

THE POLITICAL ECOLOGY OF SEWAGE SLUDGE: THE COLLISION OF
SCIENCE, POLITICS, AND HUMAN VALUES

by

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Environmental debates are often accompanied by calls for the increased use of “sound science”, yet science pertaining to environmental issues is especially subject to influence from social, political, and economic actors. This thesis seeks to evaluate the role of science in environmental decision making by examining the practice of land-application of sewage sludge of biosolids. The United States Environmental Protection Agency’s 2003 decision not to regulate dioxins, furans, and dioxin-like PCBs in sewage sludge will serve as a case study of how science is integrated into the policy world through risk assessment. A multidisciplinary analysis indicates that while the beneficial reuse of human waste is essential to sustainability, the application of biosolids on farmland as currently practiced is not environmentally or politically sustainable.

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For the seventh generation

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CHAPTER I

INTRODUCTION

Public, political, and academic debates about environmental issues or crises often appear to be centered on science. In today's preferred system of governance in the "developed" world, few policy decisions are made without resort to some kind of scientific or quasi-scientific justification. Science-based, or evidence-based, policymaking is attractive to government agencies because it offers some protection from public outcry and can be used to defend their rationale during potential judicial review of their decisions. Risk assessment is currently the most common vessel through which scientific knowledge makes its way into the policy world. Yet, in many ways, the rise of risk assessment and science-based policy has simply shifted part of the firestorm from the agencies that decide policy to the scientific community that provides the science to inform policy-makers. This pressure on science that could be used in a regulatory light has caused significant deviations from scientific ideals in fields such as toxicology and risk assessment, which call into question science's claims of objectivity and privileged knowledge status in regard to environmental decision making. Even if regulatory science functioned in an ideal fashion, we would still need to ask ourselves the following question. Does the emphasis on scientific issues in regard to the environment, and the relative lack of emphasis on social and ethical dimensions, lead to ineffective and socially unsatisfying solutions being selected? This thesis seeks to

answer this question for the case of land application of sewage sludge (the solid remnants of municipal wastewater treatment plants), and along the way, develop a broader set of tools for employing multidisciplinary analyses to help make better environmental decisions.

There is a large diversity of opinions regarding the proper role of science in decision making. While most (but not all) parties agree that more and better science would be welcome in policymaking, there are big differences in what is meant by “sound science”. This diversity of opinion suggests that a pluralist, multidisciplinary analysis of science-based decision making could be informative to the debate over the proper role of science and useful in developing broader conceptions of how to conduct environmental “assessments”. Risk assessment is currently the dominant form of environmental assessment. This thesis will take a multidisciplinary approach to examining risk assessment as a tool for environmental decision-making. The Environmental Protection Agency’s (EPA) 2003 decision not to regulate dioxins or PCBs in sewage sludge, or “biosolids”, will serve as a case study of current decision making procedures in the EPA and how they incorporate risk assessments and other scientific information.

Multidisciplinary analysis of the land application of sewage sludge suggests that while recycling of human waste is a necessary element of a sustainable society, the political, scientific, and economic dynamics of “toxic” chemical use, waste, & pollution management in the United States results in sewage sludge that is of questionable fitness for disposal or “recycling” on farmland. Risk assessment is used to provide justification for EPA’s decisions regarding biosolids, yet the issues covered in EPA’s risk

assessments fail to address the concerns of parties opposed to biosolids application, resulting in continued controversy. As including the concerns of currently marginalized stakeholders would likely alter the outcomes of the risk assessments and necessitate economic costs in improving the practice, the use of risk assessment by EPA to justify decisions can be seen as an exercise of institutional power, whereby political, economic, social, and normative influences and assumptions are masked by sophisticated mathematical models and scientific presentation.

Investigation of the combined effect of political, economic, social, and ethical influence on science destined for policy-making requires a balanced approach between the concerns of social scientists, natural scientists, and ethicists or philosophers. Only by integrating the scientific critique with the social critique and seeing them both within their political contexts, can we find the proper tools for getting as close to “objectively” looking at environmental issues as is metaphysically possible.

Unfortunately, there are a lot of barriers to work that transgresses disciplinary boundaries. Every discipline has its own traditions and own history of development, and each has addressed the problems that each has seen as most important or interesting. When disciplines turn towards complicated subjects such as environmental or resource issues, they may or may not have appropriate tools to tackle these problems, as they are embedded or have evolved out of previous traditions. Creating a multidisciplinary “toolbox” for environmental issues could allow us to pick and choose which aspects of social or natural sciences we would like to incorporate into our analysis, without having to take on all the “baggage” of every discipline we want to borrow an idea from. This strategy can certainly be criticized as taking ideas out of context, but as the discussion

of “strong” constructionism below illustrates, some pruning of ideas is necessary to be able to move forward with meaningful multidisciplinary approaches to environmental problems.

Challenges of Multidisciplinary Approaches

Inter- or multi-disciplinary approaches get a lot of lip service among environmental studies circles, but there are surprisingly few examples of truly interdisciplinary work to draw from as models of how research like this might actually look. Natural scientists typically have little knowledge of social science theories and methodology, and social scientists often have only a “popular” understanding of scientific research and theory. Bridging this gap has been challenging not only because of the difficulty in learning how to think from two broadly different perspectives at the same time, but also due to ideological friction between natural sciences and social sciences.

Closing the Rift Between the Humanities, Social, and Natural Sciences

As a long-time technician in various biology laboratories, I have always had questions about the institutions of science, the social influences on how scientific knowledge is created, and just what exactly science is and is not capable of telling us. Unfortunately, I personally have been quite disappointed with much of the literature addressing these questions coming out of the social sciences. One of the most common positions towards the natural sciences within sociology, anthropology, and other social sciences is that the knowledge produced by the natural sciences is socially constructed,

albeit with various caveats to that assertion. In this authors view, this emphasis on the construction of scientific knowledge has led to a shrinking common ground for researchers seeking to do multidisciplinary work. Many of the extreme constructivist views are only capable of “deconstructing” natural science ways of knowing, rather than enhancing “scientific” ways of knowing or suggesting better approaches to knowledge. This can easily lead to cognitive dissonance in anyone who tries to both practice natural science and social science.

The predominance of constructionist viewpoints within social studies of science has been the source of continued friction and sometimes outright hostility between social science and humanities disciplines and those aligned with the natural sciences. The debate lies along a continuum from “realists”, who believe that science presents a truly objective way of knowing, to “relativists” who hold that science is nothing more than culturally embedded rituals which produce “inscriptions” and statements of fact that are socially constructed, and no more “true” than alternative explanations proposed by astrologists, witch doctors, or any other group.

Gould (2000) has asserted that neither of these diametrically opposed poles of opinion is widely held by people actually engaged in practicing science or in serious social critiques of science. Scientists generally do not believe their work to be purely objective, and few social critics occupy the opposite pole of pure relativism, holding that all of reality is nothing but social construction. Rather, Gould attributes the rise of the “science wars” to humans’ propensity to “construct our descriptive taxonomies and tell our explanatory stories as dichotomies, or contrasts between inherently distinct and logically opposite alternatives” (Gould, 2000, p253). While there may be some truth to

Gould's assertion, there is certainly a significant body of literature on either side of the "science wars", which indicates that there is considerable disagreement as to the proper placement of scientific knowledge along the realism-relativism continuum. While I certainly claim no ability to resolve this dispute on these pages (or anywhere), I can give you my impressions and the resolution of the dispute in my own mind, as this has bearing on how we will be evaluating scientific assertions.

Although he claims not to be a relativist in the strict sense, the work of French sociologist Bruno Latour has been very influential in the rise of constructionist thought in fields such as the sociology of scientific knowledge and science and technology studies. Latour and Woolgar's 1979 treatise, *Laboratory Life: The Construction of Scientific Facts* was a seminal work in the sub-field of laboratory studies, and is often cited in papers asserting that there is "nothing special" about how scientific knowledge is formed and that scientists in fact *create* the nature of the external reality they study, rather than discovering pre-existing principles. As Latour and Woolgar originally put it:

[I]n emphasizing the process whereby substances are *constructed*, we have tried to avoid descriptions of the bioassays which take as unproblematic relationships between signs and things signified. Despite the fact that our scientists held to belief that the inscriptions could be representations or indicators of some entity with an independent existence "out there," we have argued that such entities were constituted solely through the use of these inscriptions. It is not simply that differences between curves indicate the presence of a substance; rather the substance is identical with perceived differences between curves. . . . [W]e do not conceive of scientists using various strategies as pulling back the curtain on pre-given, but hitherto concealed, truths. Rather, objects (in this case, substances) are constituted through the artful creativity of scientists. (Latour & Woolgar, 1979, p128-129)

In *Laboratory Life*, as well as in later works, Latour presents the creation of scientific facts as creative acts of persuasion and negotiations, both within scientific communities and between scientists and the objects or organisms they study. Through

this process of negotiation, evidence or “inscriptions” are offered forth to support one view or another. Ultimately, the body of evidence constructed in support of one view would require too many resources or effort to counter, and so the matter is claimed settled and the asserted statement becomes “fact”. These inscriptions are created through “bench craft”, whereby scientists and technicians use “tacit knowledge” to carry out experiments and interpret data. Latour investigates the lab as an anthropologist visiting “a strange tribe who spend the greatest part of their day coding, marking, altering, correcting, reading, and writing. What then is the significance of those activities which are apparently not related to the marking, writing, coding, and correcting?” (Latour & Woolgar, 1979, p49).

It is certainly true that science is a socially embedded activity and that its true nature is one of creativity rather than rote discovery. Similarly, all scientific conceptualizations can be regarded only as “temporarily true”, awaiting evidence that may contradict their claim to truth. By Karl Popper’s principle of “falsification”, nothing can ever be proven, only disproved. These interpretations allow for weak constructionism and flexibility in assessing truth claims, yet they maintain the principle that there is an “external” world “out there” that would go on without societies to actively construct them. But what is the added benefit of analysis offered by taking the logic a step further to declare that “entities were constituted solely through the use of these inscriptions”? While this view may be more elegant and simple in a critical theory sense, it strips all nuance from the difference between different asserted statements and takes much of the usefulness out of the social critique. If all facts are merely assertions with an equal probability of being true, how does one decide what to

do in the morning? How does one decide who to love, where to work, how to play?

Relativism seems to deny any assessment of *quality* to statements, yet common logic gives us several criteria for which to judge the quality of truth statements:

Not all theoretical alternatives are equal. Some alternative explanations cost too much in terms of changes we would have to make in other beliefs. Some alternative explanations postulate new objects or properties that we have no other reason to suppose exist, and so the postulation merely to explain this one observational data-set is *ad hoc*. Some alternative explanations increase the structural complexity of the system under investigation over what other alternative explanations do, and so the former explanations run a higher probability of being false. The ways in which competing alternative theories can be unequal with respect to their consequences for methodology, epistemology, and ontology are legion.

(Klee, in Parsons, 2003, p75)

As someone who has worked in biology labs extensively¹, I often see data that make too much sense and are too complex and non-random to explain, unless at least a thousand theories of chemistry, physics, and biology are at least approximately correct. From this perspective, the assertion that most of scientific knowledge is socially constructed seems to be irrelevant and ring of ignorance in light of the mountains of verifiable data that science has produced. Strong constructionist ideas can even “turn off” natural scientist to other ideas and research from the social sciences. Most scientists react to constructivist theories with disbelief, outrage, or a chuckle, and I would venture that extremely few take these ideas at all seriously. While the ideas of “tacit knowledge” and science as a “bench craft” do make some intuitive sense, it does not directly follow that the data that science produces are not reflective of some external reality. It makes about as much sense to suppose that since carpentry skills involve tacit

¹ I have conducted my own stint of 8 years of “participant observation” as a technician in various labs, although I could easily be accused of “going native”.

knowledge and craftwork, the chair produced by the carpenter is also socially constructed, so watch where you sit!

Perhaps the biggest problem with “strong constructivism” or relativism is that it leaves us powerless to debate scientific issues any further, since we have eliminated the means by which we could prove one assertion better or worse than another. Hence, while relativist approaches are often viewed as favoring marginalized peoples by “leveling the playing field” with dominant worldviews, relativism can also work against the oppressed and marginalized, as outlined by Kristin Schrader-Frechette:

Large industrial and technological concerns tend to be imposers of potentially catastrophic risks, while members of the public tend to be potential risk victims. But if risk imposers (chemical companies, for example) are innocent until proved guilty, and if relativism precludes accurate evaluation of harm and authentic proof that someone is guilty of imposing probable harm, then risk imposers cannot be shown guilty and must be presumed innocent. In other words, stopping unjustified or dangerous risk impositions, with a purely relativist framework, is like stopping murders within a crime context in which no one ever finds any bodies.

(Schrader-Frechette, 1997, p7)

It would appear that in addition to any philosophical challenges to the “strong program”, there are also ethical and pragmatic questions of how polluters and fraudulent scientists would be held accountable under a relativist framework. By challenging the epistemological roots of scientific knowledge, strong constructivist critics attack the most difficult and well defended of targets possible, while letting the easy prey (science with explicit and intentional construction of knowledge for gain of money or power) get by with the same verdict as science that is done in the public interest or for pure curiosity.

At least one author has criticized the some of the most common science and technology studies approaches for their often myopic view of science, focusing on

individual scientists and laboratories, rather than the influences of research institutions, corporations and government agencies (Kleinman, 1998). Much of science studies and the sociology of science is focused on actor network theory (associated with Bruno Latour) or social worlds theory (associated with Joan Fujimura). As Kleinmann (1998) points out, both of these approaches are agent-centered, and they suffer from the following weaknesses as a result:

[E]mphasis on agency has led analysts to ignore or underplay the constraints placed on agents in their efforts to act. . . . restricting the analysis to the world as seen by actors may . . . lead us to ignore distributions of resources, for example, . . . that are of no concern to the actor being followed. We may, furthermore, overlook institutional constraints to which actors are not particularly attentive.

(p288)

The emphasis on construction or co-construction of scientific knowledge in the agent centered theories has important impacts for how power is viewed within science. Since the dominant theories emphasize the actions of individuals in constructing their worlds, they are unable to adequately conceptualize many “external” or “structural” forces that are essentially power relations affecting the behavior of agents within the science world. To further clarify the exact distinction Kleinmann is attempting to make between the construction of reality by actors and the subjection of actors to structural power relations that influence their behavior, I will defer to his words in discussing this dichotomy:

Ironically, for analysts who wish not to assume distinctions, this kind of response sets up a dichotomy: structures, actors, interests, and identities must be viewed as either always in the process of construction and reconstruction, or analysts must accept them as already existing when actors arrive on the scene. In the latter case, analysts are accused of reifying the world they are studying. But this is not an either/or issue; a third position is both possible and cogent: structures, interests, actors, and identities are constructed historically, but at any given time, these phenomena have an established character, and this configuration has effects. In the case of structures, human and organizational actors are likely to confront them as “external” and sometimes “constraining”.

(Kleinman, 1998, p290)

In the end, the best approach may be to accept distinctions between “internal” and “external” influence or between “bottom-up” construction and “top-down” construction in our analysis of complex social activities such as science, for as artificial as these concepts might be, to deprive ourselves of their use blinds us to the subtleties of many of the forces that shape the production of scientific knowledge. And perhaps “weak” constructivism is not so weak after all, as it allows us to include funding sources, political, and economic factors in our analysis, rather than being trapped in the endless questioning of epistemologies.

By abandoning the “strong program” of constructivism, we allow ourselves to enter into the full range of discussions about environmental issues. Social structures and scientific knowledge are indeed constructed, but perhaps the best thing to do is to be as explicit as possible about it and wary of potential biases. To those living within society, these constructed bodies of knowledge are experienced as real, just as matter is mostly made up of empty space and energy, yet is quite present and difficult to wish away. While conceptualizing a brick wall as empty space may be more “correct” in a metaphysical sense, it has disastrous implications in the real world. Most important, allowing better recognition of institutional forces in science studies will allow analysts to see the ways in which science is currently actively constructed and perhaps inform policy reforms and other “structural” changes to improve the understanding and use of scientific knowledge, rather than simply criticizing the core beliefs of scientists. It is towards this goal that part of this thesis is directed.

Of course, some will say that the whole system is foul and must be scrapped, and they are certainly entitled to their opinion, but the vast majority of society does not consider science inherently flawed or “broken”. As such, I think it prudent to bring the analytic tools of social and natural sciences together to develop a critique that operates within a rational empiricist paradigm, but focuses on the social and political contexts of science and how these affect the coherence and plausibility within scientific theories and data.

Bringing Values into the Picture

Ethics can be brought into environmental debates by a variety of actors and for a variety of reasons. Most often, policy makers explicitly deny the inclusion of normative assumptions in environmental assessments, claiming to base their decisions on scientific data, technical judgment, and statutory requirements. In practice however, there are several situations where moral and ethical considerations are the true determinants of an outcome, whether this is recognized or not. Three reasons put forth by Paehlke (in Gillroy & Bowersox, 2002) why moral factors can be more important than scientific considerations are:

- (1) many environmental policy decisions involve extrascientific, explicitly moral dimensions;
- (2) there are many significant gaps in our scientific knowledge and decisions cannot always wait on filling those gaps; and (3) science (especially perhaps that science that ventures into the always morally active realm of human activity) is itself vulnerable to powerful political forces that are best understood, in part, on a nonscientific basis.

(p30)

In this view, ethics is seen as something to fill in for science when it is “out of its realm”. For instance, as will be discussed in detail later, no amount of science can

ever tell us what risks are worth taking or how we should balance economic progress with human and ecological health.

The environmental justice movement takes a different approach that seeks to interject ethical and moral concerns into discussion of environmental issues by asserting basic human rights to clean land, air, water, and food. This approach asserts that there is no such thing as “acceptable risk”, partially justified by the well documented fact that the risks of certain activities are distributed very unequally throughout the population, with increased risk often borne by minority populations compared to white suburbia. The highly technical nature in which most environmental science (and especially risk assessment) is presented poses significant barriers to environmental justice’s claim of “the right to participate as equal partners at every level of decision-making including needs assessment, planning, implementation, enforcement and evaluation” (in Frey, 2001, p121-2). The 17 core “Principles of Environmental Justice” are reprinted in Appendix A for reference.

A more subtle method to incorporate ethical discussions into environmental debates is simply to point out the value-laden assumptions in scientific interpretations and risk assessments that claim to be free from such “subjective” influences. Alternative scientific interpretations or statistical evaluations that represent different (and explicit) ethical assumptions can then be used alongside standard assessment methods, hopefully leading to a more ethically informed policy decision.

Proposed Criteria for What Defines a “Good” Environmental Decision

Achievement of sustainability is often used as the criterion for achieving a “good” environmental outcome, yet there are widely divergent ideas as to what this actually entails. Proponents of “sustainable development” often interpret sustainability as uninterrupted, sustainable, economic growth². A broader view of sustainability includes the environmental, social, and political components of the principle. Adger *et al* (2003) propose a model for evaluating the sustainability of environmental decisions based on the maximization and balance of four components in the sustainability equation: economic efficiency, environmental effectiveness, equity, and political legitimacy.

Lack of attention to any of these components often leads to failure for environmental decisions, yet the disciplinary nature of the academy makes it extremely difficult to address all these components at once:

Efficiency, equity, effectiveness, and legitimacy are key integrative elements for examining environmental decision-making across the breadth and range both of positivist and of critical social sciences. No single discipline can claim sole ownership of any one of these issues, though clearly some subjects may place greater emphasis on one or more dimensions than others. For example, economics tends to treat efficiency as a pivotal concept, and political science often focuses on questions about legitimacy. Most of those who participate in environmental decision-making in practice would attest to the interconnectedness of the four criteria. For example, however efficient or effective a decision, things tend to unravel if it seriously compromises equity or legitimacy. In a similar vein, the supposed equity or legitimacy of a decision does not seem to justify its lack of efficiency and effectiveness. Therefore, we need to pay simultaneous attention to the four criteria that challenge the problem-solving capabilities of most decisionmakers concerned with environmental governance and sustainability.

(Adger *et al.*, 2003, p1096-1097)

² Although the “development” mentioned could just as easily refer to human or cultural development.

The practice of land application of sewage sludge will be evaluated according to these four criteria, which I interpret as inclusive of other evaluative criteria, such as alternatives assessment and environmental justice criteria.

Towards a Multidisciplinary Analysis of Sewage Sludge

To really investigate the nature of an issue that includes a lot of involvement from the scientific community, researchers must learn to synthesize both the social critique of science and the more traditional, scientific, critique of scientific knowledge. Of course, in reality, the scientific critique is itself socially constructed (like lab practices, statistical norms, experimental design etc.), so the social critique should be inclusive of the scientific critique, but this is rarely feasible in practice because few social scientists have robust knowledge of natural sciences (of course, the converse is also true). The consideration of ethical and environmental justice principles add another layer to our filter. One more level of analysis should be borrowed from political ecology, by focusing more on institutional and political factors than sociology of science or science and technology studies have tended to in the past. In the following section, I will attempt to show what a multidisciplinary analysis would look like by investigating the scientific, social, and normative issues revolving around the science that is used to determine regulations for toxic chemicals, and sewage sludge in particular.

The framework for the multidisciplinary analysis will draw from the disciplines of toxicology, biology, political ecology, sociology, anthropology, law, environmental justice, and science and technology studies. Social critiques of science will be addressed, focusing on weak constructionist social critique, rather than strong constructionist or relativist, approaches. Special attention is given to the influence of research funding, peer review, research program selection, and control over the production and dissemination of knowledge. "Scientific" forms of critique employed focus on the unscientific nature of the "divide and conquer", reductionist, approach used by regulatory science, separating chemical from chemical, cancer from non-cancer, child from adult, and holding all chemicals innocent until proven guilty. Some distinctions will be drawn between science pursued for research and development, or pure curiosity, and science done for regulatory or public health purposes. Throughout the thesis, the goal is to maintain balance between natural science, social science, and ethical perspectives to these issues.

The issue of sewage sludge will be given some historical and social context, focusing on the different stakeholders and their respective "scientific" claims, as well as the larger-scale regulatory environment which the sewage sludge issue is nested within. The case study of the EPA's 2003 decision not to regulate dioxin-like compounds in sewage sludge will focus primarily on the risk assessment associated with that decision, highlighting important issues such as framing, political pressure, and the value laden nature of most "scientific" assumptions used in the assessment. The disparity between attention given to human health vs. ecological health, as well as the implications of risk assessments' highly technical nature for environmental justice will also be discussed.

The thesis will conclude by taking a step backwards to consider the implications of our case study for the two larger questions posed in this thesis. Firstly, what is the optimal role of science in environmental decision making? And armed with the “answer”, we may be more adept at tackling the more specific and practical question at hand: Is the land application of sewage sludge a good idea as currently practiced, and if not, what are our alternatives?

CHAPTER II

MULTIDISCIPLINARY ANALYSIS OF RISK ASSESSMENT AND SCIENCE-BASED DECISION-MAKING

By integrating the best tools applicable to “brown”³ environmental issues from several disciplines and popular debate, a comprehensive interpretation of the nature of science that is destined for the policy arena can be constructed. This chapter draws on the critiques provided by science & technology studies, political ecology, philosophy of science, environmental sociology, toxicology, policy & regulatory analysis, and the claims of environmental interest groups and trade or industry interest groups.

This chapter will outline the basic structure of risk assessment, and why some discussion of the broader body of scientific knowledge that provides the “inputs” of data for risk assessment is necessary to fully comprehend the nature of the “science-risk-policy nexus” (Webster, 2004). Social, political, and economic influences on science will be addressed, followed by a discussion of the embedded norms and values in scientific conventions and methodologies. The quality and quantity of data available for risk assessment will be critiqued from policy and scientific perspectives. The chapter will conclude by focusing on the specifics of risk assessments as they relate to the framing of environmental issues and concerns regarding environmental justice.

³ As opposed to “green” environmental issues, which are typically based on wildlife habitat conservation & restoration principles. Generally speaking, “brown” environmental issues concern the prevalence of toxins in today’s society, and the unequal distribution of risks and benefits from the use of these chemicals.

Risk Assessment and its Relationship to Scientific Disciplines

Risk assessment is the predominant current “orthodoxy” of science-based decision-making. To say it more specifically, risk assessment is the usual and preferred method in the United States for integrating basic and applied scientific research with the policy realm. The dominance of risk assessment in determining policy decisions is virtually unchallenged in the area of chemical or “toxics” regulation, which is the focus of this discussion. The rise of risk assessment is often attributed to the Supreme Court’s 1980 decision in *Industrial Union Department, AFL-CIO vs. American Petroleum Institute*, commonly referred to as the “benzene decision”. This decision struck down an Occupational Health & Safety Agency (OSHA) standard on acceptable exposure to benzene in the workplaces, ruling that OSHA could only regulate if it found that benzene posed a significant risk of harm. Unfortunately, the justices declined in offering an opinion as to exactly how a *significant risk of harm* should be defined (NRC, 1996). This decision was a strong signal to all federal regulatory agencies that they had better begin evaluating risk as part of their formulation of regulation if they expected to stay out of the courtroom. The benzene decision was in 1980, and the National Research Council study of risk assessment that led to the “Red Book” was commissioned by the FDA under direction from Congress in 1981, and published by NRC in 1983, which approximates the speed of light in the regulatory world.

In the most simplistic terms, and as it is framed by the scientific and regulatory establishment, risk assessment is defined as a method for, or the process of, collecting and evaluating scientific data as to the nature of a potential environmental or human

health hazard and also evaluating any data that would shed light onto the likelihood of humans being exposed to this hazard. By combining the results of these two analyses, the risk assessor produces a statement about the probability that these exposed populations will be harmed, and to what degree (NRC, 1996). This statement usually comes in the form of a number representing probability of harm (quantitative risk assessment). Less often, one sees the use of qualitative risk assessment, where general descriptions of risk or relative ranking of hazards is employed, but no attempt to calculate a risk value is made, usually due to the lack of sufficient data to even approximately “model” the risk. Both kinds of risk assessment are broken down into four stages, as first set forth in the National Research Council famous 1983 “Red Book”, *Risk Assessment in the Federal Government: Managing the Process*. Each step in the process will be briefly discussed as it applies to chemical regulation:

1. **Hazard Identification-** The first step is defining what the harmful substance(s) are that the assessment will concern itself with, what their distribution and concentrations are in the environment, what kinds of toxic effects can be expected from these substances (DNA mutation, oxidative stress), and what types of human disease or conditions (cancer, hypothyroidism) can be expected to result from exposure to these “chemicals of concern”. The data that informs the hazard identification stage typically come from the disciplines of toxicology (mostly animal studies), epidemiology, and general environmental monitoring data acquired by a variety of disciplines.
2. **Dose-Response Assessment-** This step is essentially a continuation of the first step, and sometimes the two together are called “hazard assessment”. Here an

attempt is made to determine the quantitative relationship between the dose (concentration) of the chemical compound and the toxic response, so as to determine what the “safe” dose might be. This usually involves a lot of animal studies, typically carried out by toxicologists. Mathematical modeling can also be used to fit the data to a particular dose-response relationship based on particular assumptions of threshold or linearity.

3. **Exposure Assessment-** Typically “involves specifying the population that might be exposed to the agent of concern, identifying the routes through which exposure can occur, and estimating the magnitude, duration, and timing of the doses that people might receive as a result of their exposure” (NRC, 1996, p26-7). The population investigated, can either be the general public, or a so-called “highly-exposed individual” who is a theoretical person designed to have occupational or lifestyle factors that result in an exposure level far higher than the general public. If the practice being assessed poses minimal or small risk to the highly exposed population, then, it is reasoned, that practice must be “safe” for the general population.
4. **Risk Characterization-** In this last step, information gleaned from the first three stages is integrated, usually through some mathematical modeling of the dosage of chemical presented in the environment, the concentration of chemical that is capable of causing harm, and the exposure of people to that chemical. The final output of a risk characterization section of a risk assessment is typically something like, “the proposed activities would result in an incremental risk of 1 increased death by cancer per million people”.

These four steps described above together compose what is referred to “risk assessment” as it is conceived of in the NRC reports, but we have not yet gotten to the point of explicit environmental decision making. The NRC goes to great lengths to separate out the activities of decision making from the more “scientific” process of environmental assessment. The NRC reports codify this separation by drawing a boundary between the activities of risk assessment and activities of risk management, which include the development of regulatory options, evaluation of these options, and any final agency decisions or actions. Figure 1, reproduced from the 1996 NRC report, *Science and Judgment in Risk Assessment*, illustrates how the NRC views the distinction between risk assessment and management, as well as drawing another distinction between risk assessment, and the experimental research that provides the input data for a risk assessment model.

Figure 1. Outline of risk assessment and management components in decision making processes. Reproduced from *Science and Judgment in Risk Assessment* (NRC, 1996, p24)

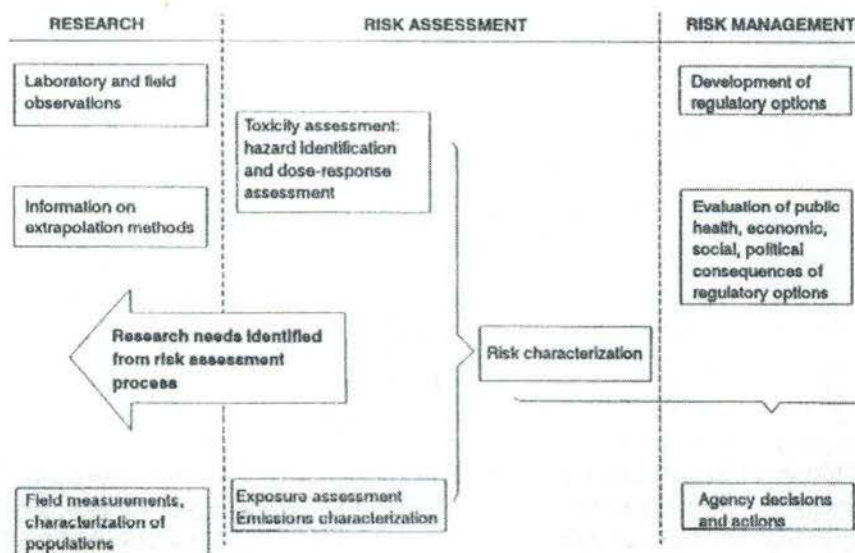


FIGURE I-1 NAS/NRC risk assessment/management paradigm. SOURCE: Adapted from NRC, 1983a.

As can be clearly seen in this diagram, the NRC views risk assessment as spanning the gap between the basic knowledge products of scientific research and the political and ethical sausage-making of the policy world. The NRC defines risk management as

[T]he process by which risk-assessment results are integrated with other information to make decisions about the need for, method of, and extent of risk reduction. Policy considerations derived largely from statutory requirements which dictate the extent to which risk information is used in decision-making, and the extent to which other factors—such as technical feasibility, cost, and offsetting benefits—play a role”.

(NRC, 1996, p28)

However, as much as the NRC committee would like to separate policy making from scientific interpretation, it is recognized that there are areas of scientific

uncertainty where there is no compelling reason to choose one way of conducting the assessment over another, and this will necessitate what the committee dubs a “science-policy choice” (for example- in regard to what dose-response model to use or what health endpoint will be the “critical effect”). While claiming that “science-policy choices are distinct from policy choices associated with ultimate decision-making”, the NRC admits in the very next sentence that “the science-policy choices that regulatory agencies make in carrying out risk assessments have considerable influence on the results” (NRC, 1996, p27). It is mostly these so-called “science-policy decisions” that will be examined in this thesis.

First, we should turn our attention to the left third of Figure 1, and examine the role of basic and applied science in creating the raw data that is fed into these sophisticated mathematical models of risk. The fat arrow drawn backwards from risk assessment to research which states “research needs identified from risk assessment process” is considered by some to be more of a hypothetical relationship, as the EPA and other regulatory agencies have very small research budgets compared to a pure research institution such as the National Institutes of Health (NIH). The labels given in the figure for types of research are extremely general, but the basic idea is that no risk assessment can occur without the underlying toxicology and exposure data that is fed into these models. Hence, we cannot have a truly frank discussion of risk assessment, without taking at least a cursory look at how the underlying science is produced and discussing its quality and claims to objectivity. We have now heard the official version of what risk assessment is, and the role of science should be in decision-making, but what of the other disciplines that have been brought under our pluralistic tent? There is

a wide range of opinion regarding the objectivity or relativity of scientific claims. In the following sections, I will attempt to focus on perspectives of science that offer a chance to improve scientific interpretation, rather than deconstructing it fully. This approach is purely pragmatic, as science is bound to be used in decision making for the foreseeable future. The question I pose is whether risk assessment is an appropriate and effective mediator of science's interaction with policy. Our multidisciplinary toolbox will hopefully help untangle this question.

Social and Political Critiques of Science with Policy Implications

This section will gradually shift its analysis from academic to popular and from social to political. Academic social constructionist views of science will first be presented, followed by more popular versions of social & political influences on science, including the effects of peer review, funding sources, fraud, suppression of science, and politically motivated scientific reviews. The section will conclude with a discussion of the essential contradictions between the worldviews of policy makers and those of scientists.

There is a vast body of work regarding the social and political nature of scientific knowledge, much of it accumulated by the disciplines of Science & Technology Studies, Political Ecology, and Philosophy of Science, among others. The most critical and in-depth critique of science as a system of knowledge has probably come from Science & Technology Studies (commonly referred to as STS). An extensive review of the field is the *Handbook of Science and Technology Studies* (Jasanoff, Markle, Peterson, & Pinch, 1995). There are several issues raised by STS

that could be beneficial in assessing the usefulness of science in environmental decision making, despite the relativist roots of much of the thinking criticized earlier. Useful concepts for toxicology include experimenters regress, boundary work/creation, blindness to lay or local knowledge, laboratory "purification" of nature, the "shop work" nature of science, and the process of translation.

Much of this research effort has been exerted in revealing universal uncertainties and biases within the core of the scientific method, by focusing on "hard science" disciplines, such as physics and molecular biology (with the notable exception of political ecology). Even these investigations have shown key differences in how social and natural relationships are manipulated between these two disciplines (Knorr Cetina, 1995). This strategy of focusing on the core values of science is questionable, especially since much of this area is covered by discussions of the philosophy of science. Since common sense and much empirical evidence points to key differences between the levels of construction in different scientific disciplines, I believe that STS would benefit from refining its analysis to differentiate between the amount of sociopolitical influence in disciplines such as toxicology, versus their traditional subjects of physics and molecular biology⁴. Toward this end, I will briefly discuss how the above-mentioned key lessons from STS can be applied to toxicology

⁴ One attempt to extend some of the critiques of STS to a particular scientific discipline was undertaken by Tim Forsyth in his book *Critical Political Ecology: The Politics of Environmental Science* (Forsyth, 2003), in which he integrates several different social science viewpoints in a critical analysis of the creation of scientific "fact" in ecology. Ironically enough, Forsyth's outlook seems to swing the pendulum too far in the other direction, as ecology is the extremely peculiar situation for a scientific discipline as being associated with and perhaps born out of environmentalist ideologies. While it certainly owes its growth as a discipline to environmental concerns, toxicology and risk assessment have been developed typically as a response of government and corporations to environmental concerns of the public or a small minority of scientists (often ecologists!). Therefore, while many of the theoretical frameworks for discussing social and political influences in science are equally applicable to toxicology

One of the basic principles of scientific inquiry is verification of data by the replication of experiments, preferably by independent laboratories. Of course, the amount of actual verification varies greatly. Toxicological studies are rarely repeated due to the large budgetary requirements (and ethical questions of animal use) of even the most basic toxicological assessment (Purchase, 2004). When toxicological studies are repeated, they may not exactly agree, which can lead to “experimenter’s regress” (Collins, 1985, p2). As the issue is discussed by Steven Yearley:

The “correct” results are, by definition, the ones produced by the better test, but there are no independent means of determining which test is better unless the “correct” outcome is known in advance. This problem is bad enough in “pure” science, where the reasons for distrusting others results are disciplinary or occasionally personal. In disputes over environmental safety, huge commercial and political motivations may also be involved, creating further incentives for discrediting the opposing side’s claims to scientific knowledge.

(Yearley, 1995, p465-6)

While most toxicological studies are not repeated, there are certainly cases (research regarding bis-phenol-A comes to mind) where different studies have come up with different results and much bickering has ensued over the respective designs of the studies, differences in how the studies were carried out, and even accusations of outright fraud or “pollution” of the scientific literature (Purchase, 2004).

Boundary work refers to the construction of conceptual boundaries around what is conceived of as scientific knowledge. This can be used to separate “pure” science from “activist” science, or in the case of the NRC report, to separate risk assessment from risk management. Agencies such as FDA and EPA draw boundaries around the types of experimental data that can be considered when they assess new chemicals.

and ecology, the answers that these types of analysis yield are often diametrically opposed. While ecology is often influenced by non-governmental organization (NGOs) or current conservation and environmentalist paradigms, toxicology appears to be shaped more by the negotiations between corporations and the governmental agencies charged with regulating them due to legislative mandate.

This means that much of the cutting edge science of the day is not used in the regulatory arena, as regulators typically prefer to wait for new methods to “prove themselves”. EPA also draws explicit boundaries around environmental problems simply by the act of carrying out a risk assessment, a point which will later be explored in depth.

Another criticism of science that comes out of both STS and political ecology is the inability or unwillingness to integrate local and lay knowledge with scientific interpretation. For scientists, the ultimate goal is to discover some universal law of nature, equally applicable in all environments, such as the law of gravity. But the real world happens in local places, with local conditions and past histories. The goal of “universalism” is merely a goal, and any abstract scientific information must always be integrated with some type of localized, “on the ground”, knowledge in order to be useful (Yearley, 1995).

A sub-field of STS, laboratory studies, has pointed to the process of “purification” of nature that occurs in the lab. Practices such as the breeding of inbred strains of animals to control for the variable of genetic variation, storage in cage on regular 12-12 day/night cycles, and numerous other impositions of the social order upon the natural order, call into question whether discoveries in the laboratory can truly be applicable to the “natural world”. While a scientist might call a certain genetic strain “wild type”, it is still a genetically homogeneous population that bears little resemblance to a genetically diverse “wild” or “natural” population (Knorr Cetina 1995). Curiously, the critique of an experiment a sociologist might base on “purification” grounds often occurs within natural science communities as a critique of

the proper methodology to control for variables while approximating a realistic scenario.

Many in the field of laboratory studies take the strong constructionist view of the creation of “fact” in laboratories, claiming that there is nothing special about scientific knowledge as opposed to other forms of knowledge. If that is what you interpret laboratories as doing (creating facts), then it is understandable that you would point out the social influences and negotiations between scientists to determine what can be considered “fact”. However, in my opinion and experience, scientists themselves do not treat the word “fact” lightly. Much of the work involved in designing an experiment is focused on identifying potential sources of bias and attempting to minimize their effects. When scientists publish their findings in a scientific journal, they are publishing them in the context of being a laboratory, and in many cases, fully knowledgeable of all of the limitations that this places on their conclusions. Yet scientist accept these trade-offs of the “situated-ness” and artificiality of their findings in exchange for the power of discovery that holding most variables relatively stable allows. Scientists are trained to ask nature extremely specific questions because that is the only way to get an intelligible answer. When they publish findings, they are not claiming the creation of new facts, but rather adding to the body of knowledge, all of which is open to question at all times upon the discovery of new information or perspectives. The attitude above refers to the discipline of molecular biology in particular, but the same may not be true of toxicology, which is much more politically charged and has larger economic and social implications. A single toxicology study can

result in thousands, millions, or even billions of dollars in expenses for complying with stricter regulations.

Much of the laboratory studies criticisms of science focus on the inherent uncertainty and place-dependency (or “situated-ness”) of scientific knowledge. In addition, these theories highlight the limits of reductionism and the view of science as an iterative process by which it is actually very difficult to produce truly “new” knowledge, since every theory and experiment is simply the progeny of one which came before it.

In regard to toxicology, I would be inclined to consider the inherent uncertainty and place-dependency to be somewhat irrelevant at this stage of analysis, since science conducted within a standard animal toxicology lab is perhaps equally uncertain and place dependent all around the world, since the artificial lab environment and use of inbred animal strains and standardized diets are specifically designed to eliminate differences in place, time of year, diet, etc. In actuality, the scientist is simply making a trade-off between the place-dependency of results and the risks of increasing “purification” of nature. So while results from a toxicology lab may be equally valid from laboratory to laboratory around the world, this doesn’t necessarily mean anything in terms of the results’ validity compared to the external reality.

While these issues of inherent uncertainty and place-dependency of knowledge would be valuable for a complete deconstruction of science, my pragmatic approach seeks only to break down science far enough to enable assessments that help discern “better” science from “worse” science, and science that isn’t really science at all. In my opinion, one of the biggest faults of science studies is its unwillingness to allow for

different levels of inherent uncertainty between different scientific disciplines. The baseline level of uncertainty is very different between particle physics, organic chemistry, toxicology, and population ecology. And besides, if we confine our argument to inherent uncertainty and “situatedness” of knowledge, thereby making any generalizing principles between places impossible, how do we then approach environmental issues? Do we have the resources to look at each local problem individually, without trying to draw generalizations that allow us to apply the lessons we learn to other contexts? If we accept that some science is more accurate than other science, we can critique methodologies and participate in the creation and design of studies.

The issue of science as an iterative process is a significant one, and one that leads into the next level of analysis, the institutions of science. The fundamental nature of science as an iterative process is exemplified by the system responsible for both the awarding of research grants and the approval of papers for publication: peer review.

Peer review is a system where the work of scientists is evaluated by their “peers” to determine if it is worthy of funding in the case of proposals and worthy of publication in the case of scientific papers.⁵ Peers are typically people in the same field as the person under review and expected to be familiar with the issues addressed in the paper/proposal, so scientists are often reviewing either allied or competing labs’ work. Some believe that this can result in certain labs becoming dominant in their fields and suppressing other labs’ work, or less explicit means of entrenching a discipline and not

⁵ Review of government agency science documents and risk assessments is a third kind of peer review that is quite different from the first two and is not directly related to science as an iterative process but has other concerns which will be addressed later.

encouraging new and innovative ideas or research. This may be especially true in toxicology due to the need to standardize research methodologies across labs to enable reasonable cross-comparison of results.

Toxicology also has institutional factors that help to entrench the methodologies of the discipline, despite their shortcomings, which will be discussed later. EPA gets most of its toxicology data from the companies that produce or use the chemicals in question, and EPA requires certain standardized studies to fulfill data requirements for registering a new chemical. If a company develops a toxicity assay (experimental procedure) that has better performance than the standard assay, they have little incentive to develop it, because the EPA frequently refuses to consider non-standard assay data in developing regulations for legal reasons.

Peer review has also been shown to have problems with gender and institutional biases (big universities over small) (Mainguy, Motamedi, & Mietchen, 2005). In addition, one study of grant peer review showed decisions to be highly influenced by such seemingly mundane factors as the voting methods of the committee (i.e. 1 person-1 vote vs. 1,2,3 rankings) and whether they used a fine (1.0-5.0) or rough (1-5) grading scale for pre-evaluation of proposals (Langfeldt, 2001). Henderson (2001) asserts that the underfunding of university libraries (which have had to drastically cut journal subscriptions) has led to a decrease in the quality of peer reviews because the turn around time for an average peer review is two weeks, while the average turn-around time to get a secondary reference on the paper through the inter-library loan desk was 16 days. Thus, most papers and grant proposals are probably peer reviewed without many reviewers checking on their references or having time to become familiar with the

body of knowledge in that specific field, and this can lead to unnecessary replication of experiments at great expense (Henderson, 2001).

Despite all these problems, few have proposed any alternative system that could solve these issues, and peer-review continues to be the “gold-standard” by which scientific data is judged. However, not all scientific knowledge undergoes peer review, and despite its biases and problems, it is certainly better than no quality control at all. Some sort of science bureaucracy could perhaps be in charge of reviewing, but this would surely be political as well and likely have even more problems. In assessing any environmental issue, it is usually a good idea to see what the evidence says when all of it is included, but then also make sure that the story is not significantly different when only peer-reviewed studies are included. The interaction of the peer review institution with the world of toxicology and how toxicological science is used to influence and determine policy is perhaps most notable by its relative absence compared to more “basic research” forms of biological sciences, since only a small portion of toxicological research is published in peer review journals.

Most of the studies on chemicals’ potential harm to health have been performed by the manufacturers (or by private labs under contract with manufacturers) of those chemicals due to the political and legal context of environmental regulation. All of the laws requiring testing of herbicides, pesticides, food additives, pharmaceuticals, and every other chemical used in our country dictate that the majority (usually all) of the required data be provided or paid for by the manufacturer. So while virtually all toxicology research performed at academic institutions is published, this amounts to only a fraction of the total body of toxicological knowledge, since the much larger body

of toxicological knowledge produced by private sector scientists is not available to the public (although much of it is shared with regulatory agencies).

While there is generally no peer review of this data, there are independent audits of industry and private labs and strict enforcement of Good Laboratory Practices (GLPs) and record keeping requirements, set by regulatory agencies such as the FDA and EPA. The GLPs include requirements on study design, proper statistical analysis, and numerous other experimental practices that could influence results (Purchase, 2004). It is perhaps important to note that this was due to the discovery of widespread abuse and falsification at contract private labs in the 1980s. Implementation and enforcement of the GLPs is generally credited with virtually eliminating outright fraud within the field of toxicology, although how this claim could be verified is uncertain.

The law that gives the EPA authority to regulate non-agricultural chemicals, the Toxic Substance Control Act (TSCA), is a perfect case study of institutional barriers and boundaries around scientific knowledge. The EPA's power to request testing for new and existing chemicals is subject to judicial review under the "substantial evidence" standard. This legal standard is much higher than the normal standard for an agency's rulemaking to not be "arbitrary and capricious", and it leads to a circularity that halts scientific inquiry, whereby "EPA must provide evidence of unreasonable risk or substantial exposure to request information to evaluate whether there is an unreasonable risk" (Powell, 1999, p88).

The fact that the EPA was cobbled together by the Nixon administration out of 12 existing offices in other agencies has significant institutional effects as well. Often more than one Office within the EPA will have jurisdiction over the same

environmental issues. This has led to situations where one office is trying to make regulation more stringent, while another office is taking action to relax standards at the same time.

The question of the impact of funding sources on the outcome of scientific research is one that I think should receive more attention from science studies since it offers such rich potential for actually seeing true construction of scientific knowledge. Forsyth (2003) discusses the co-construction of knowledge between environmental organizations and ecological science, but the frequency of this co-construction is virtually insignificant compared to the continuous, explicit, institutionalized co-production of knowledge by industry and the field of toxicology. There have been a handful of studies showing high correlation between favorable reports on pharmaceuticals and herbicides coming from manufacturer-funded research while most independently or publicly funded research was on average neutral or found the chemicals ineffective or hazardous (as cited in Rampton & Stauber, 2002; Rosenstock & Lee, 2002). Some investigative journalists have even found cases of scientists signing their names to papers ghost-written by employees of pharmaceutical companies (Rampton & Stauber, 2002). Even within academia, researchers that receive a portion of their funding from industry are more likely to withhold data from publication for patent reasons or to delay the release of unfavorable data (*ibid*).

The issue of withholding data is even more pernicious with regard to studies done by industry itself, since they are under no compulsion to release data. Although, in some cases they are supposed to, as in Section 8(e) of TSCA which requires that

industry report any studies that reasonably support the conclusion that existing chemicals pose a substantial risk. Industry's behavior was less than forthcoming:

From 1977 through 1991, however, industry had submitted only 1,350 Section 8(e) notices to EPA. Suspecting that companies were not complying with the Section 8(e) requirement, the agency established a voluntary audit program that allowed companies to submit studies they should have provided to EPA earlier at reduced penalties. One hundred twenty three companies submitted more than 11,000 toxic effects studies and were assessed over \$20 million in penalties.

(Powell, 1999, p89)

In addressing the issue of funding sources in science, the most important goal should be full disclosure of all financial interests by all scientists. It is impossible to incorporate the influence of funding sources into the analysis of an environmental issue unless that information is freely available. While we should avoid judging science based solely on its funding source, perhaps industry studies which are used as important benchmarks for policy decision should be subject to third-party peer review, or even verified by independent researchers. Industry could pay into a fund that was administered independently to disburse funds for third-party review. While this would be an added expense, the increased goodwill and public trust in industry-produced scientific data would potentially be well worth the increased costs. Perhaps companies would be able decrease their expenditures on public relations and other "damage control" operations.

The issue of funding source is more complicated than one of simple industry bias however. All researchers are competing in a milieu of research funding opportunities, with government, charities, private foundations, and industry, all providing significant funds for research and each of them coming with their own set of biases. Research programs are decided by government agencies and the funding

priorities of government are arguably the single most influential determinant of academic research focus. Just look around and compare how many labs there are specializing in bioterrorism related projects compared to how many there were on Sept. 10, 2001.

What science gets done and what doesn't is determined by a combination of congressional action, scientific peer review, and the priorities of funding institutions. This level of analysis is perhaps the most complex and the most important. The evolution of research "programs" is sometimes accidental and sometimes planned. In the case of toxicology, one sociologist has researched how the National Institutes of Environmental Health basically created the discipline of Toxicogenomics from the ground up to serve as an eventual successor to more classical toxicological research (Shostak, 2005).

While many of the social science critiques of natural science sound almost absurd in regard to physics and molecular biology, these ideas are much more plausible when considering the field of toxicology. Co-production of knowledge is certainly occurring between industry and toxicology. The institution of peer review, which is generally regarded as science's primary method for determining the quality of research, is essentially non-functional in regulatory toxicology, having been replaced by the GLPS. The effectiveness of the GLPs in eliminating fraud is often touted, but few studies have been done to attempt to confirm this assertion. Institutional influences on the field of toxicology are felt clearly through the availability of funding opportunities. In short, while the social and political nature of physics can be a matter of some debate, it is difficult for one to argue that toxicology upholds "pure" science ideals in the face

of such enormous political, economic, and social pressure. The field of toxicology is perhaps also unique in that much of its research program is due to policy needs, legal mandate, or commercial considerations, rather than theoretical explorations of scientists. This brings us to the final focus of our social analysis, which necessarily blends a bit with scientific analysis.

The interactions between the worlds of scientist and policy makers are often a source of tension and conflict due to different ideologies and career needs. Choi *et al* (2005) created stereotypical parodies of the policy-maker and scientist to illustrate their different worldviews and career needs. Scientists are generalized as having target goals of “publications, patents, and professorships” and seek to become a “Dr/Prof/Expert” in a specific field, while policy-makers are more driven by political correctness, have targets of “policy, practice, and people”, and seek to become a “Mr/Ms Fix-it” across a wide range of policy arenas. These differences are manifested by a “lack of mutual trust and respect, different views on the production of and use of evidence, different accountabilities, and [different views on] whether there should be a link between science and policy” (Choi et al., 2005). The issue of different time scales in the two careers is central. Policy makers want science that is timely to legal and political demands and have less tolerance for uncertainty, while scientists generally see uncertainty as simply a delay awaiting the appropriate experiments and caution against rashness in drawing conclusions due to the risks of traveling down an incorrect research path. The general criterion for scientific “significance” of an effect in most experiments is a 95% certainty that the observed effect was not due to chance. Most results will have to pass this test as a bare minimum if they wish to survive peer review and make it

to publication (which constitutes an institutional bias towards positive results). This fairly conservative criterion is necessary due to the iterative nature of science. Once a mistake is made in falsely accepting a result, much future work will be erroneously conducted, which could entail a huge waste of scarce time and resources for the scientist. For scientists, then, it is better to wait for "incontrovertible" proof rather than take a chance on being wrong. Policy makers do not have the convenience of being able to wait a problem out. The political nature of the issues they are tasked with resolving requires immediate attention and (sometimes) speedy resolution. In addition, when implementing proactive legislation such as the Endangered Species Act, agencies are legally bound to use a standard of "preponderance of the evidence" or 51% certainty. In the legal decision *Ethyl Corp vs. EPA* (DC Cir. 1976), Judge Wright wrote:

While awaiting [95%] certainty may constitute the typical mode of scientific behavior, its appropriateness is questionable in environmental medicine, where regulators seek to prevent harm that often cannot be labeled "certain" until after it occurs . . . Where the statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge . . . we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served.

(as quoted in McGarvey & Marshall, 2005, p75, footnote 3)

Despite the spirit of environmental regulations in their original, precautionary, forms, the current trend is to bend policy decisions towards the conservative standards of proof of science, with the presumption that a substance is "innocent" until proven "guilty". This trend is most typified by the current practice of performing external scientific reviews of science-based policy documents, which exerts even more pressure on the strained relationship between the policy and science worlds.

These reviews are a third type of “peer review” whereby panels of scientists with a wide range of expertise in fields deemed pertinent to the issue at hand are assembled to review a broad body of scientific data and suggest revisions to the policy document or risk assessment. The outcomes of these reviews are subject to influence due to possible conflict of interests with panel members, as well as limitation of the scope of inquiry due to the framing of the “charge to the panel” (directions specifying which specific scientific issues should be reviewed, and which alternative approaches should be considered). The charge to the advisory review panel is often written by White House officials or other political appointees. Some policy makers have expressed concern that the emphasis on external review “encourages the tendency to treat official science advisory review as a forum for negotiating regulatory decisions” (Powell, 1999, p141). Scientific advisory review also presents a different kind of science that bears little resemblance to idealized “scientific method” stories about how knowledge is created. Herrick (2004) brings up one such peculiarity when he writes, “When acting in a policy context, scientists are not responding to questions that they have chosen—in contrast to their research. Consequently, they are forced to transgress the limits of their competence” and are also forced to “transgress the boundaries of scientific disciplines” (Herrick, 2004, p425). Herrick argues that scientific data are effectively “policy neutral” and that a vast array of interpretations can accommodate the same data. He suggests the analysis of a policy proposal’s “narrative coherence”, a technique used in literary criticism, as a superior way to judge the overall “soundness” of a science-based policy, as opposed to an evaluation based solely on competing scientific interpretations.

The practice of peer review of science-based policy can also serve as a tactic to delay the implementation of regulations or science policy that would effect regulations. This is a knife that cuts only one direction, against environmental regulation, since there can be no policy review if there is no proposed action (Houck, 2003). This has certainly been the case with the health reassessment of dioxin, which began in 1990, and was supposed to finish up its second external peer review (which was forced by congressional mandate in 2000 at the behest of industry lobbyists) in January of 2006. Many observers have commented that the goal of industry appears to keep the dioxin reassessment going on indefinitely, thereby avoiding regulations based on the newer science as long as possible (Neff & Goldman, 2005).

In summary, the use of science in policy making is less than straight-forward and involves balance between policy-makers' desire for science that is timely, certain, and relevant to their policy concerns, while scientists want science that is novel, significant, and "high impact". At the heart of this matter is the difference between what amount of evidence constitutes "certainty" and what constitutes enough evidence to take regulatory action. This brings us to the scientific critique, where we assess the nuts and bolts of science destined policy, beginning with the basic biases and normative assumptions of scientific methods and statistics.

Embedded Norms & Values in Scientific Conventions & Methodologies

This section will seek to address the implications for toxicology of the biases inherent in the systematics of scientific inquiry as well scientific problems with more specific concepts of toxicology science. Many members of the concerned public have

bemoaned the EPA's "innocent until proven guilty" stance towards potentially harmful chemicals. While commonly thought of as a political and legal issue, this principle has its foundations in the most basic rules for experimental design and hypothesis testing. For virtually every experiment, scientists are setting up a binary situation to help inform a choice between two hypotheses, the null hypothesis (H_0) and the alternative hypothesis (H_A). The null hypothesis states that there is no effect of the treatment or no difference between experimental groups, while the alternative hypothesis is the assertion of some effect, change, or difference between groups. It is virtually universal scientific convention that in any test of statistical inference, the H_0 always receives the benefit of the doubt while H_A bears the burden of proof (McGarvey & Marshall, 2005). This is the basis for the "innocent until proven guilty" status of chemicals, yet this is not a case where the principle is actually "scientific", rather it is based on simple convention and daily practice. There is no reason why science when applied to health or ecological issues shouldn't be required to have the burden of proof fall on the null hypothesis, as would be more in line with the supposedly more precautionary missions of regulatory agencies. In effect, this is what the European Union's REACH⁶ program may attempt to accomplish.

Scientists talk about this choice of convention in terms of type I and II errors. Type I error is to say there is an effect when in fact there is none (wrongly accepting H_A), while a type II error is to say there is no effect when in fact there is (wrongly accepting H_0). Science shows an extreme preference for avoiding type I errors at all cost, as it seeks to avoid having to backtrack through previously done work to correct

⁶ Registration, Evaluation, and Authorization of Chemicals (REACH)

past mistakes. Type II errors will typically be revealed through further research.

Agencies such as EPA, however, are obliged to ensure against type II errors for the sake of public health. This leaves policy makers and scientists on opposite sides of the fence. There is a trade-off between type I and II errors, whereby to minimize the chance of one is to maximize the chance of the other (Crane & Newman, 2000; McGarvey & Marshall, 2005; Cranor, 1990). Hence the two cannot be controlled within the same system, but one could envision a world where basic research was conducted under a regime to minimize type I errors, and regulatory science was conducted with conventions that would minimize type II errors.

The third potential error in scientific investigation is ignorance, or type III errors, whereby the researchers are asking the wrong question or improperly framing the question due to insufficient knowledge (De Marchi, 2003)). There is no way to control this error other than stringent application of the precautionary principle, perhaps not allowing any new chemicals or products into society until they are proven safe. The potential for Type III errors in regard to the study of sewage sludge is a significant concern. If the chemical composition of a sludge is mostly unknown, with what confidence can we say that it is safe?

The uncertainties of a particular scientific analysis can be statistically analyzed, based on calculating the percent chance of error for each hypothesis, including the null, as was demonstrated by McGarvey and Marshall (2005) in their analysis of the NRC's report on endangered sucker-fish and the effect of the water level in Upper Klamath Lake in Oregon. Their analysis of the Klamath River Basin crisis highlights the essential principal that "in science, *failure to demonstrate that a given theory is true*

does not prove it to be false” (McGarvey & Marshall, 2005, p79). The NRC’s report concluded that there was not sufficient scientific basis to assert that diverting water from Upper Klamath Lake (UKL) to provide irrigation water for Klamath Project (KP) farmers had a significant negative effect (read 95% certain) on endangered fish. However, by analyzing both hypothesis and the statistical power of the studies used in NRC’s report, McGarvey and Marshall show that “while scientists are only 32% certain the KP is having a significant, negative effect on endangered fishes in UKL, *they are only 2% certain that it is not*” (2005, p82).

This was done, in part, by analyzing the statistical “power” of the data, which is a function of the criteria for claiming a significant effect (i.e. 95%), the sample size (number of data points per experimental group), and the “effect size” (the real magnitude of the difference between experimental groups). A study that is trying to observe a very subtle effect and is using a small number of samples may claim to have seen no effect of a toxic chemical at a certain dose when in fact the calculated “power” of the study was so low that it would have been impossible for them to detect any effect unless it was extremely strong.

Cranor (1990) gives a detailed account of the norms and ethical questions raised by setting criteria for designing studies and evaluating the results. He explains how different criteria for the probability of Type I error (α), probability of Type II error (β), sample size (N), and the “actual” size of effect or risk (δ) one is attempting to detect, carry embedded values along with them. This can range from the obvious practical and economic limits to sample size in a study, to the more subtle interplay between the “risk of error” and “standards of proof” that occur by adopting different balances between

α and β . A major portion of Cranor's paper is devoted to illustrating the "mathematical incompatibility of simultaneously protecting against small chances of false positives and false negatives, the mathematical impossibility of both doing good science and good regulation when scientific evidence depends upon the statistics of small samples" (Cranor, 1990, p177). In other words, if society really cared about getting the right scientific answers, it could only be done with very large and expensive studies to bring the sample size up to the appropriate level to detect very small effects. This would be a tremendous waste of resources compared to simply spending that much less money on science and more on implementation and monitoring of the chosen environmental management strategies.

The upshot of all of this discussion of statistics and scientific convention speaks back to our discussion of the distinctions between policymakers and scientists. The criteria for acceptable "risk of error" and "standards of proof" which are appropriate for basic scientific research are not necessarily the best fit for science that is to be used in the regulatory arena. The chosen standards of proof represent value judgments of how important it is to know something with a given certainty or what degree of protection public health should be afforded. Of course, since many of these criticisms apply to the statistical analysis of experimental data, one could go back and re-analyze pre-existing data using various balances between risks of Type I or Type II error, depending on the statutory requirements or "standards of proof" of the law encompassing regulation of the particular substance. This would likely result in many chemicals that were previously declared "safe" now being considered a significant risk, at least in the legal sense.

Data Quantity and Quality in Regulatory Science

As mentioned earlier, there are significant legal restrictions on EPA's ability to obtain information regarding chemicals of concern. This section examines just how much data is available on potentially toxic compounds, and also attempts to assess the quality and reliability of the data.

The main statute dictating the regulation of non-agricultural, non-pharmaceutical compounds is the Toxic Substance Control Act of 1979 (TSCA). TSCA set different standards for chemicals already in commerce at the date of its enactment than for new chemicals. Companies are required to provide "premanufacture notices" on new chemicals, which include expected production volumes, chemical structure, and other basic chemical information. Toxicity and exposure analysis are typically not included in premanufacture notices (GAO, 2005). The information from these notices is typically fed into structure-activity and fate-transport models⁷ that compare the new compound with similar compounds to predict the toxicity and how the compound might behave in the environment. If these screening procedures raise "red flags", then further testing by the manufacturer is required. EPA has reviewed more than 40,000

⁷ Structure-activity relationship (SAR) modeling programs take the basic chemical structure of a compound and predict several chemical properties that effect the behavior of chemicals in the environment and organisms, such as melting point, volatility, Henry's Law constant, preference for association with fats and organic molecules vs. preference for water solubility, etc. These predicted values, along with the three-dimensional shape of the molecule and any similarities to known chemicals, are used to attempt to predict the potential for toxicity. The accuracy of these models is a matter of contention (Helma, Kramer, Pfahringer, & Gottmann, 2000). Fate and transport models take data (either modeled or empirical) about the relevant chemical properties (some of which are mentioned above) and plug it into mathematical models of hydrological flows, precipitation models, decay models, and many other mathematical models of reality in an attempt to predict how a chemical will "partition" into the environment. In other words, will this chemical or its degradation products end up in the land, the water, the air, in organisms, or do they breakdown fully.

substances as new chemical submissions, of which, about 20,000 were eventually approved and manufactured (GAO, 2005). However, there are currently 82,000 chemicals in the TSCA inventory of chemicals potentially subject to regulation, so what of the other 62,000 chemicals?

As mentioned above, TSCA's standards for new chemicals are quite different than those for the 62,000 chemicals that were already in production when the law was enacted in 1979. As summarized in the recent GAO report on the limitations to EPA's implementation of TSCA:

TSCA authorizes EPA to require chemical companies to develop test data only when the agency finds that a chemical (1) may present an unreasonable risk of injury to health or the environment or (2) is or will be produced in substantial quantities and (a) there is or may be significant or substantial human exposure to the chemical or (b) it enters or may reasonably be anticipated to enter the environment in substantial quantities. EPA must also determine that there are insufficient data to reasonably determine or predict the effects of the chemical on health or the environment and that testing is necessary to develop such data. EPA has used its authority to require testing for fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979.

(GAO, 2005)

The concept of "reasonable risk" has been interpreted by the courts to "require the EPA to balance potential hazards against costs in determining which substances would be regulated" (Neff & Goldman, 2005, pS83). These legal standards have been difficult for EPA to meet, as is evident in its only gaining information on 200 out of 62,000 potential chemicals. In terms of assessing the quantity of toxicological data available under TSCA, it is immediately clear that 60,000 of the 82,000 chemicals potentially subject to regulation under this law have virtually no information regarding their relative safety or behavior in the environment. The European Union's REACH proposal seeks to address many of these knowledge gaps by requiring toxicological data on all compounds, with different levels of data requirements based upon the amounts of

the chemical manufactured or used in commerce. With the increased globalization of many corporations, REACH may have far-reaching implications for US regulations as well, and US industries and the Bush administration have launched a vigorous lobbying campaign against REACH within the EU (Thacker, 2005).

It should also be noted that virtually all of the laws regulating chemicals only cover chemicals that are being manufactured. There are few regulations to cover compounds that might unintentionally be created by reactions with approved chemicals. Nowhere is the importance of this omission more noticeable than in the investigation of the chemistry of chlorine. The implications of the production of literally thousands of uncharacterized organochlorine molecules by the processes of chlor-alkali production, pulp and paper production, and water disinfection, are discussed in detail in *Pandora's Poison: Chlorine, Health, and a New Environmental Strategy* (Thornton, 2000). Thornton argues that the production of these masses of unknown organochlorines is especially a matter of concern since the vast majority of organochlorine molecules investigated have shown negative effects on living systems. As a simple, lay method of analyzing the toxicity of organochlorine compounds, it is worth noting that many organochlorines are found among disinfectants, herbicides, and pesticides (chemicals that kill things), while very few organochlorines are found in nature or among pharmaceuticals (chemicals designed to heal or help).

Having firmly established that the quantity of data available is probably less than would be desired if one was attempting to ensure the safety of the American public from exposure to chemicals, we turn our attention to the quality of existing information and interpretations.

Much of the toxicological data provided to EPA by chemical manufacturers under TSCA can be claimed as confidential trade secrets by the submitting companies, keeping that information hidden from the general public, and even from state regulatory agencies. While EPA can challenge the right to claim trade secrets, this is resource intensive and generally not pursued (GAO, 2005). The result is that it is difficult to assess the quality of toxicological data except for chemicals that have already been shown to be of significant risk or have otherwise generated enough controversy to be pursued by academic researchers who publish in the public literature.

For the compounds that are being thoroughly investigated, there are several typical avenues of investigation, each of which brings its own challenges for data quality. If the compound is thought to act through non-cancer-causing mechanisms, then a threshold concentration below which there is no harm is assumed and experiments are designed around finding that threshold concentration. If the compound is thought to be carcinogenic (cancer-causing), then a dose-response curve must be developed so that low-dose exposure risks can be extrapolated from high-dose animal carcinogenicity studies. The preliminary screening by structure-activity relationships that EPA undertakes for assessing its "pre-manufacture notice" compounds will also be assessed as to its "scientific quality".

Non-carcinogenic compounds are regulated by determining a Reference Dose (RfD), which is the product of an experimentally derived "No Observed Effect Level" (NOEL) and safety factors to account for species differences and/or sensitive populations. The idea of a NOEL is based on a threshold theory of dose response which states that below a certain level, there is no effect of a compound on the organism. It is

the official policy of the EPA that most non-cancer effects exhibit a threshold response. The main criticism of the NOEL approach is that the level of the NOEL is highly influenced by the doses selected for testing and experimental design, most notably sample size. Concluding that because one did not see an effect there actually is no effect is faulty reasoning (Crane & Newman, 2000). NOELs for ecological risk assessments are typically derived from selected "representative" species in an ecosystem. This practice fails to take into account the effect of species' differing life history strategies (an organisms way of procuring food and otherwise "making a living") in shaping their exposure and vulnerability to toxic compounds (Stark, Banks, & Vargas, 2004).

Problems with establishing valid models in toxicological science are not limited to dose-response modeling. Simple classification of compounds as carcinogenic or non-carcinogenic based on animal studies has also been shown to be fraught with difficulty. Gottman *et al* (2001) examined the concordance between two Austrian rodent carcinogenicity databases and studies from the published literature. Only half of all assessments were in agreement for mice studies and 60% for rat studies (Gottmann, Kramer, Pfahringer, & Helma, 2001). The same authors also analyzed current databases and computer programs used to screen compounds for toxic effects through computer simulations based on structure activity relationships (SARs) and found these systems woefully inadequate to accurately predict chemical behavior (Helma et al., 2000). These are the same type of models used by EPA to screen new chemicals under TSCA. The difficulty of establishing an agreed upon dose-response relationship for dioxin despite millions of dollars of research, scientific reviews, and public discussion,

shows how politics can be a much more powerful force than scientific discourse in determining regulatory “scientific truth” (Neff & Goldman, 2005).

Toxicological models come under assault from forces both sympathetic and antagonistic to environmental causes. Environmental and public health advocacy groups often criticize government agency science to push for stricter controls on exposure to risks, while industry criticizes the science and emphasizes uncertainty to avoid or delay the repercussion of regulations. The constant push and pull between regulatory, commercial, citizen, and scientific interests and institutions leads to an at times unintelligible jumble of science and policy. However, when we integrate the social and scientific critiques of scientific knowledge, we begin to elucidate some tools that can help guide us in interpreting and giving weight to different scientific data and interpretations.

After a brief discussion of the orthodox view of risk assessment, we turned our attention to the science underlying risk assessment, and the assumptions and conventions underlying that science. Now, with a substantial repertoire of social and scientific critiques under our belt, we can revisit risk assessment, and ask in a more nuanced way, what it is, exactly, we are assessing.

Risk Assessment and Framing

While the National Research Council’s depiction of risk assessment emphasizes a separation of the political factors that impinge on risk management, and the scientific process of risk assessment, our discussion of sociopolitical influences and embedded values in science indicates that even the most basic toxicology study carries

political implications. So if the science that risk assessment is based upon can be politically influenced, what about the actual process of risk assessment itself? While all of these issues will be dealt with specifically in my case study, I present them here in abstract so that their applicability to risk assessment in general is clear.

This section will discuss the framings and assumptions that are prevalent in risk assessments pertaining to potential environmental toxins. A generalized critique of risk assessment as a decision making tool can be found Mary O'Brien's book, *Making Better Environmental Decisions* (O'Brien, 2000). O'Brien's analysis focuses on the ethical issues in the debate over risk assessment, emphasizing the (often patchwork) use of science and mathematical modeling in risk assessment as a means of obscuring value judgments and defining acceptable levels of harm when non-harmful alternatives exist. The following discussion draws from some of her critique and the arguments against the "risk paradigm" found in *Pandora's Poison* (Thornton, 2000), integrated with the social science and natural critiques that have been discussed previously. Many of these critiques of risk assessment are best viewed as highlighting the "framing" of environmental issues (Lakoff, 2002).

Framing can perhaps most easily be defined by thinking about the word framework, which is a basic conceptual structure of ideas that allows one to understand a particular issue. Framing is the active construction of the frameworks that people will use to interpret and draw meaning from an environmental issue. You can also think of it as a picture frame, where you can only see what is inside the frame, and whoever controls where the frame is "drawn" around the issue essentially controls what side of the issue the public ends up seeing. Vaughan & Seifert (1992) conceptualized two

competing framing systems for environmental and public health issues, the Scientific or Economic frame, and the Equity or Fairness frame. They note that policy officials have most often adopted the scientific or economic frame when searching for the resolution of an environmental or public health risk, employing cost-benefit analyses and risk assessments. When the public disagrees with the expert's assessment of risk, people operating out of the scientific/economic frame frequently cite a lack of technical or scientific knowledge (or even "irrational fear") as the reason for the disagreements. However, much of the public is operating in the equity/fairness frame, and therefore, many of the technical and scientific justifications provided are irrelevant to their complaints. Labor groups, local environmental groups, and environmental justice advocates frame environmental issues as revolving around the right to be healthy, the right to a choice of what chemicals are in our bodies, moral responsibility to future generations, and distributional equity (Vaughan & Seifert, 1992). With such fundamental disagreement on values and perception of what matters in these issues, it is difficult to envision some mass of "sound science" that could possibly bring the two camps into agreement.

The primary problem with risk assessment, the risk paradigm, and the system of chemical regulation in general, is the principle of chemicals being "innocent until proven guilty". I have shown that this standard is embedded both in regulatory institutions and scientific statistical conventions (avoidance of Type I errors is more important than avoiding Type II errors). This standard for industrial chemicals is opposite the one used by the FDA, whereby pharmaceuticals must be proven both safe and efficacious. Given our previous discussion of the paucity of toxicity and exposure

data for the vast majority of chemicals in commerce, the current atmosphere for regulation of chemicals appears to be one of “no data is good data”, where a chemical is proven safe as long as nothing is known about it. This is essentially framing by omission, where only the chemicals that are already acknowledged to be harmful are considered in environmental assessments.

In another imposition of social and analytical convenience, risk assessments generally only assess one chemical at a time. Of course, in the real world, we experience a milieu of chemical mixtures. To mention just one example, herbicides and pesticides are only evaluated according to their active ingredients, even though they often have “inert” surfactants and other ingredients that can drastically increase their toxicity or alter their behavior in the environment.

Risk assessments actively draw boundaries around environmental issues through the use of framing, both explicit and implicit. Here we will primarily address explicit framing. Risk-assessments typically assess only the *incremental* increase of risk. This language is typically associated with risk assessments with cancer and the critical “health endpoint”. This means that the risk due to the proposed activity will not be compounded on top of a population’s current cancer risk, but will be assessed without regard for historical exposures or background contamination.

Risk assessments typically separate cancer effects from non-cancer effects, and often choose to assess only one or the other, depending on the compound. Another boundary drawn by risk assessments is that between human health concerns and ecological health concerns. While human health risk assessments are usually very resource intensive, “thorough” investigations, ecological risk assessments are often

“screening” assessments where some numbers for basic indicator species are plugged in and a very rudimentary calculation is performed to assess the hazard. Usually only reproductive function is considered, since the only regulation truly pertaining to wildlife is the Endangered Species Act. There is a cold logic to the fact that in the regulatory world, it doesn’t matter how sick, deformed, or stressed the animals are, as long as they can reproduce. Convincing arguments have been presented for the full integration of human and ecological risk assessment (Suter II, 2004), but implementation of these ideas remains a far off prospect.

A key failure of the risk assessment process from the perspective of the equity/fairness frame is the failure of risk assessment to consider alternatives to the proposed action, and this is the focus of Mary O’Brien’s analysis. She proposes “alternatives assessment” as a more ethical and democratic alternative to risk assessment. A typical risk assessment is designed to inform a binary decision between “yes this practice is acceptable” or “no, this practice is not acceptable”. As O’Brien points out, the cases of “yes” vastly outnumber the cases of “no”. Hence, to many, risk assessment has simply become a rubber stamp on questionable environmental decisions, designed to shield public officials from criticism. O’Brien argues persuasively that alternatives assessment allows for better decision making by considering all available options in any cost-benefit analysis.

On top of the apparent bias of risk assessment for permitting rather than limiting pollution, there are serious concerns regarding the accessibility of risk assessments to the general public and elected representatives, and the implications that the technical nature of risk assessments has for maintaining democratic influences in environmental

decision making. The technical nature of risk assessments can be viewed as implicit framing whereby environmental issues are framed as a technical matter to be handled by debates between experts rather than public debate. The technical nature of risk assessments also has implications for environmental justice, which will be discussed in the next section.

The effect of all these framing activities embodied in risk assessment appears to be to isolate risks from their historical and social contexts, isolate risks from other concurrent risks, bias decisions towards technocratic solutions by ignoring alternatives, and limit public discourse in environmental issues and influence in decision making.

Risk Assessment and Environmental Justice

Environmental justice activists are adamantly opposed to the use of risk assessment to justify and set limits for “allowable” pollution. This opposition is embodied in principle 6, which “demands the cessation of the production of all toxins, hazardous wastes, and radioactive materials, and that all past and current producers be held strictly accountable to the people for detoxification and the containment at the point of production” (see Appendix A).

Mary O’Brien’s rationale for alternatives assessment is also rooted in environmental justice principles. Namely, she claims a human right to be free from harm from a particular activity when alternatives to that activity are available (O’Brien, 2000).

The technical nature of regulatory science and risk assessment fuels perceptions that science is being used to exclude lay people, and especially marginalized

communities, from the decision making process. Rich *et al* (1995) did a case study of a sewage sludge land disposal facility that eventually had to be shut down for environmental infractions and became a hazardous waste site. This occurred after a legal proceeding ignored local residents' claims that the sludge was not being handled as it was supposed to be and allowed the facility to operate for more than seven years. Virtually every one of the complaints voiced by community members in the legal proceeding came true over the seven year period, but the "court" was more swayed by "expert" witnesses from out of town who argued for the safety of the sludge and the facility's handling practices. While in this particular case, the forum for public participation was only a formality, and the farmers had no actual influence on the decision, Rich *et al* assert that even if the farmers were made "full partners" from the beginning of the planning and research phases, there are still significant barriers to achieving *instrumental* participation and empowerment revolving around the technical nature of environmental decisions:

Information alone is not enough. Almost all citizens need either training or technical assistance to be able to interpret technical information on environmental risks and the viability of various mitigation strategies. Unless citizens have access to independent technical advisers to review data, they may not trust the information and may, therefore, not be empowered by it because they do not feel free to act on it. An effective response to a local hazard should include provisions both for the release of information in user-friendly form and for citizen access to independent experts.

(Rich, Edelstein, Hallman, & Wandersman, 1995, p669-670)

The challenges to risk assessment from environmental justice circles then come in two forms: (1) the right to be free from unnecessary risks and harm, and (2) the right to be an equal part of decision making processes.

Proposals to make environmental decision-making, and even research, more democratic or open to lay estimations of risk are often met by fierce resistance from regulators and other members from the risk assessment community. The risk community typically views the public as irrational, subjective, and perhaps even incapable of properly understanding the concepts of risk and probability. Yet experts have been shown to be just as susceptible to common psychological biases as lay people, and verification of experts' risk estimations often show very poor concordance between predictions and actual experienced harm or failure (Schrader-Frechette, 1990). The environmental justice movement is at the forefront of efforts to increase the voice of the public, and communities of color in particular, in all aspects of environmental decision making. The technical nature of risk assessment, as it is currently practiced, is one of the institutional barriers to increased public participation. Whether this is intentional, or not, is a matter for debate.

In this chapter we have discussed many issues that will inform our critical analysis of environmental proposals for their environmental effectiveness, equity, and political legitimacy. The social and political nature of toxicology was discussed. The legal and scientific contexts in which regulatory decisions are made were addressed, as well as identifying several scientific issues to keep in mind when evaluating scientific data with regulatory implications. The constraints placed on scientific inquiry by various institutions, and how these institutions translate their biases through risk assessment as a process was also elucidated. As we delve into our case study of the world of sewage sludge, we take these tools with us, adding information that can inform

our criteria of economic efficiency and political legitimacy, as well as environmental effectiveness and equity, while paying more attention to issues of scale and “on the ground” implementation of environmental decisions.

CHAPTER III

THE EVOLUTION OF HUMAN WASTE: SEWAGE SLUDGE OR BIOSOLIDS, POLLUTION OR SOIL AMENDMENT?

Historical Context

As humans became “civilized” and began to spend long amounts of time congregated in the same location, it could be argued that “pollution” was born. While previously, human excrement was dispersed throughout the environment, where it was broken down into useful nutrients by scavengers and microorganisms, human wastes were now concentrated and in direct proximity to humans. This history of human excrement is given a thorough lay treatment by Abby Rockefeller (1996), in which she traces the cultural viewpoints and political machinations throughout the transition from “night soil” to biosolids. This summary of the history of sewage sludge comes from her article, “Civilization and sludge: Notes on the history of the management of human excreta”, as well as Chapter 8 of *Toxic Sludge is Good For You* (Stauber & Rampton, 1995).

When people began living in established communities, disposal or reuse of human waste was a problem encountered by all cultures. Different cultures have taken very different approaches to dealing with human excrement, although typically this entails a choice between one of two (maybe three) distinct worldviews. Either human

wastes are viewed as an essential fertilizing component for agriculture that must be reused to maintain the fertility of soils, or human waste are seen as a form of "pollution" that needs to be disposed of. The third, and much less common, possibility is a more ambivalent attitude, with some human wastes being reused, but only in an erratic fashion and not as a way of maintaining soil fertility, merely "land disposal". Many Asian cultures have a long tradition of valuing human waste for its fertilizing powers, typically waste was composted under a strict regimen that killed off pathogen organisms and reduced or eliminated foul odors (Rockefeller, 1996). Almost all of the longest-lived civilizations in history have reused human wastes, which have helped reduce agricultural failure by maintaining soil fertility. It should also be noted that the vast majority of these systems were based on dry treatment of human wastes, as water probably had to be hauled from the source, and there were many more useful applications for water than diluting and washing away fertilizer.

In Europe, on the other hand, human waste was generally considered to be what we would today call "pollution". As people began living in larger and larger cities, the problems of human wastes moved from piles in gutters and backyard cesspools, to giant "storm" sewers (so named because they would only be cleared of debris and excrement by being flushed out by large rain storms), and finally to enclosed lines of sewer pipe collecting human waste and dumping it into rivers and oceans. A major change in the management of human waste occurred with the availability of piped-in water. The toilet was not far behind, and wastes from the toilet were simply run into the backyard cesspools, which now often overflowed with fecal-contaminated water, leading to massive outbreaks of cholera and other diseases (Rockefeller, 1996). The design of

closed sewer systems to take the waste away from the cities “solved” the disease problems, and pollution of waterways was not thought to be a concern due to the “purifying capacity” of running water to actually clean pollution (a sentiment echoed by some regarding the properties of *soils* in today’s biosolids debate). While Western society was up to the challenge of preventing diseases with further technological “advance”, other problems due to the dynamics of human waste were also mounting, and some thinkers noted that the links between human waste and soil fertility cannot be severed simply because society wishes it so.

During the industrial revolution, England’s soil fertility was drastically declining, leading to imperialist adventures simply for the purpose of securing supplies of bird guano (which is high in phosphorous and nitrogen) from Peru (Foster 1999). Among others, Karl Marx chose to comment on this situation, and his remarks are quite insightful and introduce a key concept that has been expanded upon and promoted within the discipline of sociology by John Bellamy Foster (1999). Marx addressed the rural-urban, core-periphery structure of capitalist society, and alludes to negative effects of this artificial separation of the people from the land:

Large landed property reduces the agricultural population to an ever decreasing minimum and confronts it with an ever growing industrial population crammed together in large towns; in this way it produces conditions that provoke an inseparable rift in the interdependent process of the social metabolism, a metabolism prescribed by the natural laws of life itself.

(Marx 1981, pp. 949, as quoted in Foster, 1999, p379)

As for what those effects might be, there are many social implications of the separation of people from the land, too numerous to enter into, but Foster also presents Marx’s arguments on the effect of this “metabolic rift” on soil fertility:

Capitalist production collects the population together in great centres, and causes the urban population to achieve an ever-growing preponderance. This has two results. On the one hand it concentrates the historical motive force of society; on the other hand, it disturbs the metabolic interaction between man and earth, i.e. it prevents the return to the soil of its constituent elements consumed by man in the form of food and clothing; hence it hinders the operation of the eternal natural condition for the lasting fertility of soil.

(Marx 1976, pp. 637, as quoted in Foster, 1999, p379)

Marx's collaborator Engels shared his concern for the disconnect between the metabolic flows of matter and energy through society, noting that "in London alone a greater quantity of manure than is produced by the whole kingdom of Saxony is poured away every day into the sea with an expenditure of enormous sums" (Engels [1872]1975 p92, as quoted in Foster, 1999, p383-4).

To summarize, while countries like China have (perhaps until very recently) composted and reused virtually all of their human wastes for agricultural purposes, Western countries have generally taken an engineering approach based on using water as a vessel for transporting waste and have not sought to reclaim the nutrients present in human waste for agricultural use. This approach has been enabled by the discovery of methods to synthetically produce fixed (plant-available) forms of nitrogen. The practice of simply dumping untreated sewage (as well as industrial waste) into bodies of water eventually led to environmental problems that were too significant for society to ignore. The United States' approach to this problem was the Clean Water Act of 1977

Entrenching Sewerage: The Clean Water Act of 1977

Pressure from the public and environmental groups to clean up the United States' waterways mounted in the 1970's. The Federal Water Pollution Control Act amendments of 1972 required municipal wastewater to be treated to remove at least

85% of all pollutants entering the system. The Clean Water Act amendments of 1977 created the second largest public works program in US history (after the highway program), which helped fund the design and construction of thousands of municipal wastewater treatment plants to meet this goal. The Clean Water Act of 1977 is largely credited with creating a large wastewater treatment industry, and has been called by some a “sewerage act” (Rockefeller, 1996). With shrinking federal budgets for public works projects, federal assistance for construction of wastewater treatment plants was phased out in 1990 (Hammer and Hammer, 2004, p150).

Several seemingly opposing groups had intersecting interests that helped result in the development of centralized collection of wastes and top-down, engineered solutions. This is especially notable due to the extreme costs of the sewerage program to American taxpayers. Environmental groups had lobbied heavily for action on the polluted state of the nations water bodies, and at the time tended to favor an “end of the pipe” approach to ensuring water quality. Regulatory agencies, as well as sanitary engineers, preferred technological, centralized, approaches, as the public was generally not thought capable of managing problems themselves (Rockefeller, 1996). Industry and business were also heavily in favor of sewerage, because it would provide a boom in construction, as well as providing the cheapest possible method of disposal for industrial and commercial wastes. Currently, the Code of Federal Regulations section 40 CFR 403.12(p) allows each business and/or industrial facility to dump 33 lbs of certain kinds of hazardous waste *per month* down the sewer without even reporting it to publicly operated treatment works (POTWs) or environmental agencies (Snyder 2005).

Western culture's entrenched views of human waste as useless and water as a medium to transport wastes certainly also helped to preclude the consideration of other alternative methods of sanitation management. As Rockefeller points out, it was not pressures from human wastes that forced centralized sewerage, since only 10% of the nation's septic systems were overloaded or otherwise failing. These could have been repaired or expanded at a much lesser cost than the installation of centralized treatment facilities.

A schematic diagram of a typical wastewater treatment plant is shown in Figure 2. This shows a plant capable of primary and secondary treatment of wastewater, as well as a fairly sophisticated solids treatment system.

Figure 2. Schematic diagram of a POTW typical of a large community (Hammer & Hammer, 2004, p358)

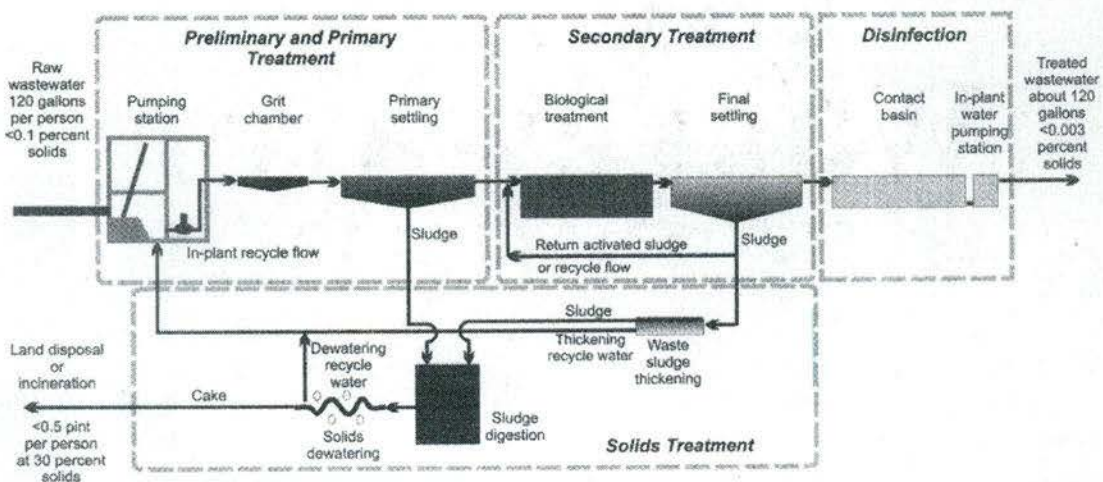
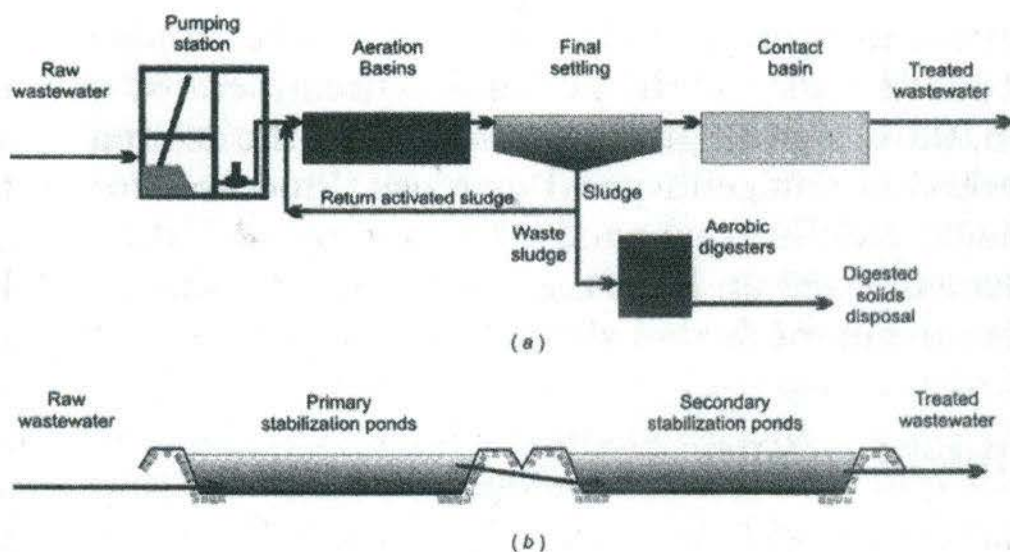


Figure 3. Schematic of representative POTW designs for smaller municipalities (a) biological processing without primary sedimentation, or (b) “natural facultative stabilization ponds (Hammer & Hammer, 2004, p359)



Comparison of the POTW represented in Figure 2 with those depicted in Figure 3 reveals significant differences between large and small POTWs in the degrees of treatment of the water (and hence the concentration of pollutants in sludge) and the extent of treatment of the sewage sludge (which can greatly affect pathogen content and the level of decomposition of organic pollutants). Some plants have systems for “tertiary” treatment of wastewater, which can remove up to 98% of the pollutants in input wastewater, but these plants are very expensive and fairly rare. A schematic diagram of inputs and outputs for one of these highly sophisticated wastewater treatment plants (Figure 4) shows that adding tertiary treatment adds more nitrogen and phosphorous to the sludge, although it is uncertain how available these macronutrients

are, due to being bound tightly to the chemicals used to precipitate them out of the water.

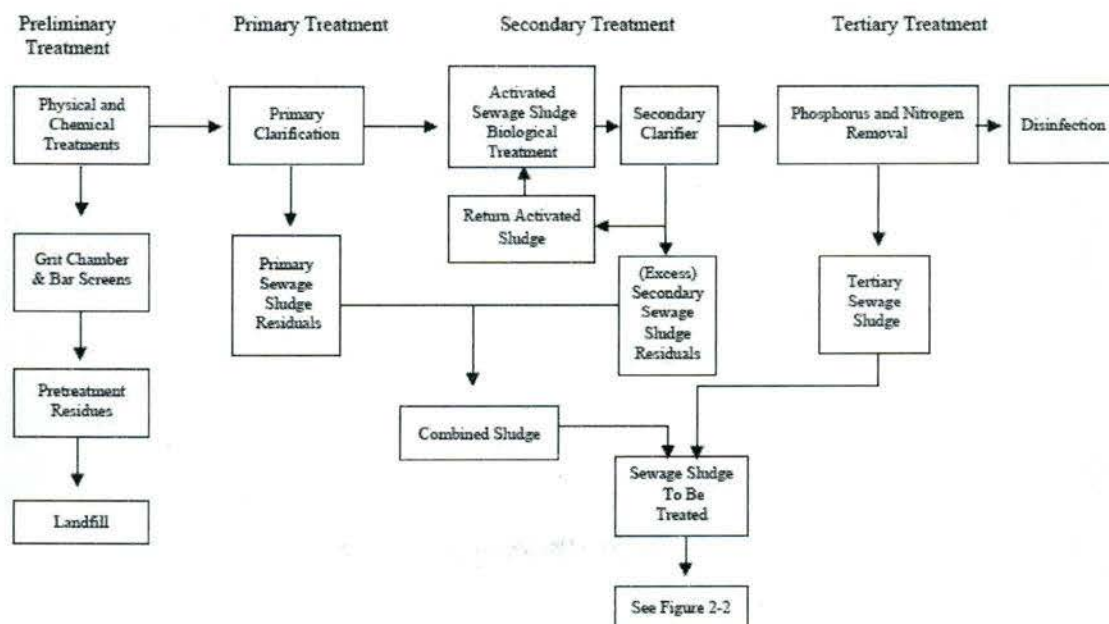


Figure 4. Flow diagram of wastewater treatment flows and resulting sludge residuals.

Reproduced from NRC 2002, p26

Primary treatment is nothing more than the screening of wastewater to remove debris and slowing down the flow of the water enough to have the larger suspended solids fall out of solution due to gravity. The sludge or grit from this stage settles to the bottom, while the “effluent” water moves onto secondary treatment, which is a primarily biological treatment based on “activated sludge” (a mixture of microorganisms and sludge) or trickle filtration through rocks or media coated with microbes that breakdown some pollutants and organic matter in the wastewater. Water that has undergone this treatment is again settled, and the sludge is drawn off the bottom

to be either disposed of, or as it is depicted in Figure 2, undergo further digestion (another stage of biological treatment) and dewatered into cake or biosolids pellets. A simple comparison of the solids content of the input wastewater ($< 0.1\%$) with the solids content of the sludge “cake” (30%), shows that the treatment process results in a concentration factor of 300 throughout the process (Hammer & Hammer, 2004).

This is quite impressive in terms of the relative cleanliness of the water, but for the numerous chemicals that partition with solids and are not broken down by the biological treatment process, the pollution has simply been shifted from a dilute form in the input wastewater, to a vastly increased concentration in the sludge. Wastewater treatment systems employing tertiary treatments could even further increase the concentration of some pollutants. The Clean Water Act of 1977 is a case in point of why “end of the pipe” regulations rarely result in genuine pollution reduction. It may be that unless a toxic chemical is prevented from coming into circulation in the first place, the only options for “pollution control” entail deciding which environmental “sink” (air, water, or land) should be used for its disposal.

What Do We Do With Sewage Sludge?

With the evolution of ideas about natural resources, we have come to recognize that extractive resources are not the only kinds of resources. We are beginning to realize the importance of the use of the air, water, land, and organisms (including humans) of the earth as “sinks” for everything we produce in commerce and in our daily lives, from CO₂ we exhale and that comes out our tailpipes, to human excreta, to trichloroethylene. These are the “sources”, which migrate into the “sinks”. The

analogy of a sink obviously implies that it could overflow and sinks could become sources, a point which will be important later in regard to dioxins and PCBs.

The available sinks for sewage sludge include the air, water, and land. While the inclusion of water may seem ridiculous since enormous amounts of money were spent to remove these pollutants from the water, the practice of ocean dumping of sewage sludge was common until it was banned in 1988. The Environmental Defense Fund (EDF) and the Natural Resource Defense Council (NRDC), among other leading environmental organizations, signed a "consent decree" agreeing to support land-based application of sewage sludge in exchange for the banning of ocean dumping (Rockefeller, 1996). It is unclear just how broad this consent decree is, but to my knowledge, no major or national environmental group has ever come out against biosolids applications to farmland.

Air can be used for a sink through the incineration of sewage sludge, as is done for much of the nations' trash and hazardous waste. Of course, the incineration of sludge is just shifting the pollution from the water to the air, as well as mounting concerns that the incineration process can result in many new toxic compounds being created, especially during the frequent occurrences where the composition of the fuel feedstock for incinerators changes and they are not running at optimal conditions.

Another possible option for sewage sludge with some "recycling" component is the gasification of sludge to methanol, which could substantially reduce the volume of solid waste to be disposed of on land, although significant amounts of pollutants may be released into the air during the gasification process. The gasification process is also fairly costly and would probably not be adopted without some sort of legislative or

regulatory encouragement. Very little research has been done on this option, probably due to the questionable economic viability.

In terms of using land as the “sink” for sewage sludge, there are essentially two options. The sludge can be disposed of in a landfill at significant expense and with the risk of leaching after a certain number of years. Alternatively, the sludge can be “recycled” by adjusting its pH, dewatering or pelletizing it, and distributing it to farmers and home gardeners as a low cost, or even free, fertilizer and soil amendment. Of course, nothing has actually changed between the sludge that would have been dumped in the ocean or burned in the incinerator and the sludge that is processed and marketed as a beneficial agricultural product. One thing that has changed is the profitability of sludge operations. As a disposal company landfilling the sludge, the cities pay you to take their sludge, but you have to pay tipping fees at the landfill as well as being potentially liable for superfund damages if the landfill leaches or otherwise fails. When the sludge is applied on farmland, municipalities pay sludge marketers and haulers to take their sludge, which is often given away to farmers, but can also be sold for a double profit. Regardless, the expense of the landfill costs is avoided, making the business of farm disposal of biosolids quite lucrative, at least when controversy can be avoided.

Stakeholders in Sewage Sludge Decisions

One of the basic principles of any pluralistic, multidisciplinary, environmental analysis should be the listing and description of stakeholder groups or individuals and their respective relationships of power, authority, knowledge, and whether they are the

benefactor or recipient of risk. We have alluded to many of the stakeholders in our history of sewage sludge, but here we try to gather a complete list of the different groups influencing or impacted by sewage sludge related decisions.

- **Regulatory agencies** such as EPA are responsible for drawing up regulations to govern the use of sewage sludge, yet are committed to public relations campaigns promoting its use and have typically only developed regulations when forced to by the courts. Some critics have suggested that EPA has sought only to further the goals of the wastewater treatment industry rather than protect human and ecological health (Snyder, 2005). It should be noted that the interests of regulatory agency employees may be different depending on if they are regular long-term employees or political appointees (usually upper-management positions).
- **Scientists** can be stakeholders on many different sides of this issue, depending on their affiliations (regulatory, academic, industry) and their area of training (i.e. public health vs. agronomist vs. toxicologist). Much more research is available with supportive views of biosolids, since there are multiple funding sources for beneficial use of biosolids research, while essentially no money is available within the US for studies attempting to take a more critical examination of biosolids.
- **Wastewater treatment industry (or POTWs)** has heavily promoted biosolids as it is far and away the cheapest available disposal method for the tons of sludge that their treatment plants produce. Since they collect sewer fees from a large portion of the population (virtually all urban & suburban residents), the

industry has considerable resources to pursue its interests through lobbying, initiating and supporting grass roots campaigns, and supporting research and publication of favorable articles in peer reviewed journals (Stauber & Rampton, 1995).

- **Municipalities** typically own the wastewater treatment plants and have the ultimate legal responsibility for finding a place to dispose of their sludge. The larger the city, the more sludge that needs to be disposed of legally and cheaply.
- **General industry and business** needs centralized sewerage to provide a means for cheap disposal of wastes, and is generally supportive of biosolids use as a necessary extension of their access to the city sewers. These parties would vigorously oppose any attempt to separate out industrial waste from the human excrement waste stream.
- **Construction and engineering contractors** make significant sums of money from laying sewer pipe networks and designing and building wastewater treatment plants.
- **Biosolids distributors & marketers** can profit off from the land application of biosolids, but more stringent disposal regulation could easily make their businesses unprofitable instantaneously, as can public controversy about the reuse of biosolids on farmland. This stakeholder group obviously has a vested interest in sewage sludge being regarded as safe and “natural” by the public. The workers that haul and apply the biosolids are recipients of some of the risks of this practice.

- **Farm owners** should probably be divided into two subcategories, small rural farmers and industrial agriculture operations. Both are likely use biosolids as a way to fertilize fields at a significantly reduced cost, but while industrial agriculture will mostly pass the risk onto workers and the rest of society, small farmers using biosolids are also recipients, as well as beneficiaries, of the risks of land application of biosolids.
- **Farm laborers** receive almost no benefit from the application of sewage sludge to farmland, yet they are on the front lines in terms of being the recipients of risk from the practice, often having to work out in field soon after biosolids applications and coming into direct contact with sludge.
- **Environmental organizations** have generally supported land application of sewage sludge on the national level, while smaller scale environmental groups and local grassroots groups have often been vigorous opponents to sewage sludge projects.
- **Non-farming rural residents** do not receive any direct benefits from land application of biosolids, yet they are often the primary recipients of the risks of this practice. In the current system of regulation, there are few mechanisms for this stakeholder group to influence decisions regarding how or where biosolids will be applied.
- **Food consumers** may be exposed to increased health risks due to plant and animal uptake of biosolids contaminants and/or decreased nutritional value of crops and animals grown under stressed conditions due to the modification of soils by biosolids.

- **Future generations** will depend on much of the same land we are currently using for agriculture to produce food for themselves. If the use of farmland for disposal of biosolids is truly to be a path to sustainability, as many of its proponents claim, then loading of persistent chemicals and heavy metals to soils needs to be managed for long-accumulation, rather than short-term toxicity.

The interplay of these different stakeholder groups has generally resulted in outcomes that reflect the differential power that each of these groups has within the current political system. The interests of regulatory agencies, the publicly-owned treatment works (POTW) industry, biosolids marketers, and general industries have been in substantial agreement, and these interests have dictated much of the policy. Scientists, environmental groups, and farmers have often been split on their opinions of biosolids use on farmland. While all of these groups see some obvious advantages to the reuse of sewage sludge, many within these groups have serious questions as to whether this reuse is safe as it is being currently practiced and given the current contents of our society's waste stream. Farm laborers, non-farming rural residents, consumers, and future generations are obviously the odd-folks-out of the debate over biosolids, with no official mechanism for input and little available information on what biosolids are or how they behave in the environment. A resolution to the sewage sludge issue and the EPA's much desired "increase in social acceptance of biosolids" will perhaps require a more balanced approach to decision making that attempts to consider the needs of all stakeholder groups, including those without a seat at the table currently.

We now turn our attention to the details of the current regulations governing the land application of biosolids.

Current Regulatory Regime for Sewage Sludge: The 503 Rule & Ensuing Controversy

Sewage sludge land disposal has essentially been endorsed and even promoted by the EPA since its inception. EPA promoted the “beneficial reuse” of sewage sludge for years without conducting any science on the subject or making any attempt to regulate the practice. The EPA often participated in public relations (PR) campaigns to promote sewage sludge, including a campaign that asked for ideas to shed the “sludge” moniker that resulted in the selection of “biosolids” as the new terminology for sewage sludge, which was rapidly adopted by the EPA, the wastewater industry, and many academics (Stauber & Rampton, 1995).

Concerns about the EPA’s lack of regulation of biosolids application, as well as several legal cases asserting injury and death due to sewage sludge exposure, led to Congress directing the EPA to develop “a comprehensive framework to regulate the disposal and utilization of sludge” in 1987 (as cited in Snyder, 2005, p146). The Part 503 Rules were the first permanent regulations to define acceptable pollutant and pathogen levels in sewage sludge. As Snyder notes, “The fact that EPA developed these regulations post hoc to justify an existing policy was problematic. Would the regulations be truly science-based and protective, or would they merely rationalize an existing policy?” (p416). After the banning of ocean dumping in 1998, it was clear in the minds of most that the future of sewage sludge disposal was going to be land-application. Snyder’s description of the events that followed offers a glimpse of the

relative influence and power differentials between the public, government, and corporations:

From 1989 to 1992, land application was governed by a stringent interim rule, the 1989 proposal. In the absence of good science, this first version of the 503 rule included strict precautionary metal standards as well as standards for 12 toxic organic chemicals. The interim rule met with strong opposition from municipalities and sludge-management companies. Sludge generated in many urban centers could not meet these strict standards. In addition, the extra testing requirements for toxic organics would be time-consuming and expensive. . . . Robert O'Dette, representing the sewerage industry, warned in 1990 that if the interim rules were adopted, beneficial reuse of sludge would end.

Thus pressure from municipalities and the sewerage industry ensured that the final rule, the 503 rule, would be so lenient that virtually all municipal sewage sludge could be land applied. . . . Based on risk analyses and a national survey of priority pollutants found at approximately 180 wastewater treatment plants throughout the country, the final part 503 sludge rule exempted all organic priority pollutants and regulated only ten heavy metals: arsenic, cadmium, chromium, copper, lead, mercury, molybdenum, nickel, selenium, and zinc. Chromium was later delisted and molybdenum was largely deregulated.

(Snyder, 2005, p416)

As noted above, the survey used to develop the part 503 rule examined the sludge of 180 POTWs, compared to a national total of over 10,000 such facilities. The 503 rule also set up two distinct classes of biosolids based on the levels of indicator pathogens present, with different use restrictions and time-limits before grazing or human contact with sludge amended solids. Class A sewage sludge has "no-detectable pathogens", while Class B sludge has detectable pathogens below a certain concentration. Both of these classifications are determined by testing sludge for either of two indicator microbes, salmonella and enteric coliform bacteria. The validity of this approach has been questioned since these microbes are among the easiest to kill (sanitize) and there are numerous other bacteria and viruses that could easily survive treatment techniques designed to eliminate coliform and salmonella bacteria (Gattie & Lewis, 2004).

In addition, the same former EPA researcher has promoted the idea that the irritant chemicals present in biosolids may make people more susceptible to respiratory infections with pathogens present in those same biosolids (Lewis, Gattie, Novack, Sanchez, & Pumphrey, 2002). This highlights one of the shortcomings of risk assessment that was discussed earlier and will be revisited in the dioxin case study: the inability, or unwillingness, of risk assessment science to account for the interactions that occur between the different hazards present in complex mixtures.

Both of the studies mentioned above were co-authored by David Lewis, a scientist with EPA who had been studying claims of illness by rural residents exposed to sewage sludge. The reaction to Dr. Lewis's work was summarized as one of many case studies of research suppression in a recent law journal paper highlighting the special vulnerability of environmental science to suppression since its products often challenge the economic interests of the powerful (Kuehn, 2004). Dr. Lewis actually filed labor complaints claiming retaliation by his superiors at EPA for his views critical of the safety of land-application of biosolids:

U.S. Department of Labor investigators agreed, finding that, in reaction to an article in *Nature* critical of EPA's sludge rule, agency officials applied ethics rules on the print size of publication disclaimers in a discriminatory fashion and unlawfully denied Lewis his promotion. Other efforts to suppress Lewis's work included sludge industry representative attempts to have EPA withdraw financial support for Lewis's research, and an EPA official's solicitation of industry help in writing a negative internal peer review of Lewis's research.

(Kuehn, 2004, p338-9)

This a chilling story for any scientist, but given the influences of funding sources, peer review, and the priorities of policy requirements which we have discussed up to this point, it is perhaps not so surprising. Science that challenges the claims of fact by powerful vested interests will rarely go unchallenged. Typically those

challenges are viewed as being limited to debates within the scientific literature, but the case of Dr. Lewis cautions that vested interests are not above personal attack and the undermining of scientists' credibility and financial support.

The limits set for the heavy metal pollutants present in sewage sludge are no less contentious of a matter than the standards for pathogens. The EPA chose to take a risk based approach to setting limits for metals in biosolids, and in cases where it chose to use other standards (as in the case of molybdenum, chromium, and selenium) these regulations were struck down or weakened by the courts in response to legal challenge (NRC, 2002). So while Snyder's criticisms of the EPA's procedure and lack of scientific basis for setting the pollutant limits on sludge it did are valid, in a sense, the agency's options are constrained by the institutions it is nested within. In many cases, government agencies are required to form regulations based on risk, even when there is insufficient information to accurately estimate that risk. The 503 regulations are practically required by the framework of the risk paradigm, where there is no problem as long as there is no data, which is entrenched in the US legal system. More stringent guidelines based on precaution, in the face of lack of evidence of safety or harm, would likely not have withstood the certain legal challenges from municipalities and sludge-related industries.

Comparison of the US regulations on biosolids with other countries' regulations around the world reveals both differences in how different countries derived risk-based values for total loading of metals to the soil and alternative methods for setting regulations, such as those used in Canada where the total loading of metals to soil allowed is based on no more than doubling the background concentration of the soil.

This would seem to be a case where the interest of future generations and the ethics of land stewardship have been at least somewhat incorporated into the regulatory framework.

A comparison of some different standards for the total loading of metals to soils from the land application of biosolids is shown in Figure 5:

Table 1. Maximum permitted metal loadings in soil (kg/ha) established by the USEPA-503 regulations, compared with other standards.† The international standards are based on total metal content in soil, including background level.

Metal	USEPA-503	N.E.‡	Germany	Netherlands§	Ontario
As	41	—	—	60 (100)	14
Cd	39	5	6	10 (40)	1.6
Co	—	—	—	100 (600)	30
Cr	3000	500	200	500 (1600)	210
Cu	1500	125	200	200 (1000)	150
Hg	17	—	4	4.0 (20)	0.8
Mo	18	—	—	80 (400)	4
Ni	420	50	100	200 (1000)	32
Pb	300	500	200	300 (1200)	90
Se	100	—	—	—	2.4
Zn	2800	250	600	1000 (6000)	330

† For direct comparison, standards based on mg/kg units have been converted to kg/ha using a factor of 2. The exact conversion depends on soil density and depth of sludge mixing.

‡ Data from Northeastern U.S. Regional Research, 1985.

§ The values are considered to represent moderate soil contamination requiring additional study, while those in parentheses are considered to represent a serious threat to humans or the environment.

Figure 5. Comparison of US limits for heavy metal loading to soils with international standards.

(reproduced from McBride, 1995, p6).

A detailed discussion of the standards for sludge in the European Union can be found in the National Research Council (NRC) report *Biosolids Applied to Land: Advancing Standards and Practices* (2002). This analysis shows that most of the higher income states of the EU have more stringent regulation of biosolids than the US, while

heavily agricultural states such as Greece, Ireland, and Portugal are generally in favor of sludge reuse for fertilizer and have regulations similar to those in the US (NRC, 2002). Generally speaking, US regulations are fairly permissive, especially in respect to cadmium, chromium, and copper, as well as their lack of regulation for organic chemical contaminants. It should also be noted that extremely strict regulations can eliminate any reuse of biosolids, as is the case in the Netherlands (NRC, 2002).

The risk-based values of “safe” metals loading onto soils are based on field trials with sludge amendments where the uptake of metals into plant shoots and leaves was measured. Generally, the metals were found to be mostly tightly bound to the sewage sludge “matrix”, although there is debate as to what components of the matrix are most responsible for keeping the metals unavailable, with different implications for the long term fate of those metals. Scientific debate about the fate of metals in biosolids has split into two opposing camps. Proponents of the “sludge protection hypothesis” argue that the heavy metals are irreversibly bound to the inorganic Ferric and Manganese oxides of the sewage sludge, which will permanently hold them in place, unavailable for plant uptake (Hettiarachchi, Ryan, Chaney, & Fleur, 2003). The other camp argues that heavy metals are more likely absorbed onto insoluble organic material such as humic acids. While this may stabilize the metals in sludge for a couple of decades (long enough to avoid problems even in a lengthy field trial), eventually this organic matter will fully breakdown or be “mineralized”, and the metal previously bound up could be mobilized. This view has been called the “sludge time bomb” hypothesis (McBride, 1995).

Another version of sludge as a potential time bomb has to do with the effect of pH stabilization on metal mobilization. Metals may remain bound to the sludge or soil as long as pH is maintained above 6.5, but if a farm ceases production or otherwise fails to keep up its liming regimen, large quantities of metals could suddenly be made soluble as the soil turns more acidic. It is also recognized by soil chemists that *speciation* and *activity* (concentration of active ions as influenced by pH and all other soil solution constituents) is a much better indicator of heavy metal toxicity than simple concentration. This has led some to conclude:

The total contents of heavy metals in soil-sludge mixtures may not reflect their bioavailability. Higher contents of heavy metals in the soil do not always mean higher plant contents. For some authors, the total metal concentration is the most useful index to assess the degree of metal accumulation in a soil, but metal bioavailability is better reflected by soil solution composition. (Silveira, Alleoni, & Guilherme, 2003, p802)

Even if plants do not uptake the metals present in sewage sludge and animals are safe from negative effects, we may still be undermining the foundations of agricultural productivity. Soil microorganisms are especially sensitive to heavy metal pollution in soils because they live their lives essentially bathed in the soil solution. Some studies have shown drastic changes in microbial health and diversity even forty years after the cessation of metal inputs to the soil (Abaye, Lawlor, Hirsch, & Brookes, 2005). Others have documented the loss of the ability of microbial communities to fix nitrogen following sludge application (Giller, Witter, & McGrath, 1999). The loss of microbial communities capable of producing fixed nitrogen could offset any beneficial use of biosolids as fertilizer.

Now that the regulations covering pathogens and heavy metals in land-applied of sewage sludge have been discussed, we can turn our attention to the infinitely larger subject of what is in biosolids that isn't regulated.

Sewage Sludge: Poster Child for Uncharacterizable Chemical Mixtures

Recalling the earlier discussion of wastewater treatment, sewage sludge could perhaps be most easily described as a highly diverse, yet fully homogenized, biologically active material. By definition, anything that is sent down the sewers that isn't water soluble is probably in sewage sludge. One of the most recent papers discussing the determination of organic compounds in biosolids indicated that analytical limitations of working with biosolids make chemical detection very difficult even when one knows what they are looking for (Kester et al., 2005). While the paper generally takes the position that biosolids are safe, it also acknowledges that there is much more unknown than known about the content of biosolids. In fact, given the sheer number of possible compounds and the analytical difficulties of finding them and establishing concentrations, it seems virtually impossible to fully characterize the components of biosolids, much less assess each of those components on a one by one basis for signs of toxicity. When faced with a substance as complex, yet homogenized, as biosolids, the risk paradigm appears almost foolish in its hope to characterize and analyze each compound, one by one.

In regards to the chemical mixtures, a recent study investigating the effects of sewage sludge as a chemical mixture suggests that assessing the mixture directly (and

looking at different toxicity “endpoints”) may result in quite different determinations as to the safety of sewage sludge. The study of endocrine (hormonal) disruption has experienced rapid growth in recent years, amid concerns that traditional toxicology’s focus on cancer, organ failure, and behavioral endpoints has failed to identify compounds that are capable of mimicking or interfering with animal’s hormone signaling pathways that direct much of development and reproductive fitness.

Paul *et al* (2005) combined this focus on endocrine disruption with an attempt to determine effects directly from real-world exposures to chemical mixtures, and the research group happened to use sewage sludge as the target of its investigation. Pregnant female sheep were pastured on fields fertilized with biosolids or with conventional fertilizer, and their male fetuses were examined for hormone levels and testicular development. The experiment showed a 36% reduction in testosterone levels in male fetuses whose mothers had grazed on the sewage treated pasture compared to controls, along with abnormalities in testicular development (Paul *et al.*, 2005). The authors make no attempt to attribute the effects observed to any particular component in the sewage sludge, choosing rather to treat the sewage sludge as a whole. Large-scale field studies of biosolids using these types of methods would be far more informative than a thousand risk assessments on the concentrations and potential for exposure for individual compounds found to be present in sewage sludge. A glimpse at the possible compounds that could be analyzed with the same depth that we’ll investigate in our dioxin case study shows the complexity of the mixture and the challenges of determining simply what it *is*, never mind how risky it is.

Pollutants present in sewage sludge can include organic chemicals of all kinds (Kester et al., 2005), including pharmaceuticals and personal care products (Xia, Bhandari, Das, & Pillar, 2005), detergent residues (La Guardia et al., 2004), lawn fertilizer, pesticides, and herbicides, and just about anything you can imagine. Poly-brominated diphenyl ethers (PBDEs) are also rising stars among bioaccumulative, persistent pollutants that are also present in biosolids in high amounts and accumulate in soils and sediments (La Guardia et al., 2004). Most recently, the topical antiseptic triclocarban has been found in dewatered sewage sludge at concentrations of ~50 mg/kg dry weight, or 50 parts per *thousand* (Heidler, Sapkota, & Halden, 2006). This is the active ingredient in antibacterial soap and other consumer products used in mass quantities all across the country. It is a perfect model for developing “super-bugs”, or antibiotic resistant bacteria, as it cannot be degraded by most microorganisms and due to the “beneficial reuse” of sewage sludge it will be present in the environment at sub-lethal yet persistent concentrations. In fact, in some sludge, the concentrations may be almost high enough to be lethal, contributing to stress on desirable soil microorganisms. All these potential contaminants are in addition to the metals and pathogen contaminants already present in biosolids.

The risk paradigm assumes no interaction between these chemicals, and it also assumes that assessing the risks of these chemicals individually is a sufficient surrogate for assessing the risk of the mixture. Both of these assumptions are standard practice in the field of risk assessment, yet there is little to no scientific evidence to back these claims up, and they are coming under increasing scrutiny from the scientific community. In fact, the NRC’s 2002 report on biosolids cites the complexity of

chemical/pathogens mixtures in concluding that EPA cannot reliably guarantee that the risks of biosolids application are “acceptable”:

It is important to note that, even if a summary index of the risk of an adverse response to mixtures was available, it would not necessarily reflect the total hazard of exposure to biosolids because of the inability to identify all of its hazardous constituents and their potential for interaction in vivo. Moreover, the composition of biosolids is susceptible to unanticipated changes from time to time and place to place. Thus, it is not possible to conduct a risk assessment for biosolids at this time (or perhaps ever) that will lead to risk-management strategies that will provide adequate health protection without some form of ongoing monitoring and surveillance. There is a degree of uncertainty that, when exceeded in the risk-assessment process, requires some form of active health and environmental tracking in the risk-management strategy to ensure against unanticipated outcomes. This situation led the committee to conclude that although the Part 503 agent-specific risk-assessment process can be improved with new risk assessment methodology, *the remaining uncertainty for complex mixtures of chemicals and biological agents is sufficient to preclude the development of risk-management procedures based on these agent-specific analyses that can reliably result in acceptable levels of risk.* Some form of process quality assurance and ongoing surveillance must be done to ensure that effects not anticipated by the chemical- and pathogen-specific risk assessments do not occur. Strategies for the management of risks arising from biosolids exposure should include audits of process performance and management practices, periodic hazard surveillance, and studies of health outcomes, including epidemiological studies and studies in response to episodic events.

(NRC, 2002, p 328-9, emphasis added)

The NRC committee’s discussion of the role of uncertainty in assessing risk shows considerable concern about the relative lack of knowledge with respect to biosolids as they will be experienced in the real world. The review committee recommended extensive programs for monitoring the quality of sludge, auditing the compliance of sludge industries, and conducting epidemiological studies of sludge workers, farmers, and nearby residents. However, due to the budgetary constraints and policy decisions made by offices within the EPA, it is doubtful that any of these monitoring recommendations will be implemented.

Despite these uncertainties and questions, land-application of biosolids has expanded dramatically in the years since the 503 rule was finalized in 1993. Given this time of experience with biosolids as practiced in the real world, one would perhaps

guess that many of the social and scientific controversies might have been resolved.

Unfortunately, this has not been the case, for a variety of reasons. Due to the scientific controversy regarding metals and pathogens, and the patchwork nature of available science on issues key to determining the safety of biosolids land application, it is clear that science alone cannot tell us whether the 503 regulations are protective of the public health. If this were theoretically possible, we would still be left with the ethical question of how safe is safe enough? And even if the 503 rule regulations of EPA were considered by all to be fully protective of public health, the practice of land application of biosolids could still be harmful if the regulations are not enforced or followed.

Land Application of Biosolids in the Real World

An important lesson from studies of environmental issues by political ecologists is the idea of “state capacity” and rules and regulations as they are felt “on the ground”. State capacity generally refers to the infrastructure and capability for control by the government. State capacity regarding environmental issues is generally thought to be much higher in the so-called “First World” than in “developing” countries, but the wisdom of this assumption has been questioned by McCarthy (2002). Developed nations are obviously not immune to government corruption that turns a blind eye to regulatory infractions, and in the United States, protracted wars and soaring debt, along with a Republican leadership antagonistic to environmental regulation in general, have led to a constantly shrinking budget for the EPA and other regulatory agencies which are charged with enforcement of regulations. As a result, the state capacity with regard to land-applied biosolids is quite low due to a stated policy of disinvestment, and this

results in “on the ground” implementations of biosolids land-applications that are quite different than the balanced and site-specific approach that is outlined in the 503 rules.

According to the EPA narrative the practice of biosolids is, and always has been, a safe and economical way to supply nutrients and organic matter to farmland. A key part of this narrative is that the application of biosolids is subject to strict controls on both the quality of sewage sludge and the practices used to handle, store, and apply this sludge.

Biosolids must meet regulatory requirements for stabilization and metals content. In addition, nutrient content and physical characteristics, such as percent solids, are used to determine the appropriate application rate for the crop that will be grown and the soil in which the crops will be grown. Site suitability is determined based on such factors as soil characteristics, slope, depth to groundwater, and proximity to surface water.

Biosolids Technology Fact Sheet (USEPA, 2000a)

The consistent response of the EPA to any allegations of health or environmental risks is that given by an EPA regional administrator in response to health complaints in Virginia. “Available evidence indicates that when biosolids are properly used or disposed of according to all federal and state regulations, there are no significant risks to public health or the environment” (as quoted in Brennan, 2005). This type of response points to the tensions and conflicts with the public that occur because of government agencies’ reliance on risk-based, “scientific” approaches to evaluating proposed activities. As circular as the logic may seem, officials often argue that individuals’ claims of harm cannot be true because the risk assessments say they should have been safe from harm. However, the validity of EPA’s narrative of biosolids application safely conducted in accordance with the 503 rule has been challenged. The

statement of the EPA regional administrator quoted above (and repeated by numerous other government officials and sludge industry representatives) shows an institutional blindness to the possibility that sludge might *not* be produced or applied “according to all federal and state regulations”. In fact, there is a substantial body of evidence indicating that violations of the regulations do occur, and perhaps of more concern, the EPA appears to have little interest in knowing how prevalent or severe these violations might be.

A comparison of biosolids reuse practices “on the ground” with the narrative promoted by EPA shows that sewage sludge is not always treated with the utmost care dictated by the 503 rule. Sewage sludge has been applied to frozen land and consequently flowed into waterways, resulting in a \$10,000 settlement (USSN, 2005). The largest sludge management company in the US “was fined \$35,000 by the Pennsylvania Department of Environmental Protection in September 2004 for sludge violations. ‘Violations included spreading sewage sludge on frozen ground, spreading sewage sludge on adjacent landowner’s property without written consent and the improper storage of sewage sludge, and failure to prevent runoff from entering nearby waterways’” (Sheilds, 2005).

Two examples from Oregon illustrate the inability of regulations to account for noncompliance and unforeseen events:

Two Florence families, their friends and relatives became ill in 1996 after a giant sprinkler-like device called a “big gun” malfunctioned, causing what the city estimated was 300 gallons of sludge to flow down a hillside and into a creek from which the families drew their water. The sludge was inappropriately applied for seven months, according to court documents. And the city had been in such a hurry to get rid of the sludge that it was virtually untreated to reduce pathogens, according to court and DEQ documents. . . . A Metolius family in 1998 abandoned their home after it became flooded during a rainstorm with sludge applied to a nearby hillside.

Snyder also presents evidence suggestive of fraud in the monitoring of contaminants in biosolids. A wastewater treatment plant in Georgia showed very high levels of cadmium that suddenly dropped to levels under regulatory requirements as soon as the regulations took effect. The same plant was shown to have discrepancies between lab notebook values and reported concentrations of heavy metals in sewage sludge in a case in Georgia that resulted in the death & illness of dairy cattle herds fed forage on sludge amended fields. The EPA's investigation of the incident "found no substantiation for the allegations" (NRC, 2002, p52), which is especially curious since a jury found in the favor of the farmers that "hazardous material in sludge had indeed caused the severe damage and death of their herds" (Snyder, 2005, p422). Perhaps EPA concluded that since sludge had been proven to be safe, the cattle could not have actually died.

One last point regarding "state capacity" and the gap between regulations and "on the ground" practice relates to the input into wastewater treatment systems. Many unauthorized discharges into municipal sewers occur on a daily basis, from black-market manufacturing operations to home methamphetamine labs, a number of completely non-regulated entities' wastes can end up in sewage sludge. This practice is more common in heavily populated and industrialized areas, which leads to differences in sludge produced by differently sized cities that are not acknowledged by EPA (which generally assumes most sludges in a given classification to be equivalent). Stauber and Rampton (1995) discussed differences in sludge with several soil scientists:

"Sludge from San Diego, Los Angeles, or New York you have to look at carefully—its different in highly industrialized areas," said Ian Pepper, a soil and water science professor . . . "I've

been eyeball deep in sewer sludge disposal on agricultural land for years,” said Kirk Brown, a soil science professor at Texas A & M University. “Some sludge you could use for 50 years before having problems—not New York City’s.” Browns’s assessment was confirmed by Ian Michaels, a spokesman for the New York City Department of Environmental Protection, who estimated that the city had 2,000 unregulated companies discharging industrial waste into the sewers, but admitted that his department had “no way of knowing how many . . . there are.”

(Stauber & Rampton, 1995, p116)

The presence of unregulated companies could lead to the introduction of chemicals into the waste stream besides the ones anticipated by EPA risk assessments.

On the other hand, every practice that is carried out on a large scale will have a certain number of accidents and mishaps that are bound to happen, and these cases could be viewed simply as bad apples among a good bunch. In order to determine if this viewpoint is accurate, effective monitoring, inspection, and compliance enforcement programs would be helpful in determining the number of violations in proportion to the number of favorable inspections, etc. An internal review by the EPA Office of the Inspector General (USEPAOIG) casts doubts on the EPA’s ability to claim that biosolids are applied in a safe manner:

EPA has not taken necessary steps to reasonably ensure compliance with Part 503 requirements. EPA reviewed fewer than 40% of the approximately 3,700 Part 503 reports submitted by POTWs in FY 1998. EPA performs almost no sludge related inspections of land application sites. EPA regions do not maintain site records needed to ensure that applicators do not exceed cumulative pollutant limits. There is no regional oversight of septage land application. . . . Therefore, EPA does not have sufficient information to determine compliance levels with the Part 503 regulatory requirements. This almost complete absence of a federal presence results from the low priority given to biosolids management by EPA’s Office of Water (OW) and the decision of EPA’s Office of Enforcement and Compliance Assurance (OECA) not to commit enforcement resources to biosolids. This may result in increased noncompliance with Part 503 requirements, which would increase the risk to the environment and human health, and cause a loss of public confidence in the biosolids program.

(USEPAOIG, 2000, p6)

In essence, the EPA's policy determination that "biosolids are a low risk to human health and the environment" (USEPAOIG, 2002), which was decided immediately after the implementation of the final Part 503 rule, has resulted in the shelving of all research efforts related to health and environmental effects of biosolids application and the "disinvestment" in monitoring and enforcement programs. The situation at the state level is highly variable, but at least one state's biosolids program shows similar difficulty in enforcing biosolids regulations.

A report by Virginia's Joint Legislative Audit and Review Commission (JLARC), brought to light the shortcomings of the state's inspection frequency and devotion to monitoring compliance in biosolids land application, although the state's performance was far superior to the USEPA, who had only done one inspection in the region since 2002, and none in Virginia (JLARC, 2005). The people conducting the review even noticed two violations of sludge application rules while they were visiting application sites for purely informational purposes. The Virginia report also noted that even when agencies do cite sludge applicators for violations, often times fines are not collected and no meaningful enforcement action takes place.

The EPA's Office of Water and the OECA have made the determination since the inception of the 503 rule, and based on the risk assessment conducted for that rule-making, that that land application of sewage sludge is a low-risk practice. Faced with competing regulatory obligations and shrinking budgets, the OW and OECA have "disinvested" staff and resources from biosolids projects, resulting in the equivalent of about 9 full time EPA employees being responsible for federal oversight of land disposal for all the biosolids in the nation. At the state level, the staff resources vary

widely from state to state, as shown in Figure 6. The staff levels of New York (4.5 FTE) & California (1.75 FTE), two of the most populous states, indicate that state staffing on biosolids is not necessarily proportional to biosolids production.

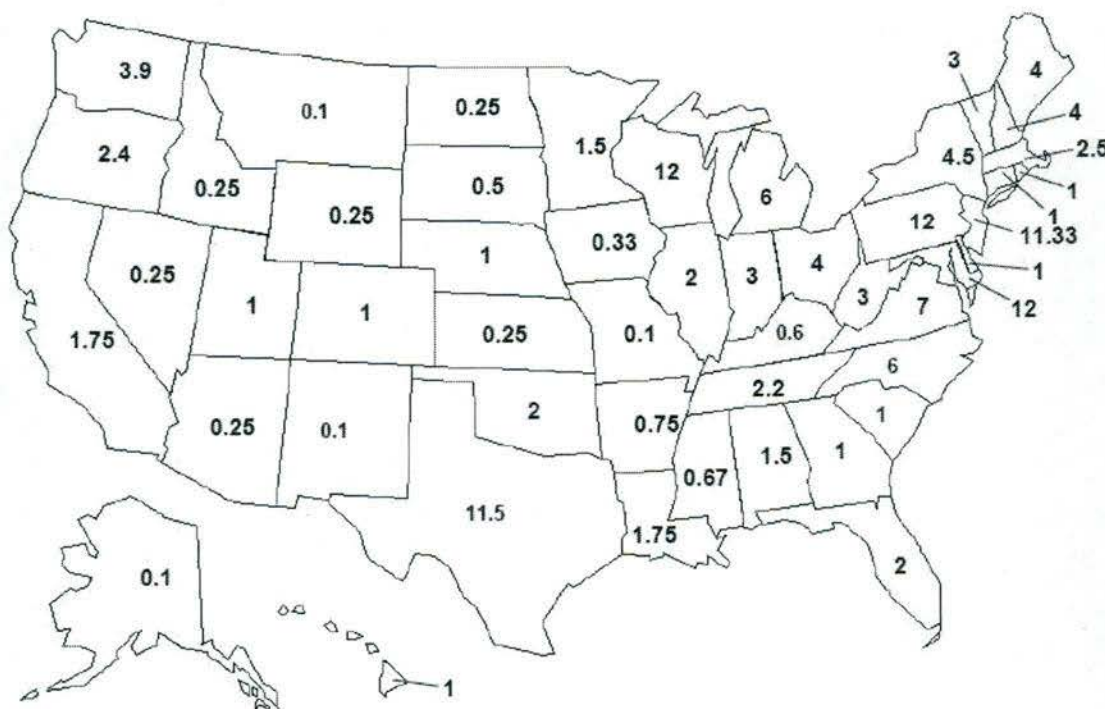


Figure 6. Number of FTEs dedicated to state biosolids programs.

Reproduced from NRC 2002, p56

Both the EPA OIG and VA JLARC reports conclude that the government agencies are not conducting sufficient monitoring to ensure the public health and that this lack of enforcement could easily lead to increased noncompliance since there appears to be little chance of punishment for violations.

This lack of enforcement, and subsequent increase in violations, could be the source of the disconnect between the narrative of the EPA and sludge application as

seen “on the ground” by local residents. What the EPA says in public statements coming from Washington often directly contradicts what people have seen and experienced at the local level. To date, EPA has not acknowledged a single case of human or livestock illness or death due to exposure to sewage sludge, despite several court settlements and jury awards that have disagreed. EPA makes this assertion grounded securely in within the scientific frame, claiming that “supporting evidence to substantiate these allegations has not been documented in the scientific literature” (NRC, 2002, p52). But how are dairy farmers supposed to recruit and perhaps compensate a scientist to do all of the work entailed in collecting data (which also costs money) and publishing a peer-reviewed paper? Only the EPA, POTWs, and sludge industries have the cash to actually recruit sympathetic scientists, support research, and get something “documented in the scientific literature”. The inequity in the relative voices of concerned stakeholders in the biosolids debate is a significant source of the friction between rural residents and the “beneficial use” community.

Even when the regulations appear to be followed, biosolids land application projects run into public opposition and controversy due to factors that EPA’s risk based worldview is incapable of accommodating. Rural communities often resent being used as “dumping grounds” for big cities’ wastes. For example, 99.9% of Los Angeles’s biosolids are trucked to Kern County, where most of it is spread on a 4,700 acre farm owned by the city of Los Angeles which grows feed for dairy cattle (Cavanaugh, 2006). The area is rural and generally low income, and public outcry over the nuisance of odors and the potential threat to groundwater has an initiative to ban the application of biosolids in the county on the ballot in June 2006.

While most parties involved think that voters will vote to ban sludge application, it's probable that the matter will ultimately be decided in the courts. Local governmental action is nested within state and federal regulatory frameworks, and courts have often ruled that municipalities and counties do not have the right to form regulations more stringent than state requirements.

A U.S. District Court ruling in 2003 in Pennsylvania forbid municipal biosolids ordinances from going beyond state Department of Environmental Protection regulations (Brill, 2005). Similar court rulings could probably be expected in California. The ultimate outcome of the Kern County case may depend on the stringency of California biosolids regulations, but an outright ban is unlikely to hold up in court. Legal institutions therefore constrain, and effectively eliminate, the prospect for local influence on biosolids application programs (other than the farmers getting biosolids applied). This can have a frustrating and disempowering effect on communities, especially when they are poor and do not have resources to hire the lawyers and experts that would be necessary to prove that the sludge was harmful to them. The involuntary nature of many non-farming rural residents' exposure to biosolids can lead to an increased resistance to the practice, no matter how small the risks might be. Depending on which narrative, worldview, or frame, one is coming from, this resistance can be described either as an environmental justice movement or as an irrational public motivated by "perceived risk" rather than calculated risk. One thing is clear however, all of the research and risk communication that has been done over the last 15+ years has not been successful in increasing public acceptance of biosolids land application. Still in 2006, whenever biosolids are applied in close proximity to non-

farming rural residents, controversy is likely to be part of the picture. Our final section of the chapter will address perceived risk and the use of risk assessment by EPA to assuage perceptions of biosolids risk through continuous refinement of risk assessment methods to give the appearance of dealing with concerns without addressing the roots of public discomfort and/or resistance.

Risk Perception, Calculated Risk, and “Real” Risk

A significant body of research in the social sciences has elucidated the principle of “perceived risk”. Many scholars have pointed out that risks are experienced differently by technical experts and the general public. Those familiar with a particular hazard tend to perceive a lower amount of risk than those who are unfamiliar with it. Men also generally tend to perceive risks to be lower and less problematic than women (Slovik, 1999). Most importantly for the biosolids debate, the risk from a particular hazard may be greatly magnified by “outrage factors” that modulate how that risk is experienced by different stakeholders (Sandman, 1987). A recent review of the influence of perceived risk on the acceptance of biosolids application concluded that public resistance to the practice could largely be explained by the involvement of large numbers of these “outrage factors” in neighbors’ and communities’ experiences (Beecher et al., 2005). Their list of related outrage factors is extensive and lengthy, but it is worth reproducing here because it summarizes many of the concerns about the practice that have been addressed in this chapter. Neighbors and communities often perceive biosolids land-application programs to be:

- involuntary (out of their control),
- artificial and industrial,
- exotic and/or unfamiliar (manure is familiar, biosolids are not),
- hard to understand (not self-explanatory),
- memorable (because of odors or other nuisances),
- dreaded (the “yuck” factor of biosolids’ origins creates dread),
- potentially catastrophic in time and space (issues raised about biosolids point to potential short- or long-term negative effects at the land-application site),
- not reversible (e.g., persistent pollutants are permanent additions to soils),
- unknowable (there is a greater level of uncertainty regarding biosolids land application than regarding, for example, animal manures; biosolids have more diverse inputs from municipal sewers and so its constituents are more variable),
- having delayed effects (some effects from biosolids may not be evident immediately),
- affecting children and mothers (because they may happen to play around biosolids and/or consume foods grown on biosolids-amended fields),
- affecting future generations (because there is some uncertainty about long-term effects),
- having identifiable victims (reported cases of harm to cows and people),
- potentially affecting them such that they have a personal stake (neighbors who believe they are affected),
- being controlled by the “system” or others,
- unfair (“the farmer gets the benefits and the neighbor only gets some added risk”),
- morally and/or ethically objectionable (if biosolids are seen as a potential threat, then it can be perceived as morally wrong for powerful cities to foist biosolids on a rural community),
- associated with untrustworthy people (social science surveys have most often shown that government officials, people from out of town, and those who have a financial interest are perceived as less trustworthy),
- operating by a closed process (communities around land application sites too often find the process closed and difficult to understand),
- having more media attention (media stories about a biosolids project heighten local interest and, if they report opposition, public concern tends to increase), and
- having limited or no visible benefits (land application occurs far from the wastewater facility and in communities that perceive little benefit to them).

(Beecher et al., 2005, p123-4)

This long list of “outrage factors” experienced by the less powerful stakeholders in the biosolids discussion poses a formidable obstacle to resolving the controversy. Proponents of sludge reuse will tend to minimize outrage factors by discussing biosolids as a stable, natural, well-researched, beneficial material, while opponents of the practice will maximize outrage factors by characterizing biosolids as an unknown, toxic material foisted on poor rural residents by powerful big cities, industries, and government bureaucrats. Actually addressing these outrage factors is a significant challenge. The

ability of science to resolve protracted environmental disputes such as the biosolids debate is extremely limited.

From the perspective of biosolids proponents, a typical sentiment towards further study is embodied by the question posed by one biosolids scientist, “having completed a thousand studies, what makes us think that the 1001st study will convince skeptics?” (Beecher *et al.*, 2005, p127). Biosolids opponents counter that the existing science is untrustworthy, citing the fact that virtually all existing biosolids research has been funded by the wastewater treatment industry, EPA, or other entities that have a financial stake in the outcome. Beecher *et al* (2005) discuss some possibilities for bridging the gap of trust in biosolids science by involving stakeholders through joint fact-finding or collaborative research efforts. Ideas such as these are the latest evolution of theories of “risk communication”.

Beecher *et al* (2005) discuss “risk communication” as the primary strategy used to address stakeholder concerns and minimize or neutralize outrage factors. The theories of risk communication have gradually evolved from simply interpreting risk assessment results “in lay terms” and “gaining public acceptance” for decisions, to the more participatory approaches touched on above. Beecher *et al.* present the four stages of risk communication as outlined by Covello and Sandman (2001):

- (i.) Ignore the public—this was common before the mid-1980s;
 - (ii.) Improve explanations of data, especially data regarding risk—this, if used alone, is usually part of the “Decide-Announce-Defend (DAD)” approach;
 - (iii.) Engage in dialogue—two way communications and sharing of information and understanding; and
 - (iv.) Affect change in individual and/or organizational values and culture
- (Covello & Sandman, 2001, as printed in Beecher *et al.*, 2005, p125)

Biosolids managers and regulatory officials have typically operated in stage two of risk communication, seeking to “gain public acceptance” through better communication of scientific information to “lay people”, but only through one-way routes of communication. Stage three of risk communication involves two-way dialogue, which would, in theory, lead to the incorporation of local and lay knowledge into technical assessments of risk. Stage four of risk communication involves the direct involvement of stakeholders in all stages of the process: research goal formulation, data collection, data analysis & interpretation, and data dissemination. While much rhetoric and publicity occur in regards to implementing programs along the lines of stage three and four of risk communication, the vast majority of public agencies still follow stage two’s Decide-Announce-Defend strategy for risk communication.

In fact, while the Beecher *et al* (2005) paper presents many examples and proposals for democratizing decision making and research in the biosolids field, the perspective is still firmly entrenched in the scientific frame that views the public’s perception of risk as “irrational”. The authors go to great lengths to maintain boundaries between “perceived” risk and “calculated” risk, even changing the terminology used by Sandman, the author they are citing in developing their analysis:

He defined “risk” as the sum of “hazard” and “outrage” ($\text{risk} = \text{hazard} + \text{outrage}$), where “hazard” referred to the calculated probability of a dangerous event and its severity. A person’s level of *outrage* is influenced by *outrage factors*. (Because Sandman’s definition of “risk” is inconsistent with more common uses of the term “risk”, this paper will refer to the sum of hazard and outrage as “perceived risk”.) Everyone is influenced by outrage factors, including technical experts. In general, technical experts focus on estimating risk (what Sandman called “hazard”) and do not consider outrage factors that contribute to perceived risk. The public, on the other hand, tends to pay less attention to the calculated hazard and are significantly influenced by outrage factors.

(Beecher et al., 2005, p123)

This slight of semantics basically takes the statement, $\text{risk} = \text{hazard} + \text{outrage}$, and transforms it into two distinct statements, $\text{risk} = \text{hazard}$, and $\text{perceived risk} = \text{risk} + \text{outrage}$. The values embodied by Sandman's representation versus Beecher *et al.*'s are quite different in terms of what "real" risk is. In Sandman's model, the outrage factors are a real component of risk, probably because they embody uncertainties that are typically not accounted for in calculated "risk" or hazard. In Beecher *et al.*'s model, the "real" risk is the calculated risk, and outrage factors are extraneous factors that distort the public's perception of the true risk. The terminology of perceived risk subtly implies an unscientific and superstitious nature to the list of complaints shown above, but are lay estimations of risk really any less "true" than those of risk assessors?

Experts may have the skills necessary to create and interpret scientific data, but this does not necessarily translate into excellence in the prediction of risk. Most attempts to empirically verify predictions of risk by experts have shown extremely poor correlation between predicted risk and the actual risk determined empirically later on (Schrader-Frechette, 1990). The Beecher *et al.* (2005) paper also cites a study where "not one of a group of internationally acclaimed geotechnical engineers, when asked to estimate within a 50% confidence limit the height of an embankment that would cause failure of the clay foundation, successfully estimated that value: some had estimates above the actual fail point, some below, but none of them made an estimate that included the fail point" (p122-3). Often the response of the risk assessment community to such criticisms is that while there may be truth to these criticisms for risk assessment as it was practiced in the past, the evolving technologies and sophistication of risk assessment techniques means that we are getting better at estimating actual risk and will

be less prone to error in the future. Does the evolution of risk assessment techniques really result in less erroneous estimations of risk? How would we know one way or the other?

Schoof and Houkal (2005) provide an analysis of the evolution of risk assessment techniques applied to biosolids issues, from the risk assessment that was performed for the formulation of the Part 503 rule on heavy metals to the risk assessment that was performed on dioxin-like compounds in sewage sludge in 2002 (which serves as our case study in the next chapter). The paper outlines a transition from a deterministic risk assessment for heavy metals which analyzed exposure pathways one at time to the more sophisticated probabilistic assessment of multiple exposure pathways which was undertaken for the dioxin risk assessment. Differences between the treatment of ecological components in the two risk assessments were also discussed. The use of probabilistic exposure models “can minimize many of the concerns related to overestimating exposure due to the compounding nature of multiple assumptions of upper-bound point estimates for individual parameters” (Schoof & Houkal, 2005, p115). This statement suggests that the “technological” advances in risk assessment result in further effort being exerted to avoid false positive, or Type I, errors (finding of harm when there is no harm). The increased adoption of Monte Carlo, probabilistic analysis in risk assessment is not a value neutral technological advance in the field of risk assessment. It contains all sorts of assumptions about what is a “conservative” estimate and what is “too conservative”.

The prevailing attitude of the Schoof and Houkal (2005) paper is one of objectively cataloguing the “advances” in risk assessment science⁸, as exemplified by the risk assessment for dioxin-like compounds in biosolids. However, as we shall see, technical advances in risk assessment procedures do not necessarily translate into more accurate depictions of reality or less value-laden interpretations of risk.

⁸ In fact, that is the dominant message throughout the January 2005 special issue on biosolids found in the *Journal of Environmental Quality*. The authors included are like a who’s who of the sludge promoters, while there are no papers included by the few remaining dissenting scientists. This lack of balance in sheer number of publications is reminiscent of Latour’s ideas of making it harder and harder to disprove and assertion such as “biosolids are safe” through the sheer volume of arguments presented, and effectively outgunning the competition until your assertion is accepted as fact. While some may say this sounds absurd in molecular biology, it appears to accurately describe the situation here. Perhaps those ideas are even more relevant whenever long, drawn-out scientific debates are involved.

CHAPTER IV

CASE STUDY: EPA'S 2003 DECISION NOT TO REGULATE DIOXINS, FURANS, AND DIOXIN-LIKE PCBs IN SEWAGE SLUDGE

Background

In October of 2003, the EPA issued a final ruling determining that there was no need to regulate the concentrations of dioxin and related compounds in sewage sludge (USEPA, 2003a). This decision was made in response to a court consent decree that had required the EPA to fulfill its obligations under the Clean Water Act amendment of 1986 to develop regulations for the use and/or disposal of sewage sludge. The ruling on dioxins was actually just the latest in a series of regulations and rulings that had come as a court-ordered response to a lawsuit filed by Citizens Interested in Bull Run in 1991 when the EPA failed to meet the deadline to create rules governing the land disposal of sewage sludge (Pyburn, 2003a).

This highlights one reason why the dioxin in biosolids decision serves as an interesting case study for science-based decision-making at the EPA. EPA rulings often come only in response to court orders handed down after citizens or environmental groups have sued the EPA demanding that it fulfill its statutory obligations or other directives from the U.S. Congress. This results in delaying the enactment of environmental regulations, as the EPA can typically wait until the statutory deadline for

implementation has passed, and then wait for the civil lawsuits to work their way through the courts and appeals process. When a court ruling is finalized, it usually also includes a new revised timetable for compliance. In the dioxins in biosolids example, the law requiring the EPA to develop standards for sewage sludge was passed in 1987, yet the first round of regulations was not developed until 1993, and the second round of regulations was finally addressed in 2002 and 2003, over fifteen years after the original congressional mandate (USEPA, 2001b, 2002c, 2003a).

The decision not to regulate dioxin in sewage sludge was based on a risk assessment, the peer-review of that assessment, and a finalized risk assessment addressing some of the issues raised in the peer-review (USEPA, 2003a). The findings of the finalized risk assessment are summarized in a Notice of Data Availability (hereafter referred to as the NODA) published by the EPA in the Federal Register on June 12, 2002 (USEPA, 2002c). A draft version of the risk assessment, along with its appendices and peer review documents, is available on the EPA website at <http://www.epa.gov/waterscience/biosolids/support.html>.

Risk assessment is often described as a scientific method, with techniques, algorithms, and models that are discussed and refined in peer-reviewed journals and taught at academic institutions. Despite criticisms from a variety of sources, risk analysis is typically treated as a scientific discipline. Although risk assessment is a *predictive* exercise, few attempts have been made to validate the results empirically. This work is in its infancy and fraught with limitations in the quantity and quality of data available for the verification of predictions of risk (USEPA, 2002b). Given the complexity of the interactions between environmental exposures to toxins and human or

ecological “health”, it is not surprising that assessing the accuracy of risk assessment’s predictions as they apply to reality is virtually impossible. It would appear that much of risk assessment would fail the “falsification” requirement of scientific statements proposed by Karl Popper, since most risk assessments are never verified (or disproved) with field data.

Regardless of the scientific rigor of the modeling equations and assumptions about reality used in risk assessment, there are other important limitations to risk assessments as they are commonly carried out that occur before the assessment has even begun.

Framing: Deciding What Will Be Decided

Risk assessments are usually commissioned by an organization using a very specific “charge” or mission statement. This practice seems reasonable, given the enormity of data that is involved in even a narrowly defined assessment, but it also has detrimental consequences. In the case of the dioxin in biosolids risk assessment, the question being asked is so specific that it (intentionally or unintentionally) misses the questions that seem to be central to the decision making process:

The goal of this risk assessment was to estimate a national distribution of the incremental increase in individual lifetime risk of developing cancer due to exposure to dioxins, furans, and PCBs potentially present in the biosolids for farm families who apply biosolids as fertilizer or soil conditioner.

(USEPA, 2002a, p 1-1)

Examining the statement of purpose on page 1-1 of the 200 page (plus 346 pages of appendices) document immediately points out four major restrictions placed on any conclusions that might be drawn from the risk assessment.

- Only “incremental” increase in risk will be assessed. In other words, dioxin exposures due to exposure from sewage sludge will not be added onto background levels. Cancer risks will be assessed as if sewage sludge (through both direct and indirect pathways) was the only source of dioxin-related compounds.
- Risk will be assessed only for the likelihood of developing cancer. There are no officially accepted data or models for non-cancer effects of dioxins, furans and co-planar PCBs. Most risk assessments for potentially toxic compounds use cancer or death as the human health “endpoint”.
- Only cancer effects attributable to the dioxin-like family of compounds will be assessed. This is not a combined assessment of the increase cancer rates due to all of the potential compounds present in sewage sludge. This approach excludes both additive and synergistic effects of combinations of potentially toxic compounds.
- The risk assessment will only assess the risk for farm families that have biosolids applied on their land. The EPA uses this approach to create a “high-end” scenario of exposure. The rationale is that if the most highly exposed portion of the population experiences an acceptable level of risk according to the assessment, then the activity can be assumed to be “protective of the public health” since the risk to the general public will be substantially less than that of the “high-end” population (USEPA, 2001a).

The following sections will examine each of these four framings of the risk assessment:

Incremental Risk

The principle of calculating incremental risk of cancer incidence means that the application of sewage sludge will be the only source of dioxin exposure accounted for in the risk assessment. The rationale is that a particular activity can be assessed according to the proportion of increased cancer risk that is attributable only to that

practice. This approach is problematic because the activities to be analyzed are chosen subjectively, and a single issue may be partitioned into several different risk assessments⁹. Each of these risk assessments may conclude an “acceptable” level of risk, but the risks might be quite different if the cumulative effects of several related activities (or several risks associated with the same activity) were evaluated in a combined risk assessment.

The approach of incremental risk also precludes discussion of the nature of “background” exposures. In fact, the EPA uses the comparison of dioxin-related cancer risks attributable to sewage sludge versus the “background” exposure risks (an order of magnitude higher) to justify the assessment of risk as “reasonable” (USEPA, 2003a). Although recent studies have indicated that some dioxin-related compounds can be produced in nature, it is generally accepted that a drastic increase in dioxin levels in the environment began in the 1930s, peaked in the 1970s, and has been declining to the present day as a result of improved industrial processes and increased regulation. This spike in dioxin levels correlates well with the advent of organochlorine chemistry being applied in a variety of arenas.

Environmental groups contend that it is inappropriate for the EPA to use the term “background” or “reservoir source” to describe current exposures to dioxin compounds. These groups assert that “background” exposures are actually the result of “the long term contamination as a result of putting the chlorine materials and products into play in the environment. . . . [W]e again think this is a euphemism for human

⁹ Such as the separation of risks from metals, pathogens, volatile organic chemicals (VOCs), PBDEs, antibiotics, dioxin-like compounds, and all other organochlorines, into separate categories.

contamination, in this case, or also contamination of air, water, and soils media” (Public comment by Greenpeace found in USEPA, 2000b). The categorization of environmental dioxin levels as “background” illustrates the propensity of risk assessment to isolate environmental issues from their historical contexts.

An Aside - The Draft Dioxin Reassessment

The issue of background exposures is extremely complex due to the ongoing controversy surrounding the Draft Reassessment of Dioxin. Links to all the pertinent documents of the ongoing reassessment are available at <http://cfpub.epa.gov/ncea/cfm/part1and2.cfm?ActType=default>. This assessment has been the center of controversy from both industry and environmental movements. The reassessment was begun in 1991, but has been tied up in an endless sequence of internal and external peer reviews, revisions, and further peer reviews. The dioxins in biosolids risk assessment uses some of the newer science presented in the reassessment, but the all important dose-response relationship between dioxin and cancer was still characterized using data from 1985, since the reassessment has not yet been finalized and approved as “official science”. The reassessment also includes some information on the non-cancer effects of dioxins that was not considered in the biosolids risk assessment.

The main issue of contention in the dioxin reassessment is a new proposed cancer slope value (also known as Q^*) that is approximately six times the previous value from the 1985 assessment. The risk assessment has been debated in numerous forums, but a concise summary of important stakeholders in the debate can be found in

the observer comments to the reassessment (USEPA, 2000b). In general, environmental and citizen groups argue in support of the increased cancer slope factor (although some fault the risk assessment process as wholly inadequate), while industry representatives assert that the new slope factors were calculated without the inclusion of other data sets that show less cancer risks or even that there is not enough evidence to classify dioxins as human carcinogens at all.

The problem here is basically that the EPA reassessment finds cancer risks at the “background” levels of dioxin-related compounds (about 1 pg/kg daily intake or 5 ng/kg body burden) to be in about the 1 in 1000 range. This is far in excess of the usual “acceptable” cancer risk of 1 in a million or maybe 1 in 100,000 (although it is certainly not out of bounds with observed cancer rates). A typical EPA’s response to this new data for “background” exposures is illustrated in its discussion of non-cancer effects of dioxin in biosolids:

Conventional approaches to calculating a [reference dose] RfD for dioxins would result in an RfD that is likely to be substantially below current background intakes. For this reason, EPA believes that establishment of an RfD that is below typical background exposures is uninformative un judging the significance of incremental dioxins exposures on human health and therefore not useful for subsequent risk management decisions for dioxins. Consequently, EPA has not developed an RfD for dioxins.
(USEPA, 2003a, p61094)

Essentially, the EPA is saying that because no “reasonable” value can be found for a safe amount a dioxin, the non-cancer effects cannot be studied. This illustrates a main principle of EPA decision-making that we will revisit in several permutations. If data does not conform to the basic requirements of a risk assessment framework, as in the case of non-cancer effects of dioxins, the assessment of that risk is simply not undertaken and the risks are implicitly assumed to be zero.

Risk of cancer as sole "health endpoint"

By defining the scope of the risk assessment as only pertaining to the "lifetime risk of developing cancer", the risk assessment is framed to exclude numerous possible effects that are non-cancer related. A brief search of the scientific/medical literature turns up proposed biological links between dioxin-like compounds and neurotoxicity (Takeyama & Tohyama, 2003; ten Tusscher & Koppe, 2004), immunotoxicity (Van Loveren, Vos, Putman, & Piersma, 2003), and diabetes (Remillard & Bunce, 2002). Several of these studies emphasized the toxicity of dioxins at "critical periods" of development (Takeyama & Tohyama, 2003; ten Tusscher & Koppe, 2004; Van Loveren et al., 2003), which could influence lifetime brain, lung, and immune function. Given these concerns, it seems unreasonable for the EPA to dismiss non-cancer effects simply because it cannot determine an acceptable reference dose as discussed above.

Only cancer effects attributable to dioxins, furans, and co-planar PCBs will be assessed

Within the bounded limits of cancer effects, the risk assessment is further bounded in its mission statement to discuss only the proportion of increased cancer effects from biosolids application that is attributable to dioxins, furans, and PCBs (USEPA, 2002a). The "divide and conquer" approach is often used to isolate the risks of constituent compounds of a mixture of toxic substances. This framing excludes any additive or synergistic effects attributable to the specific combination of contaminants present in sewage sludge, such as heavy metals, volatile organic compounds (VOCs),

pharmaceuticals, flame retardants, antibiotics, and other organic compounds we have discussed that are present in biosolids and are potentially hazardous.

In regard to synergistic effects, the EPA illustrates one of the primary shortcomings of the risk assessment paradigm by again citing the lack of information as a premise for the dismissal of possible risk:

There are no models or data available to address synergistic effects with respect to the fate and transport of diverse types of pollutants. Therefore, EPA could not assess such effects from other pollutants acting in combination with [dioxins]. While such effects are always possible, EPA is not aware of scientific evidence to date suggesting that any such effects are likely to be significant for dioxins interacting with other pollutants in sewage sludge.

(USEPA, 2003a, p61095)

While certainly the absence of acceptable models for estimating risks due to synergistic effects is an understandable reason for excluding these effects from mathematical models, there does not appear to be any basis for not considering these effects at all in the decision-making process. This scientific stance is especially questionable due to the recognized mechanism of action of dioxin-like compounds as being transcriptional activators. This means that they lead to increased expression of gene transcripts within cells, and they can often amplify effects of other cancer-causing chemicals. In fact, the chlorine industry has argued that dioxin doesn't actually cause cancer itself, it just increases the likelihood of other compounds causing cancer.

In regard to additive effects, there are several contaminants that are acknowledged to be present in sewage sludge other than dioxin and the nine heavy metals currently regulated in land application of biosolids. Nitrites/nitrates and silver are contaminants that are thought to be present in levels that may pose a threat to human health, and thirteen additional chemicals failed an ecological hazard screening (USEPA,

2003b). Additive effects of the nine regulated heavy metals, nitrites/nitrates, silver, and other miscellaneous organic and inorganic compounds discussed previously that may influence the risks of dioxin exposure cannot be evaluated according to the stated goals and purpose of the dioxin in biosolids risk assessment conducted by EPA. This is an excellent example of how the simple framing of a question can have enormous scientific and policy implications.

The paper by Schoof and Houkal (2005) outlines how the advances in risk assessment have changed the techniques used in assessing heavy metals versus dioxins. It should also be noted that the pathogen regulations did not involve a risk assessment since there was not enough data available to accurately estimate risks. Schoof and Houkal do not suggest the possibility of a cumulative risk assessment in regards to biosolids, one that would combine the risks of metals, pathogens, and dioxins. Indeed, what good are improving risk assessment techniques if the old risk assessments are never revisited? Schoof and Houkal discuss the dioxin risk assessment as if the improved techniques used in the dioxin assessment somehow add legitimacy to the methods of the original risk assessment of heavy metals, yet this is obviously not the case. The advance techniques employed are of little extra value since they are used to gauge a secondary risk that one would predict to be relatively minor, rather than reanalyzing the primary risk (metal contamination).

The "high-end" scenario

This risk assessment's approach is to study the risk of the "high-end" population. The EPA constructed a hypothetical scenario where a farm family lived on a farm where sewage sludge was applied and obtained 50% of their food supply from their farm. This is indeed a very "high-end" risk population, as noted by all of the peer reviewers (USEPA, 2002b). In fact, the population is so "high-end", that the predicted population is only about 10,000 people. A cancer risk of 1 in 10,000 may seem insignificant with such a small population, but if the risk to the general population was an order of magnitude less than that of this highly-exposed group, we would be talking about approximately 3,000 additional cases of cancer due to this practice. Is that an "acceptable" risk? For whom? The EPA does not attempt to quantify the factor of safety it predicts between the highly exposed population and the general public. The above calculation uses the 2000 dioxin reassessment cancer slope value and assumes a safety factor of ten between the risk of highly-exposed populations and the general public, a number that is commonly used as a safety factor in other EPA assessments for applying dose-response curves from animal studies to humans (See O'Brien, 2000 for a critique of safety factors).

The fact that so many important variables have been overlooked or marginalized before the assessment has even begun calls into question the whole process, yet truly engaging the environmental decision-making process in the United States requires that we also investigate the assumptions contained within the body of risk assessments as well as their institutional framings.

Influence of assumptions and inferences in the risk assessment “proper”

Supposing that the reader has made it past page 1-1, there are many more aspects of the risk assessment that illustrate important “scientific” assumptions and institutional biases that contribute to the conclusion that the risks of dioxins in sewage sludge applied to land is “acceptable”. Most of these assumptions are integrated into the mathematical calculations of the risk assessment. As opposed to the framing of general questions the risk assessment will ask discussed above, these assumptions relate more to how the included data will be treated in the assessment, rather than determining which data will be included or excluded.

Equations, variables, and coefficients

Risk assessment can be qualitative, quantitative, or both. Qualitative risk assessments are not used very much by government agencies because they rely more on inference and reason (which are harder to justify in court as a basis for regulatory action or non-action) to ascertain what may be construed as “acceptable risk”. Quantitative risk assessments use highly complex mathematical models to quantify risk with a numerical estimation of risk, such as 1 in 100,000 (also shown as 1×10^{-5}) or one in a million (shown as 1×10^{-6}). Most government risk assessments are primarily quantitative, although almost all employ some qualitative analysis as well.

Quantitative risk analysis involves enormous and extremely complex mathematical models such as the “source partitioning model” and the “fate and transport model”. The source partitioning model contains fourteen variables, and the fate and transport model has 23 variables. As used in the risk assessment, a few of

these variables can be termed “coefficients”. A coefficient is a value that remains the same for every “running” of the model, and ideally it has a value that has been obtained empirically for a similar scenario as the one being assessed. Since this is often not the case, coefficients are often calculated to obtain values to use in modeling.

In addition to the calculated coefficients, many equations used in the risk assessment have variables whose values are calculated by other equations, sometimes with three or more “nestings” of equations within equations. All of these equations have many other variables and coefficients that need values to be plugged into them. Without any way to empirically evaluate the predictive models of risk assessment, it appears difficult to determine the degree to which measuring or other errors may be magnified by nesting calculated variables within other equations. It would seem worthwhile to look at how the values for some variables are chosen in the risk assessment process.

Variables can be assigned either fixed values, or can be given a different value for every iteration of the model according to some statistical distribution and within a certain range. The fixed variables in the dioxins in biosolids risk assessment were characterized as either “high-end” values, literature values or “median” (average) values. It is unclear what exactly constitutes the literature values and whether they are peer-reviewed or not, although I’m sure the appropriate reference is somewhere within the 546 page document. Median values were given to variables that have a smaller impact on the final calculated exposure, while the variables that are concerning family eating habits, cultivation practices, and scenario composition (those having a large impact on the final risk) were given “high-end” values (USEPA, 2001a). According to

the EPA's argument, this assures that the risk assessment will be highly conservative in nature. That is, any error will be on the side of over-estimating the risks to the highly exposed population. Yet there are several assumptions evident in the assignment of values to variables and the structure of the risk models that seriously undermine this explicit preference towards over-estimation of risk.

The farm scenario

The EPA's "high-end" risk scenario consisted of a farm family that had sewage sludge applied to fields adjacent to their home and obtain 50% of their diet from home produce and animal products (USEPA, 2001a). This is certainly considered to be a high-end scenario, especially when it comes to animal products consumed being produced on the home farm. Some of the peer reviewers (experts in the field of risk analysis) took issue with this scenario for being unrealistically "high-end" (USEPA, 2002b).

However, other assumptions are not so conservative. It is assumed that any farm will only receive biosolids over a range from 1 to 40 years (mean of 20 years). Since the model only has biosolids applications being performed every other year, this means that the study is only assessing the risk due to the agricultural application of biosolids a maximum of 20 times on the same field, and for the majority of iterations of the model, using a value closer to the mean of 10 applications. Is there any reason to suspect that the practice of fertilizing with biosolids is going to end after forty years? It may be "typical" practice for biosolids farmers to only fertilize their fields every other year, but there are certainly numerous farms, such as those in Kern County that are

primarily run as land disposal sites with agricultural applications. To my knowledge there is no regulation against spreading sludge every year as long as the cumulative metal loading limits (which no one is monitoring) have not been exceeded. It seems likely that many farms that participate in biosolids programs apply sludge every year on at least part of their property.

Although the EPA recognizes the transient spikes that may occur in dioxin levels in sewage sludge (USEPA, 2003a), the variable for sewage sludge composition was set as follows:

For each iteration, the concentration of dioxins in the sludge was assumed to remain constant for the entire period of application since family farms would likely receive sewage sludge from a single POTW.

(USEPA, 2002c, p40562)

Since the EPA was already using a full probabilistic Monte Carlo analysis in their risk assessment, it seems odd that they would chose to hold a variable such as dioxin concentration constant, rather than giving a range of distributions, with one value selected at random to be used in each iteration of the model. It makes one wonder if the results might be quite different if dioxin concentration is treated as a probabilistic variable.

The Farm "Family"

It is perhaps in its assumptions about the "farm family" that the EPA runs most far afoul of reality. Some mistaken assumptions are obvious. For instances, infant exposure is calculated using only the breastfeeding exposure, even though an inhalation exposure for adults and children is shown in the same table (USEPA, 2002c). It seems

obvious that infants also require air to breathe, yet this exposure pathway is absent in the assessment. The problem with the assessment of infant risk does not stop there.

Infants are defined in the study as being from 0-1 years old. It may also be interesting to note that breastfeeding exposure is limited to infants only, therefore breastfeeding children older than one do not have that exposure pathway included in their risk assessment. But worse than this classification is the implicit assumption that infants born and raised on the farm will not become the same children on that farm. After the one-year exposure from breastmilk is complete, the infant's exposure is not carried over into the child phase of the assessment.

For infants, exposure during the first year of life was averaged over an expected lifetime of seventy years to derive a LADD that was then used to calculate risk.
(USEPA, 2002c, p40565)

The result of averaging exposure during one year over seventy years is to artificially dilute the exposure, and the separation between the infant and child groups is equally artificial.

In the NODA's final assessment of the risk, it notes that the calculated risk for children is consistently less than the risk posed to adults of the highly exposed population. However, the reason for this is not because the children receive a lower exposure. This conclusion is built into the structure of the risk assessment model.

[C]hildren's mobility generally is greater than that of adults. That is, overall, the period of time that a child will occupy a given residence is shorter than the period of time an adult will occupy a given residence. Therefore, individuals whose exposures . . . begins in childhood are, general, assumed to be exposed for a shorter duration than those whose exposure begins in adulthood.

(USEPA, 2003a, p61090)

Since exposure duration is a very sensitive variable in the risk model, this assumption further dilutes the "conservative" risk estimate given for children.

Similar to the relationship between infant exposures and childhood exposures, the exposures experienced by children on sewage sludge farms do not carry over into the risk assessment of adults, most notably breastfeeding women. Children of farmers often grow up to be farmers, and would have exposures spanning infant, childhood, and adult phases of life. This failure to carry over exposures is especially erroneous since dioxins have been shown to bioaccumulate in the fatty tissues of animals.

Ecological Risk Assessment

About 68 pages out of the 546 page risk assessment and supporting appendices is devoted to an assessment of the possible ecological risks of land application of sewage sludge. Many of the assumptions noted above (especially the framings of the risk assessment) apply to a discussion of the ecological assessment as well as the human health assessment. The weight given to human health over ecological impacts is repeated in most EPA risk assessments relating to pollution or toxic compounds. The “divide and conquer” approach is especially prevalent in “ecological screenings” since the combined effects of several contaminants could produce hard to predict results in ecosystems.

That being said, it would be inappropriate to characterize EPA’s ecological screenings as any sort of “ecological” analysis. In the dioxins in biosolids assessment, as in many other toxins risk assessments, representative species from all food classes (herbi-, carni-, and omni-vore) and animal types (reptile, bird, rodent, etc.) are chosen and *population* health benchmarks for exposure are chosen (i.e. only death or

reproductive disorders are represented). Plants are not included at all. It seems impractical to assess the exposure to herbivores without assessing the impact of exposure to their sole food source.

There appears to be an institutional bias within the EPA towards assessing human health first, and then “screening” ecological effects as an afterthought. This approach is then narrowed down even further by only assessing risks associated with the stability of populations of animals, perhaps as a result of the pervasive impact of the Endangered Species Act.

Trade offs in “advancing” risk assessment technologies: Sensitivity Analysis

The use of probabilistic modeling in risk assessment, most often Monte Carlo analysis, involves varying multiple variables across defined distributions of values, while holding some variables constant that are thought to be less important to risk. The variable parameters are changed randomly, and the model is run again, producing another estimation of risk. This process is repeated thousands of times, and the reported risk value is typically a 95% or 99% “upper bound value”. This means that out of 1000 iterations of the model, at least 990 (for the 99% upper bound) had a calculated risk lower than the reported risk value.

This approach is contrasted with the “deterministic” risk assessment procedure, where the values thought to be most important to risk (the ones that would be varied in a Monte Carlo analysis) are given the highest reported values, while variables deemed less important are assigned the mean or average of reported values. This analysis produces a single point estimate of risk which is asserted to be highly conservative

because of the compounding of many highly conservative values. In fact, criticism of this approach as being too conservative by industry was a major driver in the trend towards increased use of Monte Carlo analysis in risk assessment. As such, it should be noted that while the theoretical motivation for increased use of probabilistic techniques is to increase the accuracy of risk models, it generally has the instrumental effect of lowering the levels of risk calculated by risk assessments.

One of the ways with which to assess the uncertainty and quality of a particular risk assessment is through a "sensitivity analysis". The idea of a sensitivity analysis is to determine the relative impact of particular variables on the calculation of risk, based on the specific equations being used in the risk assessment in question. This can serve as an important check on manipulation of risk assessment results, since it elucidates the variables that would be most likely to affect the outcome if manipulated.

In a deterministic risk assessment, a sensitivity analysis is relatively straightforward. One simply varies all of the variables, one at a time, and observes the effect on the calculated risk:

Sensitivity analysis analyses historically were conducted by evaluating how much change in risk occurred as a result of varying an individual input variable from a median or mean value to a 90th percentile or high-end value. When the risk depends on the aggregate impact of a number of input variables, however, such an approach may not necessarily identify the most important one.

(USEPA, 2002a, p 8-4)

The interaction between the different variables being changed simultaneously makes the old form of sensitivity analysis impossible. More "sophisticated" methods of conducting sensitivity analyses have been developed in response to this problem. For the dioxins in biosolids risk assessment, statistical regression methods were used to

perform the sensitivity analysis. The EPA acknowledges several limitations of this form of analysis:

Although regression methods have distinct advantages over previous approaches, certain limitations remain. Regression methods are not capable of determining the sensitivity of model results to input variables that are not varied in the analysis (e.g. assumptions) or are not otherwise included within the scope of the analysis (e.g. model-derived variables). If, for some reason, the most important variables are not varied or their variability is improperly characterized, the sensitivity analysis may not identify them as being important.

(USEPA, 2002a, p 8-5)

These statements indicate that EPA's methods for conducting the sensitivity analysis only has the capability to determine the component of risk accounted for by the variables that it has already chosen as being most significant to risk (by varying them in the Monte Carlo analysis). Hence all of the underlying values and parameters are accepted as "fact", and variables that are held constant, such as the character and composition of biosolids, dioxin concentration in biosolids, and sludge application rate, to name a few, are also not evaluated by this sensitivity analysis. This highly technical exercise therefore seems to be of little value in determining the accuracy or potential for manipulation in this risk assessment. Perhaps the proper thing to do would have been to conduct the regression analysis, but also conduct a traditional sensitivity analysis on model parameters and variables which were held constant in the Monte Carlo analysis. The feasibility of that type of analysis is questionable, however. The real lesson here is that trade-offs have occurred as risk assessment techniques have "progressed". We may have gained some more "realness" to the models, but perhaps at the expense making risk assessment even more of a "black box" than it was previously.

Accessibility and risk assessment

Risk assessments and their supporting documents may appear to be designed to drown out opposition with a sheer volume of pages. Risk assessments are often not constructed in a user-friendly format. The language is very scientific, using lots of acronyms (which are not explained in the text when they are used, but on a separate page at the beginning of the document), and continuously refers the reader to other documents for information. Tables and figures representing the real data are often put at the end, or even sometimes in other documents and their appendices. The data which are plugged into equations are also dispersed throughout the document. In order to investigate the impact of air deposition of dioxin on exposure, one would turn to Appendix H to look up the proper equation, only to find that the values for variables in the equations are either calculated in other tables within Appendix H, dispersed between Appendixes D, E, & G, or in the case of one variable defined as "calculated by source model", without any indication of what page or appendix the relevant source model equation can be found in. These documents are written to be practically indecipherable to anyone without a high level of education, and even then it can pose a significant challenge.

Risk assessments are "expert" documents, written by experts, reviewed by experts, and to be discussed only by experts. This has significant implications for concerns regarding environmental justice. Risk assessments obscure value judgments and ethical decisions behind modeling equations, conceptual site models, and terms like "acceptable risk", or "reasonably expected exposures". Of course, this is in addition to sociopolitical influences and all of the value-laden assumptions of science's

conventions for standards of proof and acceptable error that underlie the data fed into risk assessment models.

These limitations in the accessibility of risk assessment as a decision-making process are extremely problematic in what is generally viewed as a democratic society. How can there be any debate about acceptable risks when the decisions are based on a medium privy only to an exclusive few? By obscuring value judgments and policy decisions within quantitative risk assessment, the EPA avoids diverse public comment, and limits the "peer review" of its science to a small group of scientists who are all members of the risk assessment community.

Dioxin Risk Assessments: State of the Art, Delaying Distraction, or Regulatory Canary?

The choice of EPA to conduct a risk assessment on dioxin-like compounds, as opposed to other potential contaminants in sewage sludge was largely driven by its detection in sludge and its well-known toxicity. The choice of dioxin can be viewed as being motivated by the relative wealth of data and ability to use "state of the art" models, or it could alternatively be viewed as a distraction from less studied chemicals in sewage sludge that could pose more danger than compounds that were banned 30 years ago and are typically detected only in trace amounts. Dioxin is probably the most researched chemical compound in the last 50 years. EPA has been conducting the reassessment of dioxin toxicity and exposure for the last 25 years. The amount of data available makes the sort of complex probabilistic risk assessment used in our case study

possible. The less data available, the lower the possible level of sophistication in the analysis.

Yet there are many other potential reasons for assessing dioxin in sewage sludge that are less academic and affect the political legitimacy of this risk assessment. Dioxin and related compounds have been highly regulated for the last 30 years, and their releases to the environment have been severely curtailed. Very few industries currently release dioxin into the environment, and those that do typically do it through the air as a result of incineration or wood-treatment. Hence, the choice of dioxin is that of a pollutant that is not typically released into sewers but rather ends up there from historical and diffuse sources. In addition, dioxin and related compounds are known to be extremely hydrophobic (doesn't like water, likes fats). This accounts for their highly bioaccumulative nature, but it also greatly effects the calculations of how tightly dioxin-like compounds bind to the soil and to the biosolids matrix. The studying of dioxin then virtually eliminates the consideration of potential problems such as leaching to groundwater or runoff from fields since the models predict dioxins will remain bound to soil (if it does go into waterways, it will be bound to sediment). Many other compounds that could potentially contaminate biosolids do not share these unique properties, and would result in quite different assessments.

The remaining uncertainty in risk assessments despite the resources that have been committed to dioxin research and the mountains of data produced calls into question the ultimately validity of the risk paradigm. Dioxin may be a sort of "regulatory canary", indicating the extreme expense and effort we would have to go through to evaluate all chemicals on a one by one basis. It should be obvious that this

amount of research cannot be performed for all chemicals. In fact, only about 20,200 of the 82,000 chemicals in commerce have been thoroughly tested (GAO, 2005). Of the 62,000 chemicals that were in commerce at the time of TSCA's passage, only 200 of them have been subject to in-depth evaluation. The risk paradigm's view of testing chemicals one by one is therefore neither economically or scientifically viable. If we really wanted to keep dioxin out of our bodies and sewage sludge, we would need to ban chlorine chemistry, as has been outlined by Thornton (2000).

The continued rounds of testing, conducting risk assessments, and sending them off for "scientific" review, is viewed by many to be simply a delaying tactic and a waste of resources that could be better spent on investigating new chemicals or practices to replace toxic compounds and improving enforcement of existing environmental regulations.

In this chapter we have seen in specific terms the ways that framing, political interference, scientific inferences, assumptions, and human values can influence the design and outcome of risk assessments. What this analysis has shown us is that the use of science to inform policy decisions is not as straightforward as is often implied (or explicitly claimed) by those in positions of authority. It seems there is potential for dispute and varied interpretation behind every variable, yet risk assessment is often touted as helping to make government decisions more objective.

But is objectivity a goal to be sought in making environmental decisions? What is desirable is a *good* environmental decision, which may be different from the decision supposedly indicated by a "dispassionate" look at scientific data. In the concluding chapter, we will examine the potential for improving risk assessment by making its

normative assumptions a more explicit part of the analysis and discuss alternatives to risk assessment, as well as bringing our multidisciplinary perspective to bear on potential solutions to the “problem” of biosolids.

CHAPTER V

CONCLUSIONS

This thesis asks both a general question and a specific one. The general question is: does the use of risk assessment in environmental decision making help or hinder the arrival at “good” environmental decisions? This is of course situated in the larger question of what is the appropriate role of science in policy formation and/or implementation. The specific question is whether or not current regulations and practices regarding sewage sludge are sustainable (in the broad context of economic efficiency, environmental effectiveness, equity, and political legitimacy).

Being Explicit About What is Meant by “Sound Science”

In the first two chapters of this thesis, I discussed many reasons to be suspicious of the relative objectivity and general quality of the science that feeds into risk assessment models. The influences of boundary organizations, regulatory constraints, funding pressures, peer review (or lack thereof), and statistical conventions have been shown to either have the potential to bias research outcomes or dictate what research gets done and what doesn't. Yet I do maintain that science does have a special, and useful, way of collecting and evaluating new information, when *conducted properly and within the correct social context*. But what is meant by that? It means that an environment needs to be created where influence from ever-present social and political

forces is openly discussed and addressed. Further, it means that science needs to be tailored to its intended use, rather than forced into a "one-size-fits-all" mold.

This tension between scientific ideals and science as practiced in the real world is why everyone can agree in theory that "sound science" is what we need more of, though there are few who agree on what this term means. I propose that there are different criteria for sound science when dealing with regulatory science versus exploratory or "basic research" science. The most vocal proponents of sound science are attempting to force the standards of proof for exploratory science onto science that is supposed to provide us with evidence to allow us to better protect human health and the environment. Yet our discussion of scientific conventions has shown that these standards of proof are simply choices that are based on scientists' aversion to declaring an effect when there might not be one (avoiding Type I errors). There is no logical reason why the criteria for statistical significance cannot be changed for science meant for developing health protective standards, where legal statutes suggest that it is more important to err on the side of caution (avoidance of Type II errors). As mentioned earlier, simply redoing the statistics on toxicological studies would be fairly inexpensive as it would not require new experiments.

The issues of funding sources and lack of peer review for toxicological studies also need to be addressed if the proper social and political context is to be created for better and more politically legitimate regulatory science. As discussed earlier, independent research institutions could conduct toxicological research using a fund that companies paid into, rather than doing the research themselves. Third-party review of

industry data would be a smaller change that could provide at least a little increased legitimacy to industry claims of safety.

The political framing and boundary issues are much more difficult to resolve. White House appointees will always have the final option on EPA policies. Altering or superceding TSCA would require an act of congress, and the “innocent until proven guilty” standard for general commerce chemicals is well entrenched in the courts. As the EU moves forward on its REACH program, the potential for political momentum for a similar program here could increase, although spending on lobbying and public relations to combat any such movement by industry would likely be greater than anything seen before.

Assessing Risk Assessment

Risk assessments are clearly far more guilty of constructing scientific knowledge than your typical scientific discipline. In fact, the inability of risk assessment to pass the “falsification” requirement of Popper suggests that it may be inappropriate to call risk analysis a science at all. Many of the social criticisms of science that seem absurd when applied to chemistry or molecular biology are quite noticeable, and even explicit, in the field of toxicology. Risk assessment has not achieved its prominence in environmental decision making due to its proven reliability and cost-effectiveness. Rather, it has been required by the courts due to legal cases brought by industry or required legislatively through industry and business interest lobbying efforts. In fact, the reliability of risk assessments are very difficult to determine. This is in no small part due to the lack of any interest in funding (and

possibly conducting) such studies. The risk community's policy of "no data is good data" also appears to apply to the fruits of its own labor.

Risk assessments also tend to systematically unravel environmental problems and examine them piece by piece. Of course, this reductionist strategy has worked well for things like molecules and atoms, but understanding environmental issues requires taking a step backwards and evaluating the situation within its larger context. By separating cancer from non-cancer, human from ecological, chemical from chemical, current exposure from body burden, and infant from adult, risk assessment systematically ignores the larger geographic, social, and historical contexts within which pollution occurs.

When risk assessments present environmental issues as binary decisions of "is the practice acceptable?" rather than consider all potential alternatives to the practice, they are systematically limiting the scope of the debate through framing and often showing bias towards top-down, centralized, and technocratic solutions. The highly technical nature of risk assessment, and toxicology in general, also has negative implications for efforts to improve risk communication practices and address the concerns of the environmental justice movement.

The available body of knowledge about potentially toxic compounds is infinitesimally small compared to the body of knowledge that would be required to conduct detailed risk assessments of every potential pollutant, in addition to those yet to be discovered. The result of the shortcomings of the input data, combined with the flaws inherent in risk assessment methodology, is that risk assessment is a poor mediator for bringing science into policy debates, even in its most sophisticated state.

Part of the problem is that the science isn't necessarily tailored to the needs of regulators, but based on the accuracy requirements of scientific convention and traditions of the toxicological discipline. The animal bioassays conducted to determine toxicity data for most compounds take at least two years, are of questionable accuracy or relevance to human health, and involve high-doses unlikely to ever be experienced by the public. Animal bioassays have been shown to be poorly predictive or carcinogenicity, as discussed earlier, and another detailed meta-analysis of teratology (birth-defect) research using animals concluded the studies had essentially no predictive value in determining the likelihood of birth defects in humans (Bailey, Knight, & Balcombe, 2005). So while toxicologists may consider the rodent carcinogenicity assay the gold standard, its usefulness to policymakers is actually quite limited, often delaying action and increasing uncertainty.

In vitro models using cultured cells could be used to determine some toxicological properties extremely rapidly, and human cells could be used, lowering some uncertainties due to species differences. This would certainly have its own problems, as cells are not differentiated tissues and it would not work for all types of compounds, but the cell culture testing or some other form of short-term test could be designed to minimize false negatives, and any positives could be flagged for more extensive tests to attempt to minimize false positives (Cranor, 1997). Whole organism studies could also be done much more rapidly in invertebrates with short life cycles, such as *C. elegans* (nematode) and *Drosophila melanogaster* (fruit fly). This is one way to be more explicit with our standards of proof and tailoring the values embodied in our statistics to the regulatory needs. While this would not necessarily eliminate long-term,

whole organism studies, it would provide policymakers with data with which to craft interim decisions while awaiting more complete data.

The more rapid acquisition of data would be an improvement from the status quo, but our discussion has highlighted the point that it is essentially impossible to collect enough information to even approximately determine the risks of all chemicals, in all their common combinations, and in all the situations where they are likely to be encountered. The goal of the risk paradigm to catalogue risk in the reductionist vein is probably doomed to failure, but this doesn't necessarily mean that risk assessment in some form is never useful. Risk assessment and toxicology would have to make significant institutional transformations in order to be truly helpful in making good environmental decisions. Most importantly, risk assessment would need to become more like a real scientific discipline, where theories were proposed in risk assessments and then tested or verified for their accuracy in the field. Risk assessors could be "assessed" based on how successful their past predictions have been.

Appropriate Roles for Science in Environmental Decision-making

Risk assessment only provides tools for evaluating the environmental effectiveness component of sustainable decisions¹⁰, and its capacity in that regard is quite limited, since it is mainly a predictive exercise with no follow-up to determine how accurate the assessment actually was. Herrick and Sarewitz (2000) take predictive science (or "ex ante" evaluation) to task for its inability to actually resolve

¹⁰ It should be noted that some analysis of economic efficiency is often incorporated by accompanying cost-benefit or "cost-of-regulating" analyses.

environmental issues or controversies. They propose that science should play a larger role in "ex post" evaluation, where science participates in the implementation of environmental decisions after the economic and ethical issues have been resolved in the political realm. They borrow the concept of adaptive management as a model for how this sort of science-policy relationship would work:

An adaptive policy is one that is designed from the outset to test clearly formulated hypotheses. . . . If the policy succeeds, the hypothesis is affirmed. But if the policy fails, an adaptive design still permits learning, so that future decisions can proceed from a better base of understanding.
(Lee, as quoted in Herrick & Sarewitz, 2000, p325)

The adaptive management model is useful and is conceptually very appealing, but it is difficult to see how every potential policy could be framed in the form of a hypothesis. In addition, different stakeholders may have completely different ideas of what constitutes the relative failure or success of a policy. Bringing science in as the main evaluator of policy success could easily have the result of slanting the reviews towards commercial interests, since the number of scientist associated with or funded by commerce is much greater than those who claim to represent the public interest. Still, the concept that policies should be designed with clear implementation and monitoring goals, as well as some flexibility to changes throughout time, is certainly of value, especially in regard to the sewage sludge debate. Shifting some of the energies of science from predictive exercises to implementation and evaluation exercises would certainly improve the ability of science to accurately evaluate the environmental effectiveness component of environmental decisions. Addressing equity and political legitimacy concerns will require much larger changes in how regulators and scientists are used to doing things.

Risk assessment as currently practiced is often the foundation for the “defend” component of the Decide-Announce-Defend (DAD) mode of risk communication discussed previously. Addressing equity and political legitimacy will require moving towards the two-way dialogue and cultural/institutional changes required from the more advanced modes of risk communication discussed by Beecher *et al* (2005). As outlined by Rich *et al* (1995), a partnership approach to environmental decision-making shows much better potential to resolve controversies than the adversarial approach entailed by the DAD approach, which often results in expensive legal challenges and competing scientific data.

Partnership approaches have the explicit goal of improving the democratic nature of environmental decision-making by involving public stakeholders in all aspects of the process. This includes deciding what the problem(s) to be addressed are, what data should be collected and how, and how that data should be evaluated and interpreted. This can range from community advisory panels involvement in the planning stages to participatory research where citizen actually observe and participate in data collection, allowing them to independently verify the procedures used and perhaps increasing their trust in the process (Rich *et al.*, 1995). This approach is process-oriented, rather than based on some shifting definition of “sound science”, since “the prescription for [public distrust of scientific data] is not better data or more prestigious scientists but *an open process of accumulating and evaluating information* which allows citizens to verify its objectivity” (Rich *et al.*, 1995, p669). Opening up the environmental assessment process to diverse and previously marginalized stakeholders

could have benefits in evaluating environmental effectiveness, as well as increasing equity and political legitimacy.

Schrader-Frechette (1990) has argued that, at least conceptually, a more pluralistic approach to environmental assessment could actually increase its level of objectivity:

This sketch of the scientific objectivity characteristic of a more populist notion of technology/risk assessment is premised on the Popperian assumption that open, critical, and methodologically pluralistic approaches (via citizen participation, alternative assessments, sensitivity analysis, calibration, and ethical/methodological weighting schemes) come closest to revealing the theoretical, linguistic, and cultural invariants of reality, much as a plurality of experimental perspectives helps reveal the invariants of quantum mechanical systems.

(Schrader-Frechette, 1990, p40)

This pluralistic approach is exactly what I have attempted to bring to the sewage sludge debate. Hopefully, by incorporating a multitude of viewpoints, we have collected a body of evidence that allows us to evaluate the land application of biosolids in a larger context than has been achieved previously.

Are Current Land Application of Biosolids Practices Sustainable?

Our multidisciplinary analysis of the sewage sludge issue brings several different perspectives to this question. Of primary importance is the idea that we should be wary of how narrowly we frame our responses. The questions of biosolids' sustainability encompasses questions about how we arrived at the point where sewage sludge was created, and where it became a problem.

Sewage sludge is the product of top-down, "end-of-the-pipe" regulation. Public pressure to clean up the air and water has resulted in actions that concentrated pollutants that would have been released into these sinks into the solid phase. Confining the

debate to where we put biosolids (landfill, incinerate, farms, etc.) as currently constituted severely limits our options for arriving at a sustainable solution. Therefore we will also consider solutions that would affect the quality of biosolids, and even whether they existed at all. First we will evaluate the current context of sewage sludge land application by our four criteria of political legitimacy, equity, economic efficiency, and environmental effectiveness.

Political Legitimacy

From a procedural point of view, it's hard to imagine a more exclusionary process for the development of the Part 503 rule and the decision not to regulate dioxin-like compounds. Both were highly technical, and the Part 503 rule was perhaps simply developed on an ad hoc basis to justify existing practices. The little research that has sought to address some of the concerns raised by the public regarding pathogens and heavy metals has been subject to vociferous opposition and suppression. The dioxin risk assessment was so "state of the art" that it outstripped the capabilities of sensitivity analyses to point out the importance of several key variables that could have affected the outcome, as well as embedding numerous questionable assumptions about family farm life and chemical exposures.

The complete lack of monitoring and enforcement of biosolids regulations has probably done the most to undermine the political legitimacy of biosolids regulations. What does it matter what the quality of the regulations are if there is no way of verifying if they are being followed? Nothing infuriates local residents more than when they complain to the EPA that are experiencing allergies or reactions due to nearby

sewage sludge applications, only to hear that can't be possible since biosolids, properly applied, have been shown to not cause harm. EPA has backed into a stance where it can only refuse and refute any evidence of harm from biosolids. This stance fuels the perception that EPA is colluding with POTWs and other biosolids interests, further undermining political legitimacy.

The power differential between those who benefit from biosolids application and those who bear the risks is the underlying force of public distrust, which is why political legitimacy is intimately connected to the equity of environmental decisions.

Equity

Concerns regarding the equity or justice of sewage sludge application can generally come in four forms: (1) application is unjust because of the power differential between urban and rural communities, (2) application is unjust or inequitable because non-farming residents get no benefit in exchange for added risk, (3) application is unjust because it contaminates our food supply with industrial waste streams, and (4) application is unjust because current humans receive the benefits of fertility from biosolids while future generations will have to deal with the problems of accumulated pollutants and disruption of soil biota.

The customary defenses of land application practices have addressed these concerns to varying degrees. Cities certainly compensate farmers and local communities for using their lands as disposal sites, but this has important environmental justice implications as well, since it increases the targeting of the practice to *low income*, rural areas. The response to the concerns of non-farming residents, food

consumers, and future generations has been to deny that these groups are assuming any “significant” risk¹¹. This general lack of acknowledgement or responsiveness is a main cause of the lack of legitimacy discussed above.

Assuming that more drastic changes did not take place, a first step towards addressing these concerns would be to directly address them in a research agenda on biosolids by actually measuring effects of real biosolids mixtures on plants and animals, as was done in the sheep study of male development. Allowing the different stakeholder groups to help define the research agenda would perhaps bring science to the table that could help build trust. More drastic, but perhaps more effective, measures would be to operate from the scientifically sound position that any synthetic chemical that does not readily biodegrade is going to end up polluting some media of the earth (water, air, or land). The logical conclusion would be to re-engineer production to use toxic chemicals only when absolutely necessary and in the smallest amounts possible. This should especially be the case for compounds that have been shown to be persistent and bioaccumulative.

Economic Efficiency

From the story of sewage sludge we have seen, economic efficiency seems to be the variable that the EPA has successfully maximized in its regulation of biosolids. Land application of biosolids is certainly a win-win scenario from an economic perspective. The city gets rid of its sewage waste for an affordable cost, haulers and distributors make a nice profit networking and finding sites for application, and farmers get free

¹¹ The risk to future generations is rarely discussed and has certainly not been “assessed” in any way.

fertilizer application (or even get paid!). This is in addition to the assumed increase in profit from business and industry being able to be able to cheaply dispose of all but the most hazardous wastes.

But does this story really tell the whole economic cost? That may not be known for years, as problems either do or do not arise, although we already have the enormous costs of expanding and maintaining our giant networks of sewers and treatment plants. With the end of federal funding for treatment works in 1990, facilities will soon be looking to state, county, and city taxpayers to expand and upgrade their operations. If sewerage is seen as a subsidy to industry, the economic efficiency of this expansion is questionable. Even more questionable is the exportation of this sanitation system to the "developing" world. We should be promoting decentralized waste management abroad, even if our system is too entrenched in sewerage to make a rapid conversion. Just as the discussion of equity blended with that of political legitimacy, the issues of economic efficiency and environmental effectiveness are deeply entwined. Failure to implement environmentally effective solutions can result in enormous unexpected costs and degradation of valuable resources.

Environmental Effectiveness

In this thesis, I have attempted to balance the official biosolids narrative with a collection of alternative perspectives. Since I have focused on the alternatives, I may be justly accused of not giving adequate space to the many published works asserting the safety and effectiveness of biosolids applications. However, I think that my analysis has shown that biosolids can be quite variable in their content and quality, and that a

success story in one situation does not rule out environmental degradation in another context.

Since the EPA has chosen not to pursue the recommended monitoring, enforcement, and epidemiological studies recommended by several independent reviewers of the issue, the agency still has no way of determining how well their regulations are working. The funding constraints on the EPA are a key reason for this lack of investment in monitoring programs, which is a result of the larger political climate of the past 25 years. Without monitoring and enforcement programs, there is no way of determining the environmental effectiveness of current decisions. This is the antithesis of adaptive management and could perhaps be called "blind management", where an agency makes a regulation and then immediately buries its metaphorical head in the sand.

The creation of human waste is inevitable, but the formation of biosolids, as currently constituted, is just as much a result of economic and political forces as much as chemistry and biology. Although we can't tell how effective current regulations on biosolids are, that doesn't prevent one from finding alternative practices for dealing with human wastes that would improve environmental effectiveness. Obviously, any vision for a sustainable future will need to tackle this problem sooner or later.

When considering the narrow alternatives, land application of biosolids is certainly a more favorable option of disposal than incineration or landfill in ideal situations, but at the root of the problem is the whole cultural idea of human excreta as "wastes", combined with commerce's interest in obtaining taxpayer subsidization of waste disposal. By promoting the sewerage of communities and business throughout

the U.S., the Clean Water Act essentially legislated the co-mingling of the wastes of commerce and the wastes of the public. This has resulted in the mingling of human waste with hazardous wastes, so as to enable the cheap disposal of the latter at the expense of losing the utility of the former. Of course, the public uses all sorts of chemicals as well, so cleaning up biosolids is not quite as simple as unhooking all the business from the sewers.

One option for improvement in the quality of sewage sludge, or biosolids (as its proponents prefer) is the exclusion of chemical wastes deemed to be problematic in biosolids from the waste stream, either by curtailing their use in society in general, or requiring companies and individuals that use these chemicals to arrange for their safe neutralization or destruction through means other than the public wastewater management facilities, preferably on-site treatment.

Perhaps even more productive would be scaling back sewerage projects in favor of expanding decentralized, dry treatment options for human waste, such as composting toilets. This would have the added advantage of excluding household chemicals from the farmland-applied waste stream as well. Most importantly, dry treatment options should be promoted in places where sewerage is not yet the norm. The current state of sewage pollution technology in the United States calls into question the wisdom of exporting "developed" world sanitation systems to the "underdeveloped" or "developing" world (Orlando, 2001).

Closing the "metabolic rift" between agricultural, rural lands and the populous cities would require more than just an improvement in sludge quality, however. Clean biosolids would need to be dispersed at lower concentrations across more land to

actually replenish nutrients taken from the soil to feed, house, and clothe humans.

Spreading the human waste of all of Los Angeles just in Kern County would perhaps not be sustainable even if it all came straight from dry composting toilets.

In conclusion, our multidisciplinary analysis has shown us that while the economic efficiency of current biosolids policies is high, the environmental effectiveness is unknown, and the equity and political legitimacy of the policies are quite low. This probably means that the land application of biosolids will continue to create controversy until the equity and legitimacy issues are addressed. Perhaps this could occur along with a better establishment of environmental effectiveness by involving citizens in research efforts and monitoring operations.

The largest potential for bringing sustainability to the land application of human wastes is by reclaiming this once valuable resource from the sewers before it mixes with the products and wastes of industry. Decentralized waste management systems should be promoted as populations expand onto new lands, as well as being promoted as viable alternatives to sewerage in development projects around the world.

APPENDIX A

PRINCIPLES OF ENVIRONMENTAL JUSTICE

THE FIRST NATIONAL PEOPLE OF COLOR ENVIRONMENTAL LEADERSHIP SUMMIT

OCTOBER 24-27, 1991, WASHINGTON, D.C.

PREAMBLE

WE THE PEOPLE OF COLOR, gathered together at this multinational People of Color Environmental Leadership Summit, to begin to build a national and international movement of all peoples of color to fight the destruction and taking of our lands and communities, do hereby re-establish our spiritual interdependence to the sacredness of our Mother Earth; to respect and celebrate each of our cultures, languages and beliefs about the natural world and our roles in healing ourselves; to insure environmental justice; to promote economic alternatives which would contribute to the development of environmentally safe livelihoods; and, to secure our political, economic and cultural liberation that has been denied for over 500 years of colonization and oppression, resulting in the poisoning of our communities and land and the genocide of our peoples, do affirm and adopt these Principles of Environmental Justice:

1. Environmental justice affirms the sacredness of Mother Earth, ecological unity and the interdependence of all species, and the right to be free from ecological destruction.
2. Environmental justice demands that public policy be based on mutual respect and justice for all peoples, free from any form of discrimination or bias.
3. Environmental justice mandates the right to ethical, balanced and responsible uses of land and renewable resources in the interest of a sustainable planet for humans and other living things.
4. Environmental justice calls for universal protection from nuclear testing, extraction, production and disposal of toxic/hazardous wastes and poisons and nuclear testing that threaten the fundamental right to clean air, land, water, and food.
5. Environmental justice affirms the fundamental right to political, economic, cultural and environmental self-determination of all peoples.

6. Environmental justice demands the cessation of the production of all toxins, hazardous wastes, and radioactive materials, and that all past and current producers be held strictly accountable to the people for detoxification and the containment at the point of production.
7. Environmental justice demands the right to participate as equal partners at every level of decision-making including needs assessment, planning, implementation, enforcement and evaluation.
8. Environmental justice affirms the right of all workers to a safe and healthy work environment, without being forced to choose between an unsafe livelihood and unemployment. It also affirms the right of those who work at home to be free from environmental hazards.
9. Environmental justice protects the right of victims of environmental injustice to receive full compensation and reparations for damages as well as quality health care.
10. Environmental justice considers governmental acts of environmental injustice a violation of international law, the Universal Declaration On Human Rights, and the United Nations Convention on Genocide.
11. Environmental justice must recognize a special legal and natural relationship of Native Peoples to the U.S. government through treaties, agreements, compacts, and covenants affirming sovereignty and self-determination.
12. Environmental justice affirms the need for urban and rural ecological policies to clean up and rebuild our cities and rural areas in balance with nature, honoring the cultural integrity of all our communities, and providing fair access for all to the full range of resources.
13. Environmental justice calls for the strict enforcement of principles of informed consent, and a halt to the testing of experimental reproductive and medical procedures and vaccinations on people of color.
14. Environmental justice opposes the destructive operations of multi-national corporations.
15. Environmental justice opposes military occupation, repression and exploitation of lands, peoples and cultures, and other life forms.
16. Environmental justice calls for the education of present and future generations which emphasizes social and environmental issues, based on our experience and an appreciation of our diverse cultural perspectives.

17. Environmental justice requires that we, as individuals, make personal and consumer choices to consume as little of Mother Earth's resources and to produce as little waste as possible; and make the conscious decision to challenge and reprioritize our lifestyles to insure the health of the natural world for present and future generations.

Adopted today, October 27, 1991, in Washington, D.C.

(as reprinted in Frey, 2001, p121-2)

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