Legal Aspects of Emerging Contaminants and Moving Targets – Responsible Party Perspective

by

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The topic of emerging contaminants and moving targets brings to mind several examples.

There has been a flood of recent news coverage of famous athletes contaminating their bodies with tetrahydrogestrinone (THG) to improve performance. Apparently, this is a substance that didn't even exist until recently, when it was synthesized by modifying an anabolic steroid. The FDA says that while little is known about the safety of THG, its structure and relationship to anabolic steroids suggest that its use may have serious long-term human health consequences.

Asbestos is another example. Its fibers are incredibly strong and heat resistant, making it a good acoustic and thermal insulator and fire-proofing material. One might say asbestos "emerged" as a contaminant after we learned that human inhalation of its fibers can cause asbestosis and mesothelioma.

Lead is similar. It is an excellent hiding agent in paint, but it "emerged" as a contaminant when we learned about the effects on children who ingest it.

MTBE in gasoline seemed like a good way to clean up air emissions from cars until we learned what it did when it leaked from underground storage tanks.

[1] Mr. Haughton delivered these remarks to the Groundwater Resources Association of California at a conference entitled, "1,4 -Dioxane and Other Solvent Stabilizer Compounds in the Environment," in San Jose, California on December 10, 2003.

And then there's TCE. It's a great solvent, but it "emerged" as a contaminant when we learned – or should I say "thought we learned" – about its toxicology and mobility. Now, TCE is emerging again, this time as the result of a September 2001 draft risk assessment issued by USEPA, indicating TCE's potency as a carcinogen may be 65 times higher than previously believed. (It should be noted that this tentative conclusion is the subject of considerable controversy.)

Which leads us to solvent stabilizers like 1,4-dioxane. Again, it's useful stuff, lengthening the life of solvents, but it has recently "emerged" as a contaminant because advances in detection technology have enhanced our ability to "see" it.

What do all of these emerging contaminants have in common? In each case, the contaminant emerged when we learned something new suggesting there may be a human health risk that was previously unknown. The "something new" could be a new chemical, new toxicology, new understandings about transport properties or new detection technology.

Emerging contaminants present us with the question: how should we respond to the new information about risk? If we think of legal rules regulating contaminants as "targets," the question becomes: should we move existing targets or – where there are no existing targets – create new ones? And if so, what should the new targets be?

The range of answers might be said to represent a tension between two aphorisms. One side of the spectrum might be called the "better safe than sorry" side, while the other might be called the "measure twice, cut once" side.

An example at the "better safe than sorry" end of the continuum would be to say that as soon as there is any news suggesting that a chemical may cause any risk, the following rules should be enacted:

- All use of the chemical should be banned.
- All media everywhere should immediately be tested for the presence of the chemical at the expense of the property owner.
- Wherever the chemical is found, it should be cleaned up until its presence can no longer be detected.
- Waste products from the cleanup should be chemically altered so none of the offending chemical remains, and the resulting product is broken down into naturally-occurring materials and reintroduced into naturally-occurring deposits of the materials in such a way as to eliminate any evidence of human involvement.

Conversely, an example at the "measure twice, cut once" end of the continuum would be to say no action should be taken until there is unanimity in the scientific community that it is certain that the chemical causes cancer in humans at some specified dose. Then – and only then – the rules should be as follows:

- Use of the chemical should not be banned.
- No testing for the chemical should be required unless and until someone proves beyond a reasonable doubt that a dose received from a site caused a particular individual to develop cancer.
- Where testing is required, and the chemical is found, it should be cleaned up to the specified dose level, using exposure assumptions from the person who developed cancer.
- Waste products from the cleanup should be dumped down the sewer.

Now, assuming the best answer lies somewhere between these two extremes, the question becomes: where?

Before we start looking at how we might answer that question, let's stop for a moment to consider why we should care. To some extent, it depends on your perspective: are you a water quality regulator, a water purveyor or a responsible party? Perspective does make a difference. We're all human, and it's as if each of us is hip-deep in a different alligator-filled swamp. Each of us tends to respond to the alligator that's closest to biting a part out of our anatomy.

A very capable regulator I know didn't require a responsible party to include a dioxin analysis in laboratory runs for samples from a site. This made sense at the time because considerable evidence about the site history indicated there was no reason to believe dioxins were present, and, as we all know, dioxin analyses aren't free. Years later, after the site had been closed, an unexpected sequence of events led to the discovery of dioxins at the site. The regulator almost lost his job. Now, he requires dioxin sampling at all of his sites, regardless of whether the historical evidence suggests dioxins might be present.

So yes, we're human, and perspective makes a difference. As a result, it's easy to think of a conversation about emerging contaminants and moving targets as a battleground where the opposing sides have nothing in common.

It's easy to fall into the trap of seeing the responsible party as having a single-minded desire to reduce costs at the expense of the environment and the water quality regulator as having a single-minded desire to enhance the environment regardless of the cost. After all, no regulator was ever promoted for saving responsible parties money, and no responsible party employee was ever promoted for spending an extra $10 million to clean up from a 10^{-6} excess cancer level to 10^{-7}.

But I'd like to offer an alternative way of looking at the situation. To stretch the swamp metaphor, you might say we all need to recognize our common interest in reducing the overall alligator population. When we're considering emerging contaminants and moving targets, we all have a common interest in paying attention to the unintended consequences of our actions.

Unintended consequences can cause problems directly and indirectly. Examples of direct negative unintended consequences are easy to imagine.

- I already mentioned one in the case of MTBE. It was undisputed that adding MTBE to gasoline would reduce air pollution from cars. No one thought to look at the unintended consequence of MTBE leaking out of underground fuel tanks and into groundwater.
- Another example comes from the Proposition 65 arena. Warnings about hazardous substances sounded like a good idea at the time, but warnings on nicotine gum – a product designed to help people stop smoking – can cause pregnant mothers to keep smoking, increasing the risk of reproductive harm.
- If we require babies on airplanes to have their own seats and seat belts, will the extra cost cause some parents to drive instead of flying, thereby exposing their babies to substantially more risk than the airplane's seat belt would have avoided?
- If we urge people to eat organic fruits and vegetables to decrease cancer risk from pesticides, might the increased cost decrease their fruit-and-vegetable intake, leading to a net increase in cancer risk from all sources?
- Let's say we require fire retardant to be added to kids' pajamas, and the retardant turns out to be potentially carcinogenic. Should we eliminate the cancer risk even if doing so yields a net increase in number of deaths?
- How much air pollution was caused by actively remediating gas station sites that the Lawrence Livermore Report later told us would naturally biodegrade in time to prevent any significant risk? Apparently there was some because USEPA on October 8, 2003 issued a site remediation NESHAP designed to reduce air pollution from cleanups including gas station cleanups.

These kinds of direct negative unintended consequences are relatively easy to understand, if challenging to avoid. Indirect negative unintended consequences, as the name suggests, involve a longer cause-and-effect chain, but they may also be much more significant. Indirect negative unintended consequences flow from the observation that resources are limited.

Uncontroversial though this observation may be, we tend to be blinded to its implications because of our natural moral aversion to putting price tags on human life or environmental values. But the truth is that by our actions and inactions we put price tags on such things every day. The question is whether we want to recognize that fact.

What are the implications of limited resources?

The budget crisis that precipitated the 2003 recall election made California's environmental regulators painfully aware of resource constraints. If, in response to emerging contaminants, we aren't careful about where we place moving regulatory targets, regulator resources can be wasted, both in terms of staff time spent on un-needed oversight and in terms of scarce governmental cleanup dollars misspent. To return to the example of the Lawrence Livermore Report, how much mercury could we have kept out of San Francisco Bay if staff resources devoted to needless gas station cleanups had instead been devoted to developing the mercury TMDL?

Needless to say, water purveyors and responsible parties have budgets, too. One kind of moving target that emerging contaminants lead to is new NPDES permit limits. Not only does a bad limit create the risk that the treatment technology will do more harm than good, but it also can divert money away from projects that have environmental and other human health benefits.

In the best case, a bad target will cause a water purveyor to incur needless costs that get passed along to ratepayers. In the worst case, a bad target can be the straw that breaks a responsible party's back, resulting in lost jobs for many people, possibly including some whose water and sewer rates are going up as a result of the same bad target.

To which some might respond, 'that's unfortunate, but it's not my problem." To the extent we're stewards of public health, though, it should be all of our problem. Why? Because there is a negative correlation between income and mortality. In other words, people with more money tend to be healthier and live longer. Conversely, people with less money tend to be sicker more often and die sooner.

Does this mean we should stop spending money on environmental regulation? No. But can we ignore cost-benefit analysis and claim we are serving the public good? The answer again is no.

So we've seen why we should care about where moving targets are placed on the continuum from the extreme "better safe than sorry" position – which might be called the "chicken little" answer – to the extreme "measure twice, cut once" position – which might be called the "analysis paralysis" answer.

Now let's turn to some of the legal rules that are designed to guide us to an answer that lies somewhere between these two extremes.

First, there is California Water Code section 13000, which articulates the legislative finding that,

> "activities and factors which may affect the quality of the waters of the state shall be regulated to attain the highest water quality which is reasonable, considering all demands being made and to be made on those waters and the total values involved, beneficial and detrimental, economic and social, tangible and intangible."

That's a start. The legislature commands us to consider the "total values" involved, thus generally urging us to look at all the costs and all the benefits before fixing the location of a moving target.

Let's look at the emerging contaminant *du jour*: 1,4-dioxane. Is it being regulated in a way that takes into account the "total values" involved?

Preliminarily, how is dioxane regulated? The State Department of Health Services (or DHS) has set a drinking water action level of 3 ppb, the lowest level of any of the 6 States that have established levels. There is no federal MCL. The other States that have established levels are:

Florida:	5 ppb
North Carolina:	7 ppb
Massachusetts:	50 ppb
Maine:	70 ppb
Michigan	85 ppb

That's a pretty wide spread. What's more, there are peer-reviewed studies recommending standards as high as 1,200 ppb.

And California's action level has real-world implications. For example,

- Health & Safety Code §116455 requires water purveyors to notify the local City Council and/or County Board of Supervisors when a contaminant in drinking water exceeds its action level.
- DHS recommends that, when a contaminant exceeds its action level, the purveyor should inform its customers and explain the potential for adverse health effects at high levels of exposure.
- DHS also recommends that the purveyor take the source out of service if a contaminant is present at more than 10 times any action level based on non-cancer risk or 100 times the action level, if the action level is based on a 10^{-6} cancer risk.
- For cleanup sites that are required to comply with the National Contingency Plan (or NCP), regulators are likely to consider the action level in setting remedial standards and choosing cleanup alternatives pursuant to the NCP's directives to consider ARARs (that is, "applicable or relevant and appropriate requirements") and TBCs (that is, "other pertinent advisories, criteria, or guidance" To Be Considered).
- In fact, at both NCP and non-NCP sites, regulators in California are using the dioxane action level as a basis for setting cleanup levels.
- Finally, whenever any governmental standard is set, the toxic tort plaintiffs bar is rarely far behind.

These real world effects bring us to a second legal standard that affects how we determine where on the chicken-little-analysis-paralysis spectrum the moving target for dioxane should be set.

The regulated community will argue that these real-world effects mean that, even though DHS characterizes action levels as merely "advisory," they look like rules, walk like rules and quack like rules. Therefore, they should be treated as rules, and, as such, should have been subject to notice-and-comment rulemaking, as required by the California Administrative Procedure Act (or APA).

It has been said that when you have a hammer in your hand, every problem starts to look like a nail. The lawyer's hammer is process. They're trained

to think that good process yields better substantive answers. That's the theory behind the APA. Notice-and-comment rulemaking gives all those affected by a rule a chance to weigh in, offer alternative scientific approaches, point out negative unintended consequences and explain costs. These things tend not to happen in the absence of such a process, and the outcome is likely to suffer as a consequence. Maybe there are good reasons to go with 3 ppb instead of 1,200 ppb for dioxane, but if there are, those reasons have not been subjected to the sunshine the APA requires.

A recent law that has similar import is Governor Schwarzenegger's second Executive Order (EO) S-2-03. (His first was to repeal the car tax.) Paragraphs 2 and 3 of EO S-2-03 provide:

> 2. [By December 17, 2003], each Agency shall assess and identify any present issuance, utilization, enforcement or attempt at enforcement of any guideline, criterion, bulletin, manual, instruction, order, or standard of general application which has not been adopted as a regulation in potential violation of [the APA] and submit its findings to [the Office of Administrative Law] OAL ... and the Legal Affairs Secretary;
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> 3. Upon submitting the findings to OAL and the Legal Affairs Secretary, any Agency utilizing such guideline, criterion, bulletin, manual, instruction, order or standard of general application in the normal course of business until OAL makes its determination to the Governor pursuant to California Government Code section 11340.5(c) shall do so on an opinion-only basis which will not carry the force of law.

This EO is designed to ferret out and eviscerate what are called underground regulations, that is, *de facto* rules that were put in place without following the notice-and-comment rule-making procedures required by the APA.

Three other aspects of this EO are relevant here. It (1) imposes a moratorium on new regulations, (2) requires a cost-benefit analysis before any further regulations can be enacted and (3) requires a cost-benefit analysis of all regulations adopted since January 6, 1999.

Interestingly, all of this will be accomplished, according to the EO, through existing resources.

There are similar legal constraints that operate on the Federal Level, including the Federal APA and Executive Order 12866, requiring cost-benefit analysis of certain Federal regulations. Federal law also has something California law doesn't: the Data Quality Act, enacted in December 2001. Without getting into detail, the Data Quality Act is designed to impose procedural requirements that ensure and maximize the quality, objectivity, utility, and integrity of information disseminated by Federal agencies.

These legal tools are not perfect. The best way to improve them is through the advocacy of all interested parties – regulators, purveyors and responsible parties – working together. And I do encourage us all to work together on this. None of us is benefited by either the chicken-little outcome or the analysis-paralysis outcome. We all have a stake in improving the process.