GLOBAL RBCA: ITS IMPLEMENTATION, FOUNDATION IN RISK-BASED THEORY, AND IMPLICATIONS

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I. INTRODUCTION

During the 2003 Regular Session, the Florida Legislature enacted CS/HB 1123, commonly referred to as "Global Risk-Based Corrective Action" or "Global RBCA."[2] Subsequently signed by Governor Jeb Bush on June 20, 2003, and codified at section 376.30701, *Florida Statutes*, Global RBCA mandates that risk-based corrective action, a process which bases remedial action on potential human health effects resulting from exposure to chemical compounds, be implemented at all contaminated sites in Florida.

Hardly new, RBCA has been implemented in Florida at sites impacted by petroleum products, dry cleaning operations, and brownfield sites, collectively referred to as "program sites," since the late 1990's.[3] At such sites, RBCA principles governed corrective action by establishing contaminant target cleanup levels (CTLs), risk-based target concentrations, for a variety of chemical contaminants based upon either conservative default assumptions or site-specific data. Although originally the rule for each of the program sites with CTLs for chemicals relevant to that particular program, the Florida Department of Environmental Protection (FDEP), in 1999, decided to consolidate all of the CTLs into Chapter 62-777, *Florida Administrative Code*. Although Chapter 62-777 lacked a process by which RBCA was to be conducted, it provided a regulatory repository for CTLs, enabling CTLs for identical chemicals to be located in one rule rather than scattered throughout three rules. In addition, FDEP provided the risk methodology used to calculate CTLs in the guidance document *Technical Report: Development of Soil Cleanup Target Levels (SCTLs) for Chapter 62-777, F.A.C.* (*CTL Technical Report*).[4]

The RBCA program embodied by Chapter 62-777 and the rules developed for the program sites employed a three-tiered approach that permits an increasingly detailed level of assessment when default assumptions are believed to overstate actual site

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2. Act effective June 20, 2003, ch. 2003-173, 2003 Fla. Laws 173 (codified at FLA. STAT. § 376.30701 (2005)).

3. *See generally* FLA. ADMIN. CODE ANN. r. 62-770 (2005) (Petroleum Contamination Site Cleanup Criteria) [hereinafter Petroleum Rule]; FLA. ADMIN. CODE ANN r. 62-782 (2005) (Drycleaning Solvent Cleanup Criteria) [hereinafter Drycleaning Rule]; FLA. ADMIN. CODE ANN r. 62-785 (2005) (Brownfields Cleanup Criteria) [hereinafter Brownfields Rule]; FLA. ADMIN. CODE ANN r. 62-777 (2005) (Contaminant Cleanup Target Levels).

4. CHRISTOPHER J. SARANKO ET AL., TECHNICAL REPORT: DEVELOPMENT OF SOIL CLEANUP TARGET LEVELS (SCTLS) FOR CHAPTER 62-777, F.A.C., (May 26, 1999) *superseded by* CTR. FOR EVNTL. & HUMAN TOXICOLOGY, UNIV. OF FLA., TECHNICAL REPORT: DEVELOPMENT OF CLEANUP TARGET LEVELS (CTLS) FOR CHAPTER 62-777, F.A.C., (Feb. 2005) [hereinafter CTL TECHNICAL REPORT].

conditions. Global RBCA takes these existing risk-based principles and applies them to the remainder of Florida's contaminated sites. However, due to this universal application, the prescriptive nature of RBCA,[5] and the consolidation of the rulemaking process with that of previously enacted risk-based rules,[6] environmental organizations and industry appeared in force to participate in the formal process to adopt rules implementing Global RBCA.[7] Due to this healthy debate, the formal rulemaking proved to be quite an administrative challenge.[8] In fact, although the Legislature passed CS/HB 1123 in 2003 and demanded promulgation of implementing rules by July 1, 2004,[9] the FDEP required nearly two years of debate to eventually promulgate Chapter 62-780 of the *Florida Administrative Code* on February 3, 2005.[10]

Without a doubt, Global RBCA creates uniformity amongst Florida's contaminated sites — something sought by the regulated parties, environmentalists, and the FDEP for several years.[11] However, since its inception and rise to prominence in the 1970's,[12] many view the concept of risk assessment as a "black box" — inputting data and receiving an answer without truly understanding how that answer was calculated.[13] In fact, none other than one

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5. Global RBCA utilizes a three-tier approach, which, at the first two tiers, requires use of default exposure parameters. Use of site-specific data is only permitted at later stages of the risk evaluation. *See infra* Section III.B.3.

6. Due to the common ground shared between Global RBCA and chapters 62-770 (Petroleum Rule), 62-782 (Drycleaning Rule), 62-785 (Brownfields Rule), and 62-777 (Contaminant Cleanup Target Levels) of the *Florida Administrative Code*, the FDEP elected to merge the adoption of Global RBCA rules with that of these other programs. Memorandum from John M. Ruddell, Director, Div. of Waste Mgmt., FDEP, to Directors of District Management, Waste Program Administrators, District Waste Program Staff, Division of Waste Management Staff (Sept. 24, 2003), *available at* http://www.dep.state.fl.us/waste/quick_topics/publications/wc/GlobalRBCA_Implemnt.pdf.

7. The formal rulemaking process consisted of three public workshops held by the Florida Department of Environmental Protection (FDEP) to facilitate public participation, an FDEP briefing of the Environmental Regulation Commission (ERC), the executive-appointed board responsible for adopting environmental rules, and the ERC adoption meeting. The FDEP makes the agendas and presented materials for these four meetings. Historical Information, http://www.dep.state.fl.us/waste/categories/wc/pages/RuleAdoptionHistoricalInformation.htm (last visited Nov. 12, 2006).

8. According to FDEP's website, the FDEP received 53 comments and eight proposed amendments to the proposed rules. *Id.*

9. FLA. STAT. § 376.30701(2) (2005).

10. *See generally* Chris Saranko, *The Environmental Regulation Commission Adopts Global RBCA*, 26 ENVTL. & LAND USE L. SEC. REP. 3, 3 (2005) [hereinafter *ERC Adoption*] (describing the adoption process).

11. *See* GEOFF SMITH ET AL., DRAFT REPORT, CONTAMINATED SOILS FORUM POLICY SUBCOMMITTEE CLEANUP FOCUS GROUP 8-14 (Nov. 24, 1998), *available at* http://www.dep.state.fl.us/waste/ quick_topics/publications/wc/csf/focus/112498.pdf (established by FDEP to provide a forum for discussion of Florida environmental law, the Contaminated Soils Forum consists of industry, state regulators, consultants, researchers and lawyers).

12. *See infra* Section II.A.

13. *See, e.g.,* Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 490 (1995).

of risk assessment's greatest proponents, William Ruckelshaus, once cautioned to "remember that risk assessment data can be like the captured spy: if you torture it long enough, it will tell you anything you want to know."[14]

From this author's perspective, the black-box nature of risk assessment becomes particularly enhanced when numeric standards are based upon risk principles. With published standards, in this case CTLs, an interested party only observes a not-to-exceed value for a particular contaminant without knowing the assumptions, inputs, and formulas used to calculate that value. As such, we move a step further away from the underlying exposure assessment and risk characterization which form the basis of that standard and, effectively, insulate the risk methodology from scrutiny.

With the enactment of Global RBCA and promulgation of Chapter 62-780, it becomes crucial that the science behind these now universal standards is understood by those regulated by them. Furthermore, notwithstanding the appeal of a uniform regulatory scheme, the implementation of Global RBCA is likely to create lesser known consequences, such as imposing new applicable or relevant and appropriate standards (ARARs) on Superfund sites in Florida[15] and limiting a local government's ability to regulate land use.[16]

Therefore, this Note has two purposes. First, because of the aforementioned black-box nature of risk assessment, this Note attempts to provide a solid understanding of the history of human health risk assessment and the risk-based principles incorporated into the Global RBCA program. Second, this Note evaluates two problematic implications of Global RBCA: creation of new ARARs and interference with Florida's growth management regime.

In the discussion that follows, Section II examines the origins of human health risk assessment, the judiciary's acceptance and contribution to its use, and a discussion of chemical toxicity. Section III of this Note presents the traditional regulatory structure under which environmental remediation occurred in Florida, including an in-depth discussion of the risk-based methodology employed under Chapter 62-780. Section IV of this Note explains the details of Global RBCA and the contentious issues deliberated upon during rulemaking. In addition, Section IV presents two major implications of Global RBCA's enactment: the creation of new

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14. William D. Ruckelshaus, *Risk in a Free Society*, 4 RISK ANALYSIS 157, 157-58 (1984) (echoing the *Red Book*'s warning to separate risk assessment from risk management).
15. *See infra* Section IV.B.1.
16. *See infra* Section IV.B.2.

ARARs for Comprehensive, Environmental, Response, Compensation, and Liability Act (CERCLA) sites located in Florida and the potential disruption to Florida's growth management system. Finally, Section V summarizes and concludes.

II. THE ORIGINS, JUDICIAL TREATMENT, AND TOXICOLOGICAL MECHANISMS UNDERPINNING HUMAN HEALTH RISK ASSESSMENT

To grasp why the Florida Legislature elected to implement Global RBCA and to understand the unintended implications of its enactment, it is necessary to appreciate the scientific, legislative, and judicial origins of human health risk assessment. The following sections provide a general background of risk assessment, concluding with a discussion of carcinogenic and noncarcinogenic theories of toxicity.

A. The Origins of Federal Risk Assessment Utilization

Although this Note focuses upon risk assessment and its application in environmental regulatory schemes, the Food and Drug Administration (FDA) was the first federal administrative agency to utilize risk assessment as a means of addressing potential for adverse human health effects.[17] In 1950, Congress prohibited foods containing "poisonous or deleterious" substances[18] and demanded that food additives must be "safe."[19] In what became a crucial addition to this legislation, the so-called Delaney Clause altogether prohibited carcinogenic food additives.[20] Subsequently, the FDA began analyzing and assessing the potential toxicity of food additives and established many of the metrics which are used in risk assessments today.[21]

Although Congress incorporated the Delaney Clause in 1958, outside of the FDA, federal agencies failed to utilize risk assessment until the 1970's when the U.S. Environmental Protection

17. Matthew D. Adler, *Against "Individual Risk": A Sympathetic Critique of Risk Assessment*, 153 U. PA. L. REV. 1121, 1133 (2005).

18. 21 U.S.C. § 342(a) (2000).

19. 21 U.S.C. § 348(c)(3)(A) (2000).

20. *See* Food Additives Amendment of 1958, Pub. L. No. 85-929, § 2, § 409(c)(3)(A), 72 Stat. 1784, 1786 (codified at 21 U.S.C. § 348(c)(3)(A) (2000)) ("[N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal…."). *Id.*

21. For example, FDA developed the No Observed Adverse Effect Level (NOAEL), considered a safe level for noncarcinogens, and the one-in-one-million acceptable risk level for carcinogens.

Agency (EPA) and the Occupational Safety and Health Association (OSHA) began recognizing risk assessment as a means of regulation.[22] Notwithstanding the EPA and OSHA's use of risk assessment principles, three prominent developments spurred the risk assessment's establishment as a staple of administrative decision making.[23] First, in *Industrial Union Department v. American Petroleum Institute*,[24] the United States Supreme Court demanded that OSHA make some effort to quantify the costs and benefits of health and safety regulation[25] and generally encouraged federal utilization of risk assessment.[26] Second, in 1983 Ronald Reagan appointed William Ruckelshaus, a staunch supporter of risk assessment, to the position of the EPA Administrator.[27] Third, the 1983 publication of the National Academy of Sciences' (NAS) seminal *Risk Assessment in the Federal Government: Managing the Process*, or the "*Red Book*",[28] provided a valuable, standardized framework for federal risk assessment.[29]

Although having expanded to a variety of state and federal regulatory schemes, risk assessment, at least in a procedural sense, remains nearly unaltered from the general methodology presented in the *Red Book*. In fact, the EPA adopted the *Red Book* methodology when developing its influential CERCLA risk assessment procedure.[30] The following sections examine the influential methodologies presented in the *Red Book* and the regulatory framework adopted pursuant to CERCLA.

1. The National Academy of Sciences' Red Book

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22. CRS REPORT FOR CONGRESS, ENVIRONMENTAL RISK ANALYSIS: A REVIEW OF PUBLIC POLICY ISSUES II, 98-618 ENR (1998), at 1.

23. Adler, *supra* note 16, at 1134.

24. 448 U.S. 607 (1980). Section II.B.1. provides a more thorough evaluation of *Industrial Union*.

25. *Id.* at 642-43.

26. Randall S. Wentsel, *Application of Risk Assessment in Policy and Legislation in North America*, *in* HANDBOOK OF ENVIRONMENTAL RISK ASSESSMENT AND MANAGEMENT. 261, 262 (1998).

27. John D. Graham, *Historical Perspective on Risk Assessment in the Federal Government*, 102 TOXICOLOGY 29, 39 (1995).

28. NAT'L RESEARCH COUNCIL, NAT'L ACAD. OF SCIENCES, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) [hereinafter RED BOOK].

29. Interestingly, the *Red Book* arose from a NAS study authorized by Congress in reaction to risk policy developed by the Interagency Regulatory Liaison Group (IRLG). The IRLG consisted of representatives from the EPA, OSHA, the Consumer Product Safety Commission, FDA, and the Department of Agriculture and sought to coordinate risk management across federal agencies. However, critics argued that the policy developed by the IRLG permitted politics to influence scientific judgments. *See* CRS REPORT FOR CONGRESS, *supra* note 22.

30. OFFICE OF EMERGENCY AND REMEDIAL RESPONSE, U.S. EVNTL. PROT. AGENCY, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOLUME I, HUMAN HEALTH EVALUATION MANUAL (PART A) 1-1 (Dec. 1989) [hereinafter RAGS PART A].

Unequivocally, the underlying foundation of risk assessment is that risk is a product of a chemical's toxicity and a person's exposure to that chemical.[31] As a means of quantifying that potential risk, the *Red Book* developed a four-step process: hazard identification, toxicity assessment, exposure assessment, and risk characterization.[32]

Importantly, the *Red Book* distinguishes the scientific and mathematical concept of risk assessment from the subjective and often political concept of risk management.[33] To wit, risk assessment demands a detailed evaluation of data and typically utilizes a prescriptive set of procedures to arrive at a hard, quantitative value.[34] On the other hand, risk management entails a subjective decision whether to take action upon the quantitative results of the risk assessment or to remain idle.[35] As such, risk management balances potential risks with political, economic, and social policy issues and often involves a decision as to how much risk is acceptable.[36]

Of course, the demarcation between science and policy oftentimes becomes blurred and nearly indistinguishable: an issue not lost upon the NAS.[37] An oft-criticized aspect of risk assessment is its heavy reliance on overly conservative assumptions.[38] The use of a conservative or non-conservative assumption certainly involves some level of policy judgment and casts doubts upon the existence of the risk assessment/risk management dichotomy.[39] Nevertheless, the *Red Book*'s separation of risk assessment and risk management appears throughout regulatory programs[40] and,

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31. Elaine M. Faustman & Gilbert S. Omenn, *Risk Assessment*, *in* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 75 (5th ed. 1996).

32. RED BOOK, *supra* note 28, at 19-20.

33. *Id.* at 18-19.

34. *Id.* at 19-20.

35. *Id.* at 18-19.

36. Celia Campbell-Mohn & John S. Applegate, *Learning from NEPA: Guidelines for Responsible Risk Legislation*, 23 HARV. ENVTL. L. REV. 93, 97 (1999); Ruckleshaus, *supra* note 14, at 157.

37. RED BOOK, *supra* note 28, at 14-15.

38. Utilization of conservative assumptions at data gaps constitutes a policy decision aiming to assuage public fears over the inherent variability and uncertainties of quantifying the unknown. Campbell-Mohn & Applegate, *supra* note 36, at 102. For criticism of the use of conservative assumptions, see Adam M. Finkel, *A Second Opinion on an Environmental Misdiagnosis: The Risky Prescriptions of Breaking the Vicious Circle*, 3 N.Y.U. ENVTL. L.J. 295, 333 (1995) and Shere, *supra* note 13, at 470.

39. Campbell-Mohn & Applegate, *supra* note 36, at 97-98.

40. John S. Applegate, *Risk Assessment, Redevelopment, and Environmental Justice: Evaluating the Brownfields Bargain*, 13 J. ENERGY, NAT. RESOURCES & ENVTL. L. 243, 255 (1998).

at the least, "discloses the location of policy judgments throughout the assessment-management process."[41]

2. The Development of Risk Assessment Methodology under CERCLA

The publication of the *Red Book* and its subsequent adoption by the White House[42] permitted the EPA to better address an important charge of the 1980's landmark CERCLA legislation: the requirement demanding that remedial actions be "protective of human health and the environment."[43] To meet this mandate, the EPA's Office of Emergency and Remedial Response adopted a series of guidelines, manuals, and procedures,[44] culminating in the 1989 publication of *Risk Assessment Guidance for Superfund (RAGS), Volume I, Human Health Evaluation Manual*.[45] Although designed for use during the remedial investigation/feasibility study stage of a CERCLA site cleanup, the *RAGS* framework, derived primarily from the *Red Book*, laid the foundation for all environmental risk assessment regimes.[46]

B. Judicial Affirmation of Risk Assessment Techniques

As previously stated, the United States Supreme Court's decision in *Industrial Union* established risk assessment as a legally acceptable administrative tool to protect human health from potentially toxic compounds.[47] Subsequently, the D.C. Circuit strengthened this foundation through its decisions in *Public Citizen Health Research Group v. Tyson*[48] and *Natural Resources De-*

41. Campbell-Mohn & Applegate, *supra* note 36, at 98.

42. The Office of Science and Technology formally adopted the *Red Book*'s framework in 1985. CRS REPORT FOR CONGRESS, *supra* note 22.

43. 42 U.S.C. § 9621(b)(1) (2000).

44. *See* RAGS PART A, *supra* note 30.

45. RAGS Volume I consists of Parts A through E, *available at* http://www.epa.gov/oswer/ riskassessment/ragsa/index.htm (last updated Oct 5, 2006) (RAGS Part A); http://www.epa.gov/oswer/ riskassessment/ragsb/index.htm (last updated Oct 5, 2006) (RAGS Part B); http://www.epa.gov/oswer/ riskassessment/ragsc/index.htm (last updated Oct 5, 2006) (RAGS Part C); http://www.epa.gov/oswer/ riskassessment/ragsd/index.htm (last updated Aug 22, 2006) (RAGS Part D); http://www.epa.gov/oswer/ riskassessment/ragse/index.htm (last updated Aug 22, 2006) (RAGS Part E).

46. Lorenz R. Rhomberg, *A Survey of Methods for Chemical Health Risk Assessment Among Federal Regulatory Agencies*, 3 HUM. & ECOLOGICAL RISK ASSESSMENT 1029, 1085 (1997).

47. Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980).

48. 796 F.2d 1479 (D.C. Cir. 1986).

fense Council v. EPA.[49] Taken as a whole, these three cases provided an enthusiastic judicial affirmation of quantitative risk assessment principles.[50]

1. Industrial Union v. American Petroleum Institute

As noted in Section II.A., many of the federal agencies charged with identifying chemical carcinogens in the late 1970s disagreed as to the appropriate procedures for completing this task. To wit, the EPA and the FDA believed in the development of quantitative assessment of chemical risks based upon human epidemiological and animal laboratory studies, whereas OSHA used these same studies to arrive at a qualitative assessment of risk.[51] Decided in a five-to-four vote generating five opinions and a plurality opinion authored by Justice Stevens, *Industrial Union* ended the controversy by falling squarely on the side of quantitative estimation of risk.[52]

Industrial Union concerned OSHA's promulgation of standards regulating the occupational exposure of workers to benzene, a known human carcinogen.[53] Under section 3(8) of the Occupational Safety and Health Act of 1970, OSHA bore the responsibility of promulgating a standard "reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[54] As it pertains to toxic compounds, section 6(b)(5) of the Act stated that these standards should "most adequately assur[e], to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity" of exposure to such a compound.[55] As such, and in accordance with OSHA's adopted policy that no safe level of exposure to carcinogens exists in the absence of irrefutable proof,[56] OSHA adopted an occupational benzene standard of one part per million (ppm).[57]

In response, benzene producers challenged OSHA's methodology in selecting the one ppm standard. Specifically, the benzene industry argued that a demonstration of carcinogenicity did not cre-

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49. 824 F.2d 1146 (D.C. Cir. 1987) (en banc).
50. Shere, *supra* note 13, at 428.
51. *Id.* at 422.
52. *Id.* at 420-21 (stating that *Industrial Union* "provided risk assessment with a solid legal foundation and largely ended administrative resistance to the practice.").
53. *Industrial Union*, 448 U.S. at 611.
54. 29 U.S.C. § 652(8) (2000).
55. *Id.* § 655(b)(5).
56. *Industrial Union*, 448 U.S. at 630. For a discussion of the carcinogenic mechanism, see Section II.C.1.
57. *Id.* at 626.

ate a sufficient basis for promulgating the most stringent benzene limitations technologically and was not economically feasible.[58] In finding for the benzene industry, the Court declared that OSHA must first make the threshold determination that it is reasonable and appropriate to remedy a significant occupational risk and, only then, would it be necessary to select the most protective remedy pursuant to section 6(b)(5).[59] Reiterating that "safe" does not equate to "risk-free," Justice Stevens held that, prior to promulgation of safety standards, OSHA must demonstrate that a workplace is "unsafe — in the sense that *significant risks* are present and can be eliminated or lessened by a change in practices."[60]

Fortunately for risk assessment proponents, Justice Stevens did not stop at interpreting the Act to impose a "significant risk" proponent, but continued, essentially supporting the quantification of risk. Specifically, the plurality opinion stated that one in a billion odds of a fatality would likely fall outside of what should be considered significant, whereas a reasonable person would likely consider one in a thousand odds of a fatality significant.[61] Although not creating a "mathematical straightjacket,"[62] the opinion strongly supported utilization of risk assessment to determine the significance of risk.[63]

2. Public Citizen Health Research Group v. Tyson

As demonstrated by *Tyson*, after *Industrial Union*, OSHA altered the methods by which it promulgated occupational exposure levels. *Tyson* involved a challenge to OSHA's adoption of a one ppm standard for the carcinogenic industrial compound ethylene oxide.[64] However, this time around, OSHA satisfied section 3(8) of the Act by demonstrating the potential carcinogenicity of ethylene

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58. *Id.* at 639.
59. *Id.*
60. *Id.* at 642 (emphasis added).
61. *Id.* at 655. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as "unsafe.". *Id.*
62. *Id.* In lending support to what later was argued by industry as a weakness of risk assessment, the Court stated that "the Agency is free to use conservative assumptions in interpreting the data." *Id.*
63. Shere, *supra* note 13, at 420 (citing NAT'L RESEARCH COUNCIL, NAT'L ACAD. OF SCIENCES, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 33 (1995)).
64. Public Citizen Health Research Group v. Tyson, 796 F.2d at 1482-83 (D.C. Cir. 1986).

oxide at concentrations lower than the then-current standard of 50 ppm through epidemiological and laboratory studies.[65] OSHA then quantified the significance of the risk at low levels of exposure through the utilization of a mathematical model incorporating conservative inputs and assumptions.[66]

Referring to OSHA's approach as "thorough and professional,"[67] the D.C. Circuit stated that OSHA met its burden under the Act and "has done exactly what the Supreme Court chastised the agency for not doing in [*Industrial Union*]."[68] As such, any doubts as to the judiciary's support for an administrative agency's utilization of quantitative risk assessment following *Industrial Union* likely vanished with the emphatic language of *Tyson*.[69]

3. Natural Resources Defense Council v. EPA

Demonstrating that the judicial affirmation of risk assessment did not exclusively attach to OSHA and its obligations, *Natural Resources Defense Council v. EPA* concerned a challenge to the EPA's regulation of vinyl chloride, a known carcinogen, under the Clean Air Act.[70] Like CERCLA, the Clean Air Act demanded that the EPA set emission standards at levels "provid[ing] an ample margin of safety to protect the public health."[71] Citing the drastic economic repercussions of setting a zero-emission standard, the EPA adopted a vinyl chloride standard that required reductions of vinyl chloride to the lowest level achievable through the use of the best available control technology.[72] In contrast, the National Resource Defense Council argued that the statute only considers health and any attempt to include economic or technical considerations violates the legislative intent.[73] Accordingly, the NRDC claimed that when the data failed to identify a concentration at which no harm will occur, the statute demanded that the EPA adopt a zero-emission standard.[74]

In reasoning mirroring that of the Supreme Court in *Industrial Union*, the court found that the EPA maintained limited discretion in promulgating these standards as the statute specified that the

65. *Id.* at 1489-96.
66. *Id.* at 1496-1500.
67. *Id.* at 1503.
68. *Id.* at 1499. "The agency has gone to great lengths to calculate, within the bounds of available scientific data, the significance of the risk presented by [ethylene oxide].". *Id.*
69. Shere, *supra* note 13, at 426.
70. Natural Res. Def. Council v. EPA, 824 F.2d 1146, 1148 (D.C. Cir. 1987) (en banc).
71. 42 U.S.C. § 7412(d)(9) (2000).
72. *Natural Res. Def. Council*, 824 F.2d at 1149-50.
73. *Id.* at 1152-55.
74. *Id.* at 1152.

standard must provide "an ample margin of safety."[75] In support, the court referenced Justice Stevens' statement in *Industrial Union* that safe does not mean "risk-free" as an additional source of the EPA's discretion.[76] Nonetheless, where uncertainty exists as to the health risks of a compound, the EPA could not "substitute technological feasibility for health as the primary consideration" under the Clean Air Act.[77] Rather, the statutory mandate to provide safety and protect public health demands that the EPA make a threshold determination of what level should be considered safe—a determination founded exclusively on the "risk to health at a particular emission level."[78] Furthermore, the court stated that Congress recognized the innate uncertainties involved in such a determination, hence Congressional inclusion of the "ample margin of safety" language which permits the EPA to "account for inherent limitations of risk assessment and the limited scientific knowledge" of carcinogenic compounds.[79]

C. Theories of Toxicity

As observed in the preceding case law, discussions of chemical toxicity typically concern cancer, and with good cause, due to the scientific community's focus upon finding a cure[80] and the heavily publicized tobacco litigation over the past ten years. However, a broad range of chemicals exist that cause death or deleterious health effects by means other than cancer.[81] Unfortunately, the mechanisms by which these noncarcinogens affect human health differ considerably from that of carcinogenic compounds and, as such, quantification of potential carcinogenic and noncarcinogenic risk follows separate mathematical/toxicological pathways. When elucidating what exactly a risk assessment means, one of the most difficult tasks of any public health specialist or toxicologist is explaining the two mechanisms of toxicity: car-

75. *Id.* (citations omitted).
76. *Id.* at 1153.
77. *Id.* at 1164.
78. *Id.*
79. *Id.* at 1165.
80. ROBERT L. GLICKSMAN ET AL., ENVIRONMENTAL PROTECTION: LAW AND POLICY 659 (4th ed. 2003).
81. It should be noted that chemicals often have carcinogenic and noncarcinogenic health effects. For example, depending upon the dose and the exposure level (acute or chronic), arsenic may produce such noncarcinogenic effects as cardiac arrhythmia, degeneration of peripheral and central nervous systems, and cirrhosis of the liver. However, due to its predilection for skin cells, chronic exposure to arsenic is believed to cause two forms of skin cancer, basal cell and squamous cell carcinoma. Robert A. Goyer, *Toxic Effects of Metals, in* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 696-98 (Curtis D. Klaasen ed., 5th ed. 1996).

cinogenic and noncarcinogenic. Nevertheless, because human health risk assessment differentiates between the two and environmental programs regulate based on the potential toxicological effects, it is crucial to realize the differences between the carcinogens and noncarcinogens. The following subsections attempt to explain carcinogenic and noncarcinogenic health effects.

1. Carcinogens

As discussed in *Industrial Union*,[82] *Tyson*,[83] and *NRDC*,[84] no threshold concentration, a point at which no adverse health effects occur, exists for carcinogens.[85] That is, a carcinogen at any concentration, no matter how low, is believed to have the *potential* to cause cancer.[86] To truly grasp the no-threshold concept, it is necessary to understand that, boiled down to its most simple definition, cancer is nothing more than uncontrolled cell growth.[87] This unchecked cellular growth results from a solitary molecular event in a single cell.[88] Accordingly, even a small dose may elicit cancerous growth.[89]

Therefore, a carcinogenic risk estimate equates to the probability that a chemical compound will elicit a carcinogenic effect. As such, safety is nothing more than that level of cancer risk (i.e., probability) which can be deemed insignificant.[90] So, what level constitutes an insignificant risk? Over the years, the EPA identified one-in-a-million (1×10^{-6}) as an acceptable lifetime excess cancer risk, where lifetime excess cancers are those occurring beyond the baseline cancer rate for the unexposed population or those uniquely attributable to exposure to that compound.[91] However, in the 1980s, conceding that a discrete target risk "implied an unreal-

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82. *Industrial Union*, 448 U.S. at 630.

83. *Tyson*, 796 F.2d at 1498.

84. *Natural Res. Def. Council*, 824 F.2d at 1148.

85. For a more exhaustive discussion of the absence of effects threshold theory, see FRANK B. CROSS, ENVIRONMENTALLY INDUCED CANCER AND THE LAW: RISKS, REGULATION, AND VICTIM COMPENSATION 14-16 (1989).

86. RAGS PART A, *supra* note 30, at 7-11.

87. *Id.; see* Henry C. Pitot III & Yvonne P. Dragan, *Chemical Carcinogenesis*, *in* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 201, 201 (Curtis D. Klaasen ed., 5th ed. 1996).

88. RAGS PART A, *supra* note 30, at 7-11. Of course, this solitary molecular event can take many different forms and may occur in any of a variety of cells, locations within the cell, or different periods of cellular development and growth. *See generally* Pitot & Dragan, *supra* note 87, at 201-67.

89. *See* CTL TECHNICAL REPORT, *supra* note 4, at 8.

90. *Id.*

91. *See* RAGS PART A, *supra* note 30, at 8-6.

istic degree of scientific precision,"[92] the EPA began utilizing an acceptable risk range of 1 x 10^{-6} to one-in-ten thousand (1 x 10^{-4}).[93] For example, exposure to arsenic at a CERCLA site resulting in a lifetime excess cancer risk of one-in-ten million (1 x 10^{-7}) would be deemed insignificant. However, a lifetime excess cancer risk of two-in-a-million (2 x 10^{-6}) would constitute a significant risk.

Of course, certain carcinogens are more likely than others to elicit such effects. The metric used to estimate a compound's carcinogenicity is the cancer slope factor (CSF).[94] As discussed in *RAGS*, the CSF "defines quantitatively the relationship between [the] dose and response" and represents a "plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime."[95] Although the procedures used to calculate CSFs extend beyond the scope of this Note,[96] identifying and assessing health effects at low exposure levels (especially those levels expected for human contact in the environment) in epidemiological or laboratory studies is a difficult task.[97] Therefore, CSF development typically entails low-dose extrapolation of data generated from high-dose laboratory studies to arrive at a CSF.[98]

2. Noncarcinogens

In direct contrast to carcinogens, noncarcinogens are assumed to have a dose threshold[99] and target a specific organ or organ system.[100] Stated more simply, at lower concentrations, noncarcinogens are not expected to produce adverse health effects; however, as the exposure increases, at some specific concentration, adverse health effects will occur. In fact, many compounds elicit multiple noncarcinogenic effects, each with its own threshold.[101]

Why the difference between carcinogens and noncarcinogens? As the previous section explained the mechanism behind carcinogenesis, perhaps the best means of understanding non-cancer mechanisms is through example. Basically, the threshold concept theorizes that a chemical will not elicit a manifest effect until cer-

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92. Adam Babich, *Too Much Science in Environmental Law*, 28 COLUM. J. ENVTL. L. 119, 152-53 (2003).

93. *Id.* at 153.

94. *See generally* RAGS PART A, *supra* note 30, at 7-11.

95. *Id.*

96. See RAGS PART A, *supra* note 30, at 7-11 to 7-13, for an exhaustive discussion of CSF calculation methodology.

97. *See* RAGS PART A, *supra* note 30, at 7-11.

98. CTL TECHNICAL REPORT, *supra* note 4, at 8.

99. *Id.* at 9.

100. *See generally* Pitot & Dragan, *supra* note 87, at 201.

101. CTL TECHNICAL REPORT, *supra* note 4, at 9.

tain protective mechanisms fail.[102] For example, enzymes located in nerve synapses control the transmittal of nerve impulses by regulating the flow of chloride and calcium ions across neuronal membranes. In the simplest form, one enzyme will control ion uptake and one will control ion release. However, the pesticide dieldrin inhibits the enzyme responsible for uptake of free calcium ions in the neuron, resulting in uncontrolled stimulation of the central nervous system, hence seizures. This inhibition only takes place when enough dieldrin is present in the body to overwhelm the uptake enzyme. Therefore, at lower concentrations, dieldrin will have no effect, but eventually its concentration would overwhelm the body's ability to control nerve impulses.[103]

Functionally analogous to CSFs for carcinogenic compounds, a reference dose (RfD) is a toxicity value assigned to noncarcinogenic compounds and used to estimate potential noncarcinogenic human health effects.[104] As previously noted, a chemical may elicit multiple deleterious effects, each with its own threshold. Therefore, an RfD represents the dose at which the most sensitive effect will not occur in the most susceptible individual.[105] Furthermore, each route of exposure (i.e., ingestion, dermal contact, or inhalation) has its own specific reference dose.[106]

Unlike carcinogens, an effect probability is not calculated because of the threshold nature of noncarcinogens.[107] Rather, we assume that if the intake (i.e., dose) is greater than the RfD, an adverse health effect will result. If the intake is less than the RfD, no adverse health effect will occur. Simply put, a "yes" or "no" answer exists. Whereas excess cancer risk constitutes the metric used to estimate carcinogenic risk, a hazard quotient, the intake divided by the RfD, is used to measure noncarcinogenic risk.[108]

III. HAZARDOUS WASTE REMEDIATION IN FLORIDA

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102. RAGS PART A, *supra* note 30, at 7-6.

103. *See* Donald J. Ecobichon, *Toxic Effects of Pesticides*, *in* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 643, 653 (Curtis D. Klaasen ed., 5th ed. 1996). *See id.* at 650, tbl. 22-6.

104. RAGS PART A, *supra* note 30, at 7-5.

105. CTL TECHNICAL REPORT, *supra* note 4, at 9.

106. *Id.* Although beyond the scope of this discussion, other forms of RfDs exist based upon the chemical's critical effect (e.g., developmental) or the length of exposure (e.g., chronic and subchronic). While mandating the use of route-specific RfDs, the risk assessment procedures utilized in Florida feature only the most sensitive RfD. They are based upon the no-observed-adverse-effect level (NOAEL), rather than RfDs based upon critical effect or length of exposure. *Id.* For a discussion regarding the various forms of RfDs, see RAGS PART A, *supra* note 30, at 7-5 to 7-9.

107. RAGS PART A, *supra* note 30, at 8-11.

108. *Id.*

Due to its universal application, Global RBCA changed the face of Florida environmental law—at least as far as contaminated site remediation is concerned. However, in order to understand where Florida environmental law is going it is important to know where it has been. Accordingly, the following subsections explain the traditional regulatory programs utilized in Florida and discuss the contaminant cleanup target level (CTL) concept implemented by Chapter 62-777.

It should be noted that this Note focuses on risk-based regulations as applied to soils, rather than groundwater. This biased focus is not meant to belittle the importance of groundwater contamination or its regulation. Soils, groundwater, and surface water fall within the ambit of Global RBCA. However, because the Federal Safe Drinking Water Act[109] established maximum contaminant levels (MCLs) for groundwater contaminants, Chapter 62-777 simply incorporated the federal standards for those contaminants which the Act regulated. Although MCLs are based upon a contaminant's potential human health effects,[110] groundwater and surface water CTLs developed for those contaminants for which no MCL exists may be based on potential human health effects or aesthetic factors.[111] Nevertheless, because of the extensive federal regulatory overlay vis-à-vis groundwater, state regulatory regimes such as Global RBCA are less influential in regard to groundwater concerns than soil concerns. Therefore, Global RBCA's influence, at least in regard to creating potential remedial liability, is more likely to be felt in the realm of soil remediation.[112]

A. The Traditional Regulatory Structure in Florida

Excluding CERCLA remediation projects falling entirely under the auspices of federal authority, hazardous waste sites in Florida were traditionally managed under three regulatory schemes: the Risk-Based Corrective Action program (which applied only to petroleum, dry-cleaning, and brownfield sites), the state-implemented Resource Conservation and Recovery Act (RCRA) program, and the Contamination Assessment Plan/Remedial Action Plan (CAP/RAP) process.

1. The Risk-Based Corrective Action Program

109. 42 U.S.C. § 300—300j-26 (2000). For a thorough discussion of the Federal Safe Drinking Water Act, see GLICKSMAN, *supra* note 80, at 744-53.

110. 42 U.S.C. § 300g-1(b)(3)(C)(i) (2000).

111. CTL TECHNICAL REPORT, *supra* note 4, at 7.

112. However, it should be noted that Global RBCA creates significant flexibility in remediating impacted groundwater via natural attenuation.

Accounting for more than 90 percent of contaminated sites in Florida, petroleum,[113] dry-cleaning,[114] and brownfield[115] sites constitute the bulk of Florida's regulatory concern.[116] Aware of the issue, the FDEP first promulgated rules instituting risk-based corrective action principles for petroleum sites in 1996.[117] Shortly thereafter, the Legislature authorized utilization of risk-based corrective action for brownfields sites in 1997[118] and sites contaminated by dry-cleaning operations in 1998.[119] Together, petroleum-contaminated sites, dry-cleaner solvent contaminated sites, and brownfields are referred to as program sites.[120]

Chapter 62-777 and, more correctly, its associated guidance, the *CTL Technical Report,* provide the risk methodology for Florida's risk-based corrective action program. Regulations governing program sites incorporated Chapter 62-777 by reference[121] and, as originally promulgated in 1999, Chapter 62-777 established that it only applied to program sites.[122] Discussed in greater detail in Section III.B.3., the RBCA program utilizes a three-tiered approach to risk assessment, with each tier demanding a more detailed and thorough assessment of risk.[123]

2. *The RCRA Program*

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113. FLA. STAT. § 376.303 (2005) (establishing a program to regulate petroleum storage tanks); FLA. ADMIN. CODE. ANN. r. 62-770 (2005) (establishing criteria for a rehabilitation program for petroleum sites and incorporating Chapter 62-777).

114. FLA. STAT. § 376.3078 (2005) (establishing a state-funded program to cleanup those properties contaminated due to drycleaning operations); FLA. ADMIN. CODE ANN. r. 62-782 (2005) (establishing criteria for a rehabilitation program and incorporating Chapter 62-777).

115. FLA. STAT. § 376.77, 376.85 (2005) (known as the Brownfields Redevelopment Act); FLA. ADMIN. CODE ANN. r. 62-7852 (2005) (establishes cleanup criteria for designated brownfield sites and incorporates Chapter 62-777).

116. FLA. DEP'T OF ENVTL. PROT., FINAL STATEMENT OF ESTIMATED REGULATORY COST FOR PROPOSED REVISIONS TO: CHAPTER 62-777, F.A.C., "CONTAMINANT TARGET CLEANUP LEVELS" (Dec. 23, 2004), *available at* http://www.dep.state.fl.us/waste/quick_ topics/publications/wc/ERCAdoptionHearing020205/SERC/777FinalSERC12-23-04.pdf (last visited Nov. 16, 2006).

117. CONTAMINATED SOILS FORUM, POLICY SUB-COMMITTEE FOCUS GROUP ON NEED FOR UNIFORM POLICY, *available at* http://www.dep.state.fl.us/waste/quick_topics/publications/wc/csf/focus/cufg_gs.pdf (last vistited Nov. 16, 2006).

118. FLA. STAT. § 376.77 (2005).

119. FLA. STAT. § 376.3078 (2005).

120. *Id.*

121. *See* FLA. ADMIN. CODE ANN. r. 62-770 (2005) (Petroleum Rule); FLA. ADMIN. CODE ANN r. 62-782 (Drycleaning Rule); FLA. ADMIN. CODE ANN. r. 62-785 (Brownfields Rule).

122. Memorandum from John M. Ruddell, Director, Division of Waste Management to Directors of District Management, Waste Program Administrators (Sept. 29, 2000), *available at* http://www.dep.state.fl.us/waste/quick_topics/publications/documents/soilcleanup.pdf [hereinafter Ruddell].

123. *See infra* Section III.B.3.

In contrast to CERCLA remediation sites, RCRA cleanup sites are not regulated under a comprehensive federal corrective action regime; RCRA cleanup sites are regulated on a case-by-case basis.[124] However, following a thorough evaluation of the state regulatory scheme to ensure compliance with federal guidelines, the EPA may delegate regulatory authority under RCRA to individual states.[125] The EPA granted Florida authority to implement the RCRA hazardous waste program in 1985.[126] As a result, the FDEP regulates RCRA sites in the same manner as program sites through the implementation of the risk-based requirements established by Chapter 62-777.[127]

3. The CAP/RAP Process

Prior to the promulgation of rules implementing Global RBCA, the FDEP managed those contaminated sites not recognized as program sites or regulated pursuant to RCRA under the CAP/RAP process.[128] The FDEP guidance document *Model Corrective Actions for Contaminated Site Cases* (*CACSC*) provided the structure for investigation and remediation of these contaminated sites.[129] Specifically, the *CACSC* recommended procedures for the development and approval of work plans and reports and included remediation criteria based upon applicable groundwater and surface water standards, groundwater guidance concentrations,

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124. Philip E. Karmel, *Achieving Radical Reductions in Cleanup Costs*, 487 PRACTISING L. INST., REAL EST. L. AND PRAC. COURSE HANDBOOK SERIES 315, 348 (2002).

125. 43 U.S.C. § 6926(b) (2000).

126. 50 Fed. Reg. 3908 (Jan. 29, 1985). Of course, the states must maintain a program equivalent to and as stringent as the federal program. Therefore, when the EPA amends the federal regulations, states must also amend their programs. As such, the EPA granted subsequent authorizations for the amendment of the Florida RCRA program in 1987. 52 Fed. Reg. 45,634 (Dec. 1, 1987); 53 Fed. Reg. 50,529 (Dec. 16, 1988), 55 Fed. Reg. 5141 (Dec. 14, 1990); 57 Fed. Reg. 4371 (Feb. 5, 1992), 57 Fed. Reg. 4738 (Feb. 7, 1992), 57 Fed. Reg. 21,351 (May 20, 1992); 58 Fed. Reg. 59,367 (Nov. 9, 1993); 59 Fed. Reg. 35,266 (July 11, 1994); 59 Fed. Reg. 41,979 (Aug. 16, 1994); 59 Fed. Reg. 53,753 (Oct. 26, 1994); 62 Fed. Reg. 15,407 (Apr. 1, 1997); 66 Fed. Reg. 44,307 (Aug. 23, 2001); 67 Fed. Reg. 53,886; 67 Fed. Reg. 53,889 (Aug. 20, 2002); 69 Fed. Reg. 60,964 (Oct. 14, 2004). Furthermore, and of more immediate concern, the EPA granted corrective action authority in 2000. 65 Fed. Reg. 56,256 (Sept. 18, 2000).

127. Memorandum from John M. Ruddell, Director, Division of Waste Management to Directors of District Management (Aug. 21, 2002) (on file with author).

128. Interestingly, coinciding with the FDEP's promulgation of Chapter 62-780, the Fifth District Court of Appeal declared in Kerper v. Department of Environmental Protection, 894 So.2d 1006, 1009 (Fla. 5th DCA 2005), that due to the prescriptive nature of the mandates contained in the *Corrective Actions for Contaminated Site Cases* (*CACSC)*, the *CACSC* requires compliance and, therefore, could only be adopted through formal rulemaking procedures.

129. FLA. DEP'T OF EVNTL. PROT., CORRECTIVE ACTIONS FOR CONTAMINATED SITE CASES (1999), http://www.dep.state.fl.us/legal/ Enforcement/appendix/models/correct.pdf.

chemical leachability factors, and soils exposure guidelines.[130] However, as noted in staff analyses for the Global RBCA bill, the "CAP/RAP process has always incorporated general notions of risk-based cleanup but without the clear direction and authority provided by the statute for the three true RBCA programs."[131]

Nevertheless, with the promulgation of rules implementing Global RBCA and the Fifth District's determination in *Kerper v. Florida Department of Environmental Protection*[132] that the *CACSC* constituted an unpromulgated and invalid rule,[133] the statutorily-mandated rules established by Global RBCA replaced the procedures demanded under the CAP/RAP process.

B. Risk-Based Corrective Action under Chapter 62-777

Originally published in 1999,[134] the *CTL Technical Report* fleshes out the risk-based procedures utilized in Florida for the assessment of program sites and now, thanks to Global RBCA, all non-federally regulated contaminated sites within the state.[135] Although based upon the traditional risk assessment procedures detailed in *RAGS*, the risk-based procedures of Chapter 62-777, as developed by the *CTL Technical Report,* attack remediation of contaminated sites from a different angle. The *CTL Technical Report* establishes default CTLs and the methodology used to calculate alternative CTLs for restricted use sites, both of which are discussed in Section III.B.2.

1. Brief Introduction to Risk Calculation

As previously noted, risk is the product of an organism's exposure to a particular contaminant and that contaminant's toxicity.[136] Accordingly, a risk assessment seeks to quantify an individual's exposure to a contaminant and multiply that value by a scientifically supportable toxicity value. However, where are these

130. *See generally id*.

131. Fla. H.R. Comm. on Nat. Resources., HB 1123 (2003) (Staff Analysis 1 on Mar. 21, 2003).

132. 894 So.2d 1006, 1009 (Fla. 5th DCA 2005).

133. *Id*. at 1009. In Kerper, the Fifth District held that, due to the prescriptive nature of the mandates contained in the *CACSC*, the *CACSC* requires compliance and, therefore, could only be adopted through formal rulemaking procedures. *Id.* Moreover, the court cited the legislative staff analysis language as a clear demonstration that rules did not exist for non-program sites even though Chapter 376 directed the FDEP to adopt rules for "removal or disposal standard." *Id*. at 1010.

134. SARANKO, *supra* note 4.

135. The CTL TECHNICAL REPORT was revised and republished in February 2005. *See* CTL TECHNICAL REPORT, *supra* note 4.

136. *See supra* Section II.A.1.

formulae and values found? The following subsections provide a cursory discussion of the basic formula and inputs necessary to calculate a risk estimate. The intent of this section is to provide a basic understanding of the CTL approach utilized by the FDEP and should, by no means, be interpreted as a thorough evaluation of risk assessment principles or methodology.[137]

a. Quantification of Exposure

Exposure to contaminants present in the environment occurs by a variety of routes such as contact with contaminated soil, inhalation of contaminated dust particles, or incidental ingestion of contaminated soil. Essentially, a risk assessment attempts to measure an individual's contact with a contaminant. To this end, *RAGS* contains formulae for various exposure routes that rely upon an assortment of exposure parameters.[138] Exposure parameters may be as simple as an estimate of an individual's time spent at work on a daily basis or as complex as the volume of air an individual inhales on an hourly basis. Peer-reviewed literature, most notably secondary sources such as the EPA's *Exposure Factors Handbook*,[139] the Agency for Toxic Substances and Disease Registry, state agencies, and other organizations provide estimates for seemingly any exposure parameter imaginable.[140] The *CTL Technical Report* simplifies the process by adopting default exposure parameters for residential or non-residential exposure scenarios.[141]

Of course, it would be impossible to calculate an individual's exposure to a contaminant without knowing the concentration of that contaminant in the environment. Accordingly, analytical data for soil, groundwater, sediment, and surface water samples collected at a site are used to estimate the exposure point concentration (EPC); the contaminant concentration to which an individual will be exposed. Calculating EPCs may involve the use of sophisticated modeling techniques, advanced statistical evaluations, or merely

137. *See generally* RAGS PART A, *supra* note 30.

138. *See* RAGS PART A, *supra* note 30, at 6-35 to 6-46.

139. NAT'L CTR. FOR ENVTL. ASSESSMENT, U.S. EVNTL. PROT. AGENCY, EXPOSURE FACTORS HANDBOOK (1997).

140. *See, e.g.,* OFFICE OF SUPERFUND REMEDIATION AND TECH. INNOVATION, ENVTL. PROT. AGENCY, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOLUME I: HUMAN HEALTH EVALUATION MANUAL (PART E, SUPPLEMENTAL GUIDANCE FOR DERMAL RISK ASSESSMENT) (July 2004); OFFICE OF EMERGENCY AND REMEDIAL RESPONSE, U.S. EVNTL. PROT. AGENCY, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOLUME I: HUMAN HEALTH EVALUATION MANUAL, SUPPLEMENTAL GUIDANCE "STANDARD DEFAULT EXPOSURE FACTORS" (Mar. 25, 1991).

141. *See generally* CTL TECHNICAL REPORT, *supra* note 4, at 19-29 (discussing the exposure parameters upon which CTLs are based).

the maximum detected concentration depending on the data available or the media under evaluation. Traditionally, the risk assessment community utilized a statistic known as the 95% upper confidence limit (95% UCL) on the mean, a value at least as great as the true mean to a 95% statistical certainty,[142] to describe the EPC.[143]

It should be noted that attempts to estimate exposure to a contaminant and the EPC involve a great deal of uncertainty. The scientific community addresses such uncertainty through the adoption of conservative assumptions that aim to err on the side of caution in regard to public health.[144] For example, the majority of default exposure parameters are derived from the high end, 90th or 95th percentile, of the potential values for a particular parameter.[145] To be sure, these multiple layers of conservatism aim to overstate risk[146] and many critics argue that this multilayer conservatism goes too far. As articulated in his book, *Breaking the Vicious Circle*,[147] Justice Stephen Breyer states that "monumental overestimates of health risk,"[148] based on overly conservative assumptions fuel public concern, subsequently forces "the agency to

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142. Many of the statistical concepts used to calculate exposure point concentrations likely extend beyond the scope of the Note. That being said, the concept of a 95% UCL is more easily understood if we recognize that analytical data collected from a hazardous site merely provides a glimpse into that site's true chemical composition. As such, a statistical mean derived from such data is not the true mean, but simply the mean of that dataset. Therefore, the 95% UCL uses the distribution and variance of the data to arrive at a value which, to a 95% statistical certainty, contains the true mean of the site. Accordingly, the 95% UCL will be greater, and many times, depending on the particular dataset, dramatically greater than the mean of the dataset. For a more thorough discussion of the 95% UCL, see OFFICE OF EMERGENCY AND REMEDIAL RESPONSE, U.S. EVNTL. PROT. AGENCY, CALCULATING UPPER CONFIDENCE LIMITS FOR EXPOSURE POINT CONCENTRATIONS AT HAZARDOUS WASTE SITES (2002).

143. *See id*. However, more advanced statistical methods recently began gaining acceptance, particularly in Florida, as the more appropriate means of estimating a site's EPC. CTL TECHNICAL REPORT, supra note 4, at 126 (referencing the FLUCL tool). *See also* Mills, C.F. et al., Comparison of Techniques for Calculating 95% Upper Confidence Limits (95% UCLs) on the Mean, 72 TOXICOLOGICAL SCI. (SUPPLEMENT) 395 (2003) (presentation at the March 2003 Annual Society of Toxicology meeting in Salt Lake City, UT); C. J. Saranko et al., The Effects of Using Multiple Contaminent 95% UCLs on Cumulative Risk Estimates, 84 TOXICOLOGICAL SCI. (SUPPLEMENT) 424 (2003) (presentation at the March 2003 Annual Society of Toxicology meeting in Salt Lake City, UT).

144. Shere, *supra* note 13, at 470.

145. CTL TECHNICAL REPORT, *supra* note 4, at 69 (most exposure factors are based upon the "reasonable maximum exposure"); *see also* NAT'L CTR. FOR ENVTL. ASSESSMENT, U.S. EVNTL. PROT. AGENCY, *supra* note 139.

146. Campbell-Mohn & Applegate, *supra* note 36, at 103.

147. *See generally* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (Harvard Univ. Press 1993).

148. *Id*. at 47 n.75 (quoting Albert L. Nichols & Richard J. Zeckhauser, *The Perils of Prudence: How Conservative Risk Estimates Distort Regulation*, 10 REGULATION 13, 13 (1986)).

prove it has erred on the side of safety."[149] Nevertheless, utilization of conservative assumptions at data gaps constitutes a policy decision aiming to assuage public fears over the inherent variability and uncertainty of quantifying the unknown.[150]

b. Toxicity Data

As discussed in Section II.C., CSFs and RfDs represent the toxicity of carcinogens and noncarcinogens respectively.[151] EPA's Integrated Risk Information System (IRIS)[152] represents the most complete source of toxicity data available and provides the source of toxicity data incorporated into the majority of state regulatory schemes. In fact, under a CERCLA-regulated risk assessment, information made available on IRIS "supersedes [that from] all other sources" and is continuously updated.[153] As with most states, Florida utilizes IRIS as the primary source of toxicity values.[154]

c. Forward Risk Calculation

RAGS utilizes a forward calculation of risk. That is, the *RAGS* framework arranges the exposure parameters and EPC to solve for a risk estimate. For example, *RAGS* utilizes the following equation to calculate a carcinogenic risk estimate for incidental ingestion of contaminated soils:[155]

$$\text{Risk} = \frac{EPC \times IR \times EF \times ED \times CSF}{BW \times AT}$$

Where:

149. BREYER, *supra* note 147, at 50; *see also* Adam M. Finkel, *A Second Opinion on an Environmental Misdiagnosis: The Risky Prescriptions of Breaking the Vicious Circle*, 3 N.Y.U. ENVTL. L. J. 295, 333 (1995).

150. Campbell-Mohn & Applegate, *supra* note 36, at 102.

151. *See supra* Section II.C.

152. Integrated Risk Information System, http://www.epa.gov/iris/index.html.

153. RAGS PART A, *supra* note 30, at 7-13 to 15. If data does not exist for a particular chemical in IRIS, RAGS creates a hierarchy of information sources including the EPA's Health Effects Assessment Summary Tables (HEAST), other criteria documents such as drinking water health advisories and ambient water quality reports, and toxicological profiles compiled by the Agency for Toxic Substances and Disease Registry (ATSDR). The EPA makes this information available only on-line.

154. The CTL Technical Report contains a similar hierarchy to that of RAGS, culling toxicity from the following sources in order of preference: IRIS, provisional toxicity values published by the National Center for Environmental Assessment (NCEA), HEAST, and variety of supplemental sources. CTL TECHNICAL REPORT, *supra* note 4, at 9-10.

155. Modified from RAGS PART A, *supra* note 30, at 6-40, 8-6. The formula used to calculate a hazard index for a noncarcinogen would be similar, with the RfD appearing in the denominator and the CSF, of course, being omitted.

Risk = a unit-less probability of an individual developing cancer
EPC = Exposure point concentration (milligrams(mg)/kilogram(kg))
IR = Ingestion rate (mg of soil/day)
EF = Exposure frequency (days/year)
ED = Exposure duration (years)
CSF = Cancer slope factor (mg/kg/day)
BW = Body weight (kilograms)
AT = Averaging time (days)

The EPA's *RAGS* provides the regulatory framework for a risk assessment conducted for a CERCLA site. Although the *RAGS* framework permeates the risk assessment landscape and, most certainly, forms the foundation of most, if not all, individual state-created risk-based regulatory schemes, risk-based regulation of contaminated sites may take other forms.

2. Cleanup Target Levels

In many situations and under regulatory regimes other than CERCLA,[156] it may be desirable to calculate a concentration for a particular chemical which is believed to be safe (i.e., at an acceptable level of risk).[157] In such a case, the aforementioned equation is rearranged to solve for the desired target level, the CTL in Florida, and the preferred level of risk is incorporated. In Florida, the FDEP mandates the use of a 1×10^{-6} target risk.[158] This concept forms the basis of Chapter 62-777. The following equation, modified from the forward calculation of carcinogenic risk resulting from incidental ingestion of contaminated soils presented in the previous section, would result:

$$\text{CTL} = \frac{BW \times AT \times 1x10^{-6}}{IR \times EF \times ED \times CSF}$$

156. Many other states have adopted similar rules under their regulatory regimes. *See, e.g.*, CORRECTIVE ACTION GROUP, LA. DEP'T OF ENVTL QUALITY, RISK EVALUATION/CORRECTIVE ACTION PROGRAM (RECAP) (2003), *available at* http://www.deq.state.la.us/portal/Portals/0/technology/recap/2003/RECAP%202003%20Text%20-%20final.pdf; MASS. DEP'T OF ENVTL. PROT., GUIDANCE FOR DISPOSAL SITE RISK CHARACTERIZATION - IN SUPPORT OF THE MASSACHUSETTS CONTINGENCY PLAN, INTERIM FINAL POLICY # WSC/ORS-95-141 (1995), *available at* http://www.mass.gov/dep/ cleanup/laws/rc1.pdf.

157. The CERCLA methodology for calculating Preliminary Remediation Goals utilizes this scheme. *See* OFFICE OF EMERGENCY AND REMEDIAL RESPONSE, U.S. EVNTL. PROT. AGENCY, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOLUME I: HUMAN HEALTH EVALUATION MANUAL (PART B, DEVELOPMENT OF RISK-BASED PRELIMINARY REMEDIATION GOALS) (Oct. 1991).

158. CTL TECHNICAL REPORT, *supra* note 4, at 8.

Where: CTL = Cleanup Target Level (mg/kg)

Through the use of this equation and default exposure parameters, default CTLs for residential and nonresidential (i.e., commercial and industrial) receptors are calculated and presented in the *CTL Technical Report*.[159] However, Global RBCA provides for calculation of alternative CTLs ("ACTLs") where present and future site use and exposure characteristics differ greatly from those utilized to calculate the default CTLs such that the default CTLs "do not accurately correspond to the risk goals for that site."[160] In essence, ACTLs seek to present a best estimate of site-specific conditions.

Of course, if the EPC for a site does not exceed the default residential CTLs, no further calculations would be warranted or desired as the site would have met the most stringent requirements. The calculation and use of ACTLs would only be desirable if the EPC for a chemical exceeded the default CTLs for residential use. In such a situation, site-specific exposure parameters are substituted for the defaults to calculate a CTL that better corresponds to actual site conditions.[161]

3. Florida's Tiered Approach to Risk-Based Regulation

Conducting a risk assessment is not an inexpensive process. In many instances, use of the conservative, default assumptions produces an acceptable estimate of risk. In such instances, costs would be at the low end of the spectrum. However, in other situations, use of these default assumptions results in an unacceptable estimate of risk. Here, more detailed site-specific data is necessary to calculate a more realistic estimate of potential risk. Unfortunately, more detail entails additional laboratory analyses, field work, and more advanced contaminant modeling—all resulting in greater costs.

As with many states, Florida follows a tiered approach to risk-based corrective action.[162] Under such an approach, "increas-

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159. *See* CTL TECHNICAL REPORT, *supra* note 4, at tbl. II.

160. *Id.* at 43-44.

161. Due to ACTLs heavy utilization of contaminant fate and transport concepts, an exhaustive discussion regarding the calculation of ACTLs is beyond the scope of this Note. Calculation of ACTLs may include alteration of exposure parameters as well as accounting for site-specific soil and wind characteristics. *Id*. at 44-49.

162. FLA. ADMIN. CODE ANN. r. 62-780 (2005) ("This chapter provides a phased risk-based corrective action process that is iterative and that tailors the site rehabilitation tasks to the site-specific conditions and risks.").

ingly detailed levels of risk assessment" are performed when "more generic assumptions are thought to overstate actual or expected site conditions."[163] Although the tiered approach to risk-based corrective action has its critics,[164] it permits an incremental assessment of risk and thereby avoids the substantial expenses of the oftentimes unnecessary, detailed, site-specific risk evaluation.[165]

The approach utilized by the FDEP features three tiers, known as Risk Management Options ("RMO"). Under RMO I, the FDEP grants a "No Further Action" (NFA) order if the EPC for all detected chemicals do not exceed the less stringent of their corresponding default residential CTLs or their background concentration.[166] However, if the EPC for any chemical exceeds both of these values, then the site must move to the subsequent tier, RMO II. According to RMO II, the FDEP grants a NFA order, subject to institutional controls, if the EPCs for all detected chemicals do not exceed default commercial/industrial CTLs or ACTLs adjusted for site-specific geologic or hydrogeologic conditions.[167] Finally, under RMO III, the FDEP grants a NFA order, subject to institutional controls, if the EPCs for all detected chemicals do not exceed ACTLs adjusted for site-specific exposure scenarios determined in the exposure assessment.[168]

4. Risk-Based Restrictions on Land Use

Under Florida guidance, if the EPCs for contaminants exceed default CTLs, ACTLs based on site-specific exposure parameters may be calculated to account for the expected future use of the site. However, where site-specific exposure parameters are used the FDEP demands that "engineering and/or institutional controls … would reliably restrict exposure frequency and duration."[169] Such controls may consist of engineered or non-engineered impediments to exposure. Engineered controls consist of paved parking lots, clean backfilled soil, or clay caps.[170] Non-engineered controls often include deed restrictions, restrictive covenants, or conservation easements, but may include less-preferred methods such

163. Campbell-Mohn & Applegate, *supra* note 36, at 275.
164. *See id*. at 274-75 (presenting a rather cynical and apprehensive view of tiered risk-based approaches).
165. *Id*.
166. FLA. ADMIN. CODE ANN. r. 62-780.680(1) (2005).
167. *Id*. at r. 62-780.680(2) (2005).
168. *Id*. at r. 62-780.680(3) (2005).
169. CTL TECHNICAL GUIDANCE, *supra* note 4, at 44; FLA. ADMIN. CODE ANN. r. 62-780.200(25) (2005) (defining institutional controls).
170. John Pendergrass, *Sustainable Redevelopment of Brownfields: Using Institutional Controls to Protect Public Health*, 29 ENVTL. L. REP. 10,243, 10,243 (1999).

as consent orders and zoning restrictions.[171] Nevertheless, employment of an engineered control at a contaminated site necessitates the use of institutional controls to protect the engineered control from human activities.[172] Although discussed further in Section IV.B.2., Florida defines institutional controls as "the restriction on use or access to a site to eliminate or minimize exposure to … contaminants."[173]

Global RBCA permits the use of institutional controls only after the FDEP approves the proposed restrictions and the regulated party provides the local government and directly affected adjacent residents and landowners constructive notice and a thirty-day comment period.[174] Furthermore, upon FDEP acceptance of a proposed institutional control such as a restrictive covenant or conservation easement, the agreement must be recorded with the city or county clerk of the local jurisdiction.[175]

IV. SECTION 376.30701, *FLORIDA STATUTES*, AND THE GLOBAL RBCA RULE

Section 376.30701, *Florida Statutes* simply demanded that the aforementioned risk-based corrective action principles established by Chapter 62-777 apply to all contaminated sites in the state[176] and authorized the FDEP to establish rules implementing this mandate.[177] In essence, it authorized the FDEP to take the existing regulations in Chapter 62-777 applicable to program sites and apply them to the remainder of Florida's contaminated sites.

However, as simple as this legislation and the Global RBCA rule may sound, certain provisions deserve a closer examination. Moreover, implementation of risk-based corrective action principles at traditionally non-program sites may create some problem-

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171. *See generally* DIV. OF WASTE MGMT., FLA. DEP'T OF ENVTL. PROT., INSTITUTIONAL CONTROLS PROCEDURES GUIDANCE 3-12 (2004), *available at* http://www.dep.state.fl.us/waste/quick_topics/ publications/wc/csf/icpg.pdf.

172. *Id.* at 6; *see also* Seth Schofield, *In Search of the Institution in Institutional Controls: The Failure of the Small Business Liability Relief and Brownfields Revitalization Act of 2002 and the Need for Federal Legislation*, 12 N.Y.U. ENVTL. L.J. 946, 974 (2005).

173. FLA. STAT. § 376.301(21), 376.79(10) (2005).

174. FLA. STAT. § 376.30701(2)(d) (2005). Adjacent landowners or residents are granted the ability to comment only if the point of compliance extends through or to their property. *Id.* Although not discussed in this Note, a point of compliance is typically established for monitored natural attenuation of groundwater contaminant plumes. *See generally* FLA. ADMIN. CODE ANN. r. 62-780.690 (2005) (discussing the requirements for monitored natural attenuation under Global RBCA).

175. DIV. OF WASTE MGMT., FLA. DEP'T OF ENVTL. PROT., *supra* note 171 at 15-16.

176. *See* Fla. H.R. Comm. on Nat. Resources, *supra* note 131, at 4.

177. FLA. STAT. § 376.30701(2) (2005). Although the Global RBCA rule was not adopted until February 3, 2005, the statute mandated that the FDEP establish rules implementing Global RBCA by July 1, 2004.

atic implications. As such, the following subsections discuss, first, the finer elements of the legislation and the rule and, second, the unintended implications of Global RBCA in Florida.

A. The Substantive Effects of Global RBCA

With the main thrust of Global RBCA being the implementation of Chapter 62-777 at all contaminated sites, the question quickly turned to: what does Florida consider a "contaminated site." Evidently, in an effort to avoid the appearance that Global RBCA sought to grant the FDEP additional authority, the Legislature vigorously emphasized that Chapter 376.30701 does "not create or establish any new liability for site rehabilitation."[178] Accordingly, the Legislature mandated that Global RBCA only applies to those sites "where legal responsibility for site rehabilitation exists pursuant to [chapter 376] or chapter 403."[179]

1. Offsite Migration and the Notice Provision

During the consolidated rulemaking process, the Environmental Regulation Commission (ERC), or the executive-appointed board responsible for adopting environmental rules, evaluated over fifty amendments; the amendments were proposed by concerned citizens, environmental organizations, and trade groups to the FDEP's proposed Global RBCA rule and the existing rules regulating cleanup criteria and program sites.[180] Although many of these proposed amendments dealt with minor housekeeping issues or the program site rules,[181] a couple of concerns resulted in the revision of the FDEP's proposed Global RBCA rule.

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178. *Id.* § 376.30701(1)(a) (2005). This language appears as the very first sentence of the statute.

179. *Id.*

180. *ERC Adoption*, *supra* note 10, at 3.

181. *Id.* Certainly, a couple of these proposed amendments drew attention. Although beyond the scope of this Note, the Legal Environmental Assistance Foundation's (LEAF) proposed an amendment to Chapter 62-777 that would eliminate the use of a 33% bioavailability factor for arsenic. This was a particularly contentious subject and eventually failed. The culmination of an FDEP-funded study conducted by Dr. Steve Roberts and his staff at the University of Florida, the new bioavailability factor, which substantially increases the concentration of arsenic deemed acceptable in soil, was the subject of extensive debate over the past couple of years by Florida's Contaminated Soils Forum. *Id.*

In addition to the debate surrounding LEAF's proposed amendment, the Florida Petroleum Marketers and Convenience Store Association (FPMA) offered three amendments to the Petroleum Rule established by Chapter 62-770. *Id.* Following the ERC's rejection of these amendments on February 3, 2005, the FPMA filed a formal challenge of the Petroleum Rule alleging an invalid exercise of delegated authority and, ultimately, delaying the adoption of this rule. *Id.*

First, following an August 3, 2004 workshop discussing the consolidated rulemaking, the FDEP elected to scale back the notice provisions written into the proposed Global RBCA rule.[182] Originally, the notice provision demanded that, following discovery of off-site contamination, the responsible party must notify adjacent property owners of the release.[183] However, opponents of this provision commented that such notice would attract third-party lawsuits and questioned the FDEP's authority to establish new notice provisions.[184] Accordingly, in order to avoid a potential rule challenge, the FDEP modified the final version of the Global RBCA rule originally adopted on February 3, 2005; this required that the responsible party only provide notice to the FDEP and the county health department in which the site is located when the responsible party discovers that contamination has migrated off-site.[185]

Second, but also relating to the aforementioned notice provision, many comments focused on the proof necessary to determine that contamination had migrated off-site. Specifically, the proposed Global RBCA rule required that the responsible party provide notice upon a reasonable inference of off-site contaminant migration.[186] However, the FDEP eventually increased this burden of proof by requiring positive analytical data to demonstrate off-site migration.[187]

2. Controversial Technical Issues under Chapter 62-780

Outside of the procedural realm, many comments expressed concern over two other complex and technical aspects of the proposed Global RBCA rule, both of which remained in the final rule.[188] First, as previously noted, in an effort to reduce costs by

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182. Chris Saranko, *FDEP Briefs the ERC on Global RBCA, The Environmental Regulation Commission Adopts Global RBCA*, 26 THE EVNTL. AND LAND USE L. SEC. REP. 1, 1 (2005) [hereinafter ERC Briefing]. In fact, the large volume of public comments received regarding the notice provision resulted in a delay of the subsequent meeting in which the FDEP briefed the ERC on the proposed rule. *Id.*

183. FLA. DEP'T OF EVNTL. PROT., AUGUST 3RD WORKSHOP DRAFT: CONTAMINATED SITE CLEANUP CRITERIA CH. 62-780, F.A.C. 10 (2004) (presented at the Aug. 3, 2004 Rulemaking Workshop), *available at* http://www.dep.state.fl.us/ waste/quick_topics/ publications/wc/Rule_Workshops/780TextFinalAugust2004Workshop.pdf.

184. Saranko, *supra* note 182, at 1.

185. *See* FLA. ADMIN. CODE ANN. r. 62-780.220(2) (2005); *ERC Adoption*, *supra* note 10, at 3.

186. *ERC Adoption*, *supra* note 10, at 3.

187. FLA. ADMIN. CODE ANN. r. 62-780.220(2) (2005); *ERC Adoption*, *supra* note 10, at 3.

188. Although briefly discussed in this Section, the 3X "not to exceed" mandate and the apportionment provision exceed the scope of this Note. Both concepts deal with highly technical concepts that underlie the foundations of risk assessment and the target cleanup level concept.

remediating only that contamination which presents unacceptable risk (as long as EPC calculated for a chemical falls below that chemical's CTL) the responsible party may leave soils in place that exceed that CTL.[189] However, Global RBCA added a ceiling to the concentration which may be left in place. Specifically, no chemical detected in soil may exceed three times its appropriate CTL (i.e., residential or industrial) regardless of the institutional controls implemented.[190]

Second, the FDEP incorporated a concept known as apportionment into Global RBCA. Apportionment deals with the underlying foundation of Florida's risk-based corrective action program that the target excess cancer risk should not exceed $1x10^{-6}$ for carcinogens and that the non-carcinogenic risk should not exceed one. Specifically, at a site where multiple chemicals have been detected, the target risk should be "apportioned" amongst the detected chemicals, resulting in dramatically reduced CTLs.

Primarily, opponents of the 3X "not to exceed" mandate and the apportionment provision commented that these requirements undermine many of the technical foundations of risk assessment.[191] Furthermore, opponents argue that these provisions create considerable financial obstacles to site remediation and uncertainty in reaching a successful outcome, such that responsible parties may select the substantially more costly route of remediating to default CTLs, rather than leave contaminated soils, contributing little to overall risk, in place.[192]

B. The Problematic Implications of Global RBCA

Practitioners and regulators alike appreciate the uniformity which Global RBCA brings to Florida environmental law.[193] Nevertheless, the new rule is not without disadvantages. The following subsections present two, under the radar, substantial implications of Global RBCA.

1. The Dawn of New ARARs

189. *See supra* Section III.B.4.

190. *See* FLA. ADMIN. CODE ANN. r. 62-780.680(1)(b)1.d.(II) (2005); FLA. ADMIN. CODE ANN. r. 62-780.680(2)(b)1.e.(II); FLA. ADMIN. CODE ANN. r. 62-780(3)(b)1.b.

191. Saranko, *supra* note 182, at 2.

192. *Id.*

193. *See, e.g.*, CONTAMINATED SOILS FORUM: POLICY SUB-COMMITTEE: FOCUS GROUP ON NEED FOR UNIFORM POLICY, *available at* http://www.dep.state.fl.us/waste/quick_topics/publications/wc/csf/focus/cufg_gs.pdf; SMITH, *supra* note 11, at 8-14.

Although RCRA permits the EPA to delegate program authority to individual states, regulatory authority under CERCLA remains solely in the hands of the federal government. However, notwithstanding the federal retention of authority, state regulations may play an important role in the remediation of a CERCLA site. Specifically, in order to "assur[e] protection of human health and the environment,"[194] the remedial action selected for the site must account for all "legally applicable or relevant and appropriate … requirement" ("ARAR").[195] According to CERCLA, any standard established under federal law constitutes an ARAR.[196] Moreover, ARARs include those standards, promulgated by the state in which the site is located, that are more stringent than federal standards.[197]

Often, whether a state standard constitutes an ARAR is not as clear cut as one might believe. Generally, the judiciary interprets ARARs to be those state standards that are: (1) properly promulgated; (2) more stringent than federal standards; (3) legally applicable or relevant and appropriate; and (4) timely identified.[198] According to the EPA regulations, promulgation refers to "laws imposed by state legislative bodies and regulations developed by state agencies that are of general applicability and are legally enforceable."[199]

Interestingly, in *United States v. City of Fort Lauderdale*,[200] the United States District Court for the Southern District of Florida answered the question of whether pre-Global RBCA soil CTLs constituted ARARs. *Fort Lauderdale* concerned an action brought by the United States against the City of Fort Lauderdale and numerous other public and private entities for alleged disposal of hazardous wastes at the Wingate Road Landfill.[201] Subsequent to filing of the action, the parties agreed to a consent decree for remedial action, including approximately twenty million dollars in payments

194. 42 U.S.C. § 9621(d)(1) (2000).

195. *Id*. at § 9621(d)(2)(A)(ii).

196. *Id*. at § 9621(d)(2)(A)(i). According to the statute, these federal laws include, but are not limited to, the Toxic Substances Control Act, 15 U.S.C. § 2601-2692, the Safe Drinking Water Act, 42 U.S.C. § 300(f)-300(j)(6), the Clean Air Act, 42 U.S.C. § 7401-7671(q), the Clean Water Act, 33 U.S.C. § 1251-1387, the Marine Protection, Research and Sanctuaries Act, 16 U.S.C. § 1431-1445, § 1447-1447(d), 33 U.S.C. § 1401-1445, § 2801-2805, and the Solid Waste Disposal Act, 42 U.S.C. § 6901-6992(k).

197. 42 U.S.C. § 9621(d)(2)(A)(ii) (2000).

198. *See* United States v. Akzo Coatings of Am., Inc., 949 F.2d 1409, 1440 (6th Cir. 1991).

199. *Id*. (quoting the EPA, Superfund Program; Interim Guidance on Compliance with Applicable or Relevant and Appropriate Requirements; Notice of Guidance, 52 Fed. Reg. 32,495, 32,498 (Aug. 27, 1987)).

200. 81 F. Supp. 2d 1348 (S.D. Fla. 1999) (omnibus order and order granting motion to enter consent decree).

201. *Id.* at 1349.

from the defendants.[202] However, multiple third parties filed motions in opposition of the consent decree, bringing about the cited order.[203]

Although the district court disposed of the third-party motions on standing grounds,[204] these motions raised issues the court considered "significant" and "requir[ing] this Court's close and careful scrutiny."[205] Specifically, one of the third parties argued that the requirements of Florida's brownfields, dry-cleaning, and petroleum programs contained in Chapter 376, *Florida Statutes*, constitute ARARs which the selected remedial action must attain.[206] In rejecting this argument, the district court cited the Sixth Circuit's discussion in *Akzo Coatings* regarding the EPA's definition of "promulgated."[207] The district court concluded that these three programs established within Chapter 376 "are not enforceable pollution standards that apply across the state, and thus are not 'promulgated' for CERCLA purposes."[208]

Interestingly, the district court in *Fort Lauderdale* noted that the FDEP believed that the cleanup standards established by the three cited Chapter 376 programs were ARARs.[209] Nevertheless, the court concluded that federal law, not state law, determined whether a state statute constituted an ARAR.[210] However, following the Southern District's decision in *Fort Lauderdale*, the FDEP declared that the soil CTLs contained in Chapter 62-777 of the *Florida Administrative Code* only apply to program sites and "*may not be imposed* by the agency as rule, standards, or to deny a permit" for sites outside of those programs.[211]

Of course, Global RBCA applies the CTLs to "*all contaminated sites* resulting from a discharge of pollutants or hazardous substances where legal responsibility for site rehabilitation exists pur-

202. *Id.*

203. *Id.*

204. *Id.* at 1350. "CERCLA contains a statutory bar to public participation in federal court at this point in time." *Id.*

205. *Id.*

206. *Id.* at 1351.

207. *Id.* (quoting *Akzo Coatings,* 949 F.2d at 1440).

208. *Id.* at 1351-52. "The state statutes in question provide incentives to particular industries to comply with stricter standards in return for liability protection and or streamlining of other regulations, and are by their own terms are (sic) not applicable to the Wingate site." *Id.*

209. *Id.* at 1352 n.6 (citing Letter from Jack Chisolm, Deputy General Counsel, Fla. Dep't of Envtl. Prot. to Phyllis Harris, Director and General Counsel, Envtl. Accountability Div., U.S. Envtl. Prot. Agency, Region IV, at 3 (June 3, 1998)).

210. *Fort Lauderdale*, 81 F. Supp. 2d at 1352 n.5.

211. Ruddell, *supra* note 122 (emphasis added). Furthermore, the memorandum states that "[t]his guidance supersedes previous guidance memos dated September 29, 1995, January 19, 1996, and September 22, 1999." *Id.*

suant to [Chapters 376 and 403]."[212] Therefore, because it established "pollution standards that apply across the state" and was developed by the FDEP pursuant to legislative mandate, Global RBCA abruptly eliminated the argument utilized by the district court in *Fort Lauderdale* that cleanup target levels fail to satisfy the definition of properly "promulgated" standards.[213]

Moreover, the regulations enacted pursuant to Global RBCA satisfy the remaining three ARAR criteria identified by the Sixth Circuit in *Akzo Coatings*. Specifically, CTLs certainly constitute "legally applicable or relevant and appropriate" standards as the Legislature expressly applied them to all "contaminated sites" identified by the state.[214] Furthermore, and a substantial concern for those determined to be potentially responsible parties of a CERCLA site in Florida, CTLs are likely to be more stringent than federal standards. Due to the 1 $x10^{-6}$ target risk level utilized by the FDEP in the calculation of CTLs[215] and the EPA's utilization of an acceptable risk range of $1x10^{-4}$ to $1x10^{-6}$ when calculating remediation goals for those chemicals lacking an ARAR,[216] it may be necessary for CERCLA remediation projects to attain cleanup standards that differ by orders of magnitude than those required by the EPA for pre-Global RBCA sites. Undoubtedly, potentially responsible parties prefer the flexibility offered by the EPA's risk range rather than the rigidity of Florida's CTL approach.[217]

Departing from the required elements of common law tort litigation, CERCLA lacks the "traditional elements of tort culpability"[218] and applies strict liability to cost recovery actions.[219] Accordingly, liability under CERCLA is not dependant upon a causal connection between a release or threatened release and harm to the environment,[220] but is dependant upon whether the release or threatened release resulted in response costs.[221]

As such, though implementing Global RBCA, the Florida Legislature lacked the desire to "establish any new liability for site

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212. FLA. STAT. § 376.30701(1)(b) (2005) (emphasis added).
213. *Id.; Fort Lauderdale*, 81 F. Supp. 2d at 1351.
214. *Akzo Coatings,* 949 F.2d at 1441, 1421.
215. *See supra* Section III.B.2.
216. SMITH, *supra* note 11, at 12.
217. *Id.*
218. United States v. Monsanto Co., 858 F.2d 160, 168 (4th Cir. 1988).
219. GLICKSMAN, *supra* note 80, at 854-56.
220. Control Data Corp. v. SCSC Corp., 53 F.3d 930, 935 (8th Cir. 1995).
221. *Id.*; *see also* United States v. Hercules, Inc., 247 F.3d 706, 716 n. 8 (8th Cir. 2001) ("The argument that the government must prove a direct causal link between the incurrence of response costs and an actual release caused by a particular defendant has been rejected by 'virtually every court' that has directly considered the issue." (quoting United States v. Alcan Alum. Corp., 964 F.2d 252, 264-65 (3d Cir. 1992) (citing cases)).

rehabilitation."[222] Even if the Legislature wished to, the interpretation of CERCLA provisions constitutes a federal question of law and, therefore, liability would remain strict. However, as stated by the Fifth Circuit in *Amoco Oil Co. v. Borden, Inc.*,[223] "[a]s [ARARs] define the limits of appropriate response costs, and therefore recoverable expenses, they are also useful for establishing the limits of liability."[224] That is, ARARs establish the monetary extent of liability and, most certainly, the more stringent the ARAR, the more expenses will be incurred meeting that standard.

2. The Unhealthy Reliance upon Institutional Controls

As discussed in Section III.B.4., Florida's RBCA regulations permit remediation to contaminant concentrations greater than residential standards subject to implementation of institutional controls. Essentially, institutional controls "ensure that the actual use to which a site is put after cleanup is compatible with the level of cleanup completed."[225] As such, institutional controls enable the liable party to leave contamination on site, thereby potentially saving millions of dollars in remediation costs.[226] Furthermore, proponents of institutional controls claim that institutional controls often create greater protection of human health and the environment through two routes. First, remedies relying upon institutional controls often avoid extensive excavation and construction activities that may result in human health risks or further release of contaminants into the environment.[227] Second, remediation of the last ten percent of contamination often costs exceedingly more than that of the first ninety percent, thereby subjecting responsible parties to substantial costs which provide little additional human health protection.[228]

222. FLA. STAT. § 376.30701(1)(a) (2005).
223. 889 F.2d 664 (5th Cir. 1989).
224. *Id.* at 671.
225. John Pendergrass, *Use of Institutional Controls as Part of a Superfund Remedy: Lessons from Other Programs*, 26 ENVTL. L. REP..10,109, at 10,110 (1996).
226. Karmel, *supra* note 124, at 361.
227. *Id.* at 391-92 (citing a CERCLA remediation project in which the construction workers risk of death equaled approximately 20 in 10,000 — far greater than the 1x10-4 to 1x10-6 risk range used by the EPA).
228. BREYER, *supra* note 147, at 10-19.

a. Opposition to Institutional Controls

The concept of institutional controls is not without its critics.[229] Primarily, opponents decry the lack of certainty created by institutional controls. That is, removal or remediation of contamination eliminates any potential exposure in the future, whereas institutional controls depend entirely upon future enforcement of their restrictions to ensure efficacy.[230] Further still, other opponents argue that even though institutional controls may be financially attractive in the short-term, in the long-term institutional controls may actually cost more than remediating to residential standards once the property's less economically valuable land use, enforcement costs, litigation costs, and potential health costs are considered.[231] Finally, as discussed more thoroughly in the subsequent subsection, institutional controls often rely heavily upon a local government's control of local land use.[232]

According to FDEP guidance, restrictive covenants and conservation easements constitute the preferred institutional controls in Florida.[233] Unfortunately, both methods are problematic. Restrictive covenants restrict the use of property and purport to run with the land such that successor landowners are bound as well.[234] However, critics posit that because the government holds the covenant such agreements do not "touch and concern the land" and, therefore, are in gross and lack enforceability.[235]

On the other hand, a conservation easement grants a third party the right to use the property of another and, therefore, is more easily held in gross.[236] Nevertheless, due to the nature of an

229. *See, e.g.*, Jeffrey M. Gaba, *Tulk v. Moxhay and Texas Environmental Law: Land Use Restrictions under the Texas Risk Reduction Program,* 55 SMU L. REV. 179 (2002) (arguing that institutional controls applied pursuant to Texas' RBCA program fail to effectively restrict subsequent owners); *see generally* Seth Schofield, *In Search of the Institution in Institutional Controls: The Failure of the Small Business Liability Relief and Brownfields Revitalization Act of 2002 and the Need for Federal Legislation*, 12 N.Y.U. ENVTL. L.J. 946 (2005).(discussing the inadequate legal mechanisms of the institutional controls promoted by the Brownfields Act of 2002).

230. Karmel, *supra* note 124, at 362.

231. *See* Schofield, *supra* note 229 at 966-67.

232. Karmel, *supra* note 124, at 362.

233. *See generally* DIV. OF WASTE MGMT., FLA. DEP'T OF ENVTL. PROT., *supra* note 171 at 7-14.

234. Schofield, *supra* note 229, at 981.

235. *Id.*

236. *Id.* at 982.

institutional control as a negative encumbrance, concerns exist as to the efficacy of such easements as the judiciary typically discourages negative easements.[237] Therefore, as with restrictive covenants, enforceability of conservation easements may constitute a valid concern.

b. Institutional Controls and Florida's Growth Management System

Simply stated, "[t]he key to the success of land-use-restricted environmental cleanups is to allow them to be done only in situations where the use of the contaminated property will not change to an unanticipated use with greater exposures."[238] In essence, because they restrict use to commercial or industrial purposes, land use restrictions should only be implemented when it is certain that the property will remain non-residential.

Therein lies the problem. Drawn by Florida's warm weather, sunny beaches, and absence of a state income tax, Florida's population growth remains amongst the greatest in the nation.[239] Between 1990 and 2000, Florida's population growth rate was 23.5%.[240] Although it creates a boom in the real estate market, this rapid growth stresses Florida's growth management system substantially. Notwithstanding attempts to address the issue such as the enactment of Florida's Local Government Comprehensive Planning and Land Development Regulation Act (Growth Management Act),[241] the State Comprehensive Plan,[242] and the development of a regulated riparian water rights system to ease water consumption concerns,[243] growth management remains one of Florida's most difficult challenges.[244] Most recently, the lack of affordable housing, particularly in South Florida following the 2004

237. *Id*. It should be noted, however, that an affirmative obligation to maintain an engineered control may not face such judicial scrutiny. *Id*.

238. Alex Geisinger, *Rethinking Risk-Based Environmental Cleanup*, 76 IND. L.J. 367, 376-77 (2001).

239. FLORIDA'S GROWTH MGMT. STUDY COMM'N, A LIVEABLE FLORIDA FOR TODAY AND TOMORROW 5 (2001). According to 2000 census data, approximately 16 million people reside in Florida, a population which is expected to reach 22 million by 2025 and 24 million by 2030. *Id.*

240. Florida Quick Facts: Florida Population, http://www.stateofflorida.com/portal/desktop defaultaspx?tabid=95.

241. FLA. STAT. § 163, Part II (2005).

242. FLA. STAT. § 187 (2005).

243. *See* FLA. STAT. § 373.012-.197 (1995).

244. David L. Powell, *Growth Management: Florida's Past as Prologue for the Future*, 28 FLA. ST. L. REV. 519, 531 (2001).

hurricane season, has raised anxiety among those with an eye towards growth management.[245]

So, how does Global RBCA tie into growth management? Perhaps the most correct answer is: it does not. A thorough review of Section 376.30701, *Florida Statutes*, and Chapter 62-780 fails to reference growth management or the Growth Management Act. Moreover, the Growth Management Act fails to mention risk-based institutional controls.

Unfortunately, the guidance document, published as an aid to FDEP personnel considering implementation of institutional controls, provides for only limited communication with a local government, despite such institutional controls forming the lynchpin of any remedial option developed pursuant to RMO II or III.[246] Although Global RBCA grants a local government the ability to comment on proposed institutional controls within the local government's boundaries, the FDEP need not seek the approval of the local government when agreeing to an institutional control.[247] This paucity of local government input may not seem all that damaging when evaluating a single parcel. Yet, when multiple parcels become the subject of institutional controls, the resulting patchwork of restricted use may dramatically affect a local government's ability to regulate land use.

In addition, although the FDEP maintains a database containing institutional controls,[248] the only means available to inform a local government of the existence of an institutional control, beyond the aforementioned actual notice provided at approval, is through recordation of the restrictive covenant or conservation easement with the county or city clerk's office.[249] Regrettably, such recordation does not transfer to that local government's comprehensive plan. As the legislation controlling a local government's growth management,[250] the local comprehensive plan serves as the primary source of information for a party interested in the allowable uses of a piece of property.

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245. Dee Carper, *2005 Legislative Priorities: Hurricanes Force Focus on Affordable-Housing Shortage,* FL. LEAGUE OF CITIES, *available at* http://www.flcities.com/legislative/affordable_housing.asp (last visited Oct. 8, 2006).

246. *See supra* Section III.B.3.

247. FLA. STAT. § 376.30701(2)(d) (2005).

248. *See* INSTITUTIONAL CONTROLS REGISTRY, *available at* http://www.dep.state.fl.us/waste/categories/ wc/default.htm (follow the link titled "Institutional Controls Registry" in the bottom right hand corner) (last visited Nov. 16, 2006).

249. *See generally* FLA. DEP'T OF EVNTL. PROT., INSTITUTIONAL CONTROLS PROCEDURES GUIDANCE 15 (2004).

250. Thomas G. Pelham, *Restructuring Florida's Growth Management System: Alternative Approaches to Plan Implementation and Concurrency*, 12 U. FLA. J.L. & PUB. POL.'Y, 299, 303 (2001).

Finally, related to the aforementioned enforceability concerns, no privity of contract exists between the owner of the restricted property and the local government, making the local government incapable of enforcing the agreement.[251] Instead, the local government must persuade the FDEP to evaluate the situation and bring the landowner into compliance. Due to the perpetual nature of institutional controls, placing sole responsibility for their enforcement with a single state agency seems overly burdensome. For example, although the FDEP does not provide data as to the number of contaminated sites under institutional controls,[252] as of December 2004, 17,627 contaminated sites were regulated as program sites.[253] As the ability to utilize institutional controls in Florida first became available in 1997 for use at program sites, the volume of contaminated sites utilizing institutional controls will only increase, especially following the enactment of Global RBCA which allows their use at all sites, rather than only program sites.

V. CONCLUSIONS

Florida's application of RBCA to all contaminated sites within the state certainly creates the uniformity that regulators, environmentalists, and regulated parties have desired since the first application of these principles to petroleum sites in 1996. The location of the site or the contaminants of concern will no longer govern the remediation methodology employed to cleanup the contamination.

However, a rich and detailed science underlies the risk-based values used to regulate these contaminated sites. This author fears that the interested parties' lack of understanding vis-à-vis the scientific and historical foundations of risk assessment will result in a failure to question risk-based decisions when these decisions deserve questioning and closer scrutiny. Because once a numerical value is published, for the most part that number becomes the guidance for any actions to be taken, notwithstanding the

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251. See Amy L. Edwards, *Institutional Controls: The Converging Worlds of Real Estate and Environmental Law and the Role of the Uniform Environmental Covenant Act*, 35 CONN. L. REV. 1255, 1261 (2003) (discussing enforcement concerns relating to a lack of privity in restrictive covenants).

252. *See generally* INSTITUTIONAL CONTROLS REGISTRY, *supra* note 248. FDEP Institutional Controls Registry allows the user to search for sites at which institutional controls are utilized via a geographic information system interface; however, it does not provide summary data. *Id.*

253. *See generally* FLA. DEP'T OF EVNTL. PROT., FINAL STATEMENT OF ESTIMATED REGULATORY COST FOR PROPOSED REVISIONS TO: CHAPTER 62-777, F.A.C., "CONTAMINANT TARGET CLEANUP LEVELS," *available at* http://www.dep.state.fl.us/waste/categories/wc/pages/ERCAdoptionHearing020205.htm (last visited Nov. 16, 2006).

many assumptions and inputs, applicable to the immediate situation or not, used to calculate that value.

Furthermore, although the appeal of uniform remedial assessment across the state is great, implementation of Global RBCA will have other legal consequences. Most notably, Global RBCA will create more stringent ARARs for remediation at CERCLA sites. Although many may argue that this increased stringency is not a detrimental result of Global RBCA, it will reduce remedial flexibility for both the EPA and potentially responsible parties. Moreover, Global RBCA will impose considerable restraints upon a local government's ability to control land use within its borders. These restraints contradict Florida's Growth Management Act which grants a great deal of land use control to local governments.