate, it is clear from the information presented here that a wide range of MCLs might be justified based on consideration of target values of Pc, HQ, F and C. It is further evident that, at least for one case where increased confidence could be associated with an increased cost of compliance, that a willingness to decrease confidence slightly could significantly reduce compliance costs. At the very least, we believe such methods of uncertainty and variability analysis must become the norm, if for no other reason than to allow comparisons of the margin of safety purchased by different regulations. These advances will allow society to better understand the degree to which specific policies will bring about improvements to the public health, and to balance the allocation of limited resources across an array of potential strategies.

References

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