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NOTE

EPA FINDINGS OF UNREASONABLE RISK UNDER THE TOXIC SUBSTANCES CONTROL ACT: EVIDENTIARY WEAPONS IN TOXIC TORT PLAINTIFF’S ARSENAL

Joe Daly, a grouter in the field of sewer repair, suffered from peeling palms and fingers, muscle weakness and loss of muscular coordination. His speech was frequently slurred, he had uncontrollable tremors and he was always tired. A neurologist determined that his symptoms resulted from consistent exposure to a neurotoxic substance.

Acrylamide grout is a chemical substance frequently used in sewer repair to prevent groundwater seepage from sewers and manholes. Joe’s exposure to this substance occurred daily, both through inhalation and dermal exposure. He suspected that acrylamide grout was the cause of his physical problems.

Joe hired an attorney to file suit against the parties responsible for his condition. In researching Joe’s possible remedies, the attorney learned that the EPA had recently proposed a ban on the manufacture, importation and commercial distribution of acrylamide grout.1 The EPA had determined that the grout presented an unreasonable risk of neurotoxic and carcinogenic effects, which could not be reduced to a reasonable level with the use of personal protective equipment.

Joe’s attorney brought a strict liability action for abnormally dangerous activity against the grout’s commercial distributor. He relied on expert testimony to establish the grout’s magnitude of harm and probability of risk, ignoring the relevance and persuasive evidentiary value of the EPA finding of the grout’s unreasonable risk. Defendant’s experts ultimately persuaded the court that the grout was not inherently toxic.

This battle of experts and its unpredictable outcome could have

been avoided. Joe's attorney should have argued that the EPA finding of unreasonable risk and proposed regulation of the grout be accorded conclusive weight by the court, analogous to an irrebuttable presumption, in establishing both the grout's risk and the risk of commercial distribution.

I. INTRODUCTION

The risks posed by toxic substances have been recognized and addressed by Congress as well as by the regulatory and legal communities. The deterrent effect of these efforts has been hobbled however, by a lack of coordinated focus. As illustrated in the preceding hypothetical, the failure to recognize that toxic risk data generated in the regulatory context is relevant and applicable in the common law context can produce onerous results for the toxic tort plaintiff.

In the common law context, attempts to redress toxic injury are often made under a strict liability cause of action for abnormally dangerous activities. The determination of whether an activity is abnormally dangerous is a question of law to be made by the court. Under this theory of recovery, strict liability is imposed regardless of whether the activity was conducted with all reasonable care. The Restatement (Second) of Torts ("Restatement") establishes six factors which aid the judiciary in making this determination, and while each of these factors is relevant, no one factor is determinative in a court's

2. Carl B. Meyer, The Environmental Fate of Toxic Wastes, the Certainty of Harm, Toxic Torts, and Toxic Regulation, 19 ENVTL. L. 321, 387 (1988) (noting that "the bottleneck in fighting pollution is the transfer of existing knowledge between the basic scientific community, the regulatory community, and all segments of the legal profession and the public").

3. See T & E Indus., Inc. v. Safety Light Corp., 546 A.2d 570, 578 (N.J. Super. Ct. App. Div. 1988) (noting that the strict liability theory, as well as judicial holdings and the Restatement (Second) of Torts, "are clear evidence of a trend toward absolute liability" in cases of toxic injury); see also G.Z. NOTHSTEIN, TOXIC TORTS: LITIGATION OF HAZARDOUS SUBSTANCE CASES 323 (1984) (noting that greater awareness of dangers to the environment, coupled with the broadened scope of abnormally dangerous activities contained in the Restatement (Second) of Torts, has "affected the willingness of courts to consider certain activities to be abnormally dangerous"); Meyer, supra note 2, at 326 (stating that "most common-law proposals for redressing toxic injury are either under a theory of negligence or strict liability").


5. See RESTATEMENT (SECOND) OF TORTS § 520 cmt. f (1977) [hereinafter RESTATEMENT (SECOND)] (noting that "the essential question is whether the risk created is so unusual, either because of its magnitude or because of the circumstances surrounding it, as to justify the imposition of strict liability for the harm that results from it, even though it is carried on with all reasonable care").
analysis. The sixth Restatement factor requires judicial balancing of the value of the activity to the community against the activity’s risk. This analysis mandates judicial inquiry into the “reasonableness” of the activity at issue in order to justify imposition of liability.

The outcome of toxic tort strict liability actions often depends on whether plaintiffs’ experts can persuasively refute the attempts of defendants’ experts to controvert key elements of the Restatement factors. Judicial risk assessments are largely dependent on the testimony of these subjective experts, as the court system is unable to generate the toxicity and risk data needed to make impartial and informed findings of abnormal dangerousness. Similarly, the judicial system is unable to independently validate the data submitted by the parties. Judicial reliance on these experts would be minimized however, if courts gave conclusive weight to the independently generated toxicity data, findings of risk and regulatory actions promulgated in the regulatory context.

The Environmental Protection Agency (“EPA”) generates toxic-

6. Id. § 520. The six factors to be considered are:
   1) existence of a high degree of risk of some harm to the person, land or chattels of others;
   2) likelihood that the harm that results from it will be great;
   3) inability to eliminate the risk by the exercise of reasonable care;
   4) extent to which the activity is not a matter of common usage;
   5) inappropriateness of the activity to the place where it is carried on; and
   6) extent to which its value to the community is outweighed by its dangerous attributes.

7. See NOTHSTEIN, supra note 3, at 323 (stating that “[t]he determination of whether an activity is abnormally dangerous involves a risk-utility balancing . . . .”).

8. See W. PAGE KEETON ET AL, PROSSER & KEETON ON THE LAW OF TORTS 555 (5th ed. 1984) [hereinafter PROSSER & KEETON] (noting that “the extent to which an activity’s value to the community is outweighed by its dangerousness is . . . quite relevant on whether or not conduct is unreasonable”).

9. See JAMES T. O’REILLY, TOXIC TORTS PRACTICE GUIDE 6-22 (2d ed. 1992) (noting that courts have been inconsistent in weighing the factors, and key terms will be disputed by the defense).

10. See John S. Applegate, The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control, 91 COLUM. L. REV. 251, 300 (1991) (noting that “the judicial process is institutionally ill-suited for generating useful toxics information . . . and courts have little ability to investigate independently, due to lack of expertise, funds, and legal authority”).

ity and risk data on chemical substances and maintains an extensive database pursuant to the statutory mandate of the Toxic Substances Control Act ("TSCA"). TSCA was enacted in response to a recognized need for a comprehensive, multi-faceted statutory approach to toxic risk. This statute authorizes the EPA to focus on toxic harm prevention through the generation of toxicity data and the regulation of risk. TSCA establishes a standard of "unreasonable risk" as the threshold for EPA regulatory action, and gives the EPA the discretion to implement this standard in a manner consistent with the statutory mandate.

Findings of a substance's "unreasonable" or "abnormal" risk are therefore made in two contexts: 1) by the court in a toxic tort strict liability action for abnormally dangerous activity; and 2) by the EPA pursuant to TSCA's mandate in the regulatory context. The purpose of EPA findings is to prevent unreasonable toxic risk creation and to control existing toxic risks at a reasonable level. The purpose of judicial findings of abnormal risk is to justify the imposition of liability for actual harm. This difference however, does not undermine the logical conclusion that the EPA's extensive database on toxic characteristics of specific chemical substances and findings of unreasonable risk are a valuable source of objective, relevant and reliable data for the toxic tort plaintiff.

Judges obviously cannot make a determination of abnormal dangerousness in a factual vacuum. They are dependent upon the data submitted by the parties and their experts. The evidentiary problems...
inherent in this judicial reliance could be resolved by judicial construction of a rule of decision which recognizes EPA findings of risk and regulatory actions as determinative on the issue of a substance's risk. Such a rule of decision, or presumption of evidentiary sufficiency, would increase the deterrent effect of toxic tort claims by producing more predictable and consistent decisions. Judicial economy would also be maximized by reducing the need for costly, time-consuming and subjective battles of experts.

This Note will examine the similarities in the risk decision-making and risk-utility balancing analyses conducted in both the regulatory and common law contexts. Part II discusses the court's role in a strict liability action for an abnormally dangerous activity within the context of toxic tort litigation. It analyzes judicial treatment of the six Restatement factors, in an effort to determine the circumstances under which courts have found an activity to be abnormally dangerous.

A toxic tort plaintiff cannot persuasively argue the relevance of an EPA finding of unreasonable risk without understanding the statutory context and components of the standard. Part III therefore examines the EPA's statutory mandate under TSCA to make findings of "unreasonable risk." These findings are the requisite triggers for all EPA regulatory action, so the components of the standard are also explored. EPA implementation of the unreasonable risk standard varies depending upon the statutory context of the proposed regulatory action so part III examines the two most common forms of regulatory action under TSCA; pre-manufacturing rules for testing of substances not yet on the market and regulatory control of substances already on the market. Part IV discusses the similarities in factors and analytical methodology between the common law and regulatory contexts. The author concludes that the evidentiary weight of pre-manufacturing testing rules should be analogous to a rebuttable presumption. Regulatory controls of substances on the market should be entitled, however, to the conclusive weight analogous to an irrebuttable presumption.

16. The evidentiary consequences of the terms "rebuttable and irrebuttable presumptions" are not uniform throughout the judicial system. This lack of consistency has been the subject of much academic debate. See generally Mason Ladd, Presumptions in Civil Actions, 1977 ARIZ. ST. L.J. 275. Although "presumption" is essentially a label affixed to an evidentiary decision of the court, this term is used throughout the Note to connote a sufficiency of evidence which typically results in a reallocation of the burden of production, burden of persuasion, or both. See, e.g., Ronald J. Allen, Presumptions in Civil Actions Reconsidered, 66 IOWA L. REV. 843, 862 (1981) (noting that "a presumption is simply a label applied to a choice concerning the evidentiary relationships of the parties that is reached for policy reasons having nothing to do with any independent meaning of the word "presumption").
II. STRICT LIABILITY FOR ABNORMALLY DANGEROUS ACTIVITIES IN TOXIC TORT CASES

Strict liability in the toxic tort context requires judicial characterization of an activity as abnormally dangerous and imposition of liability for ensuing harm, even though all reasonable care may have been used. The imposition of strict liability reflects a social policy that liability for hazardous waste should be imposed on those responsible for its creation, regardless of whether their acts were intentional. This theory of recovery therefore attempts to provide an incentive for the development of alternate methods of conducting an activity so as to reduce accidents.

The determination of an activity's abnormal dangerousness is a question of law for the court which requires a case-by-case analysis. Although abnormal dangerousness is a function of the activity at issue and not of a substance, the toxicity of a substance is a critical component of a determination of an activity's abnormal dangerousness.

17. See RESTATEMENT (SECOND), supra note 5, § 520 cmt l; see also Indiana Harbor Belt R.R. v. American Cyanamid Co., 916 F.2d 1174, 1177 (7th Cir. 1990) (analyzing Restatement factors (a) and (b), the court stated that "[t]he greater the risk of an accident . . . and the costs of an accident if one occurs . . . the more we want the actor to consider the possibility of making accident-reducing activity changes; the stronger, therefore, is the case for strict liability"); Amland Properties Corp. v. Aluminum Co. of Am., 711 F. Supp. 784, 804 (D.N.J. 1989).

18. See Kenney v. Scientific, Inc., 497 A.2d 1310, 1321 (NJ. Super. Ct. Law Div. 1985) (noting that "despite the economic hardship involved, the creators of abnormally dangerous substances are far better able than the victims to sustain the costs of the injuries resulting from those substances").

19. Indiana Harbor, 916 F.2d at 1177 (noting that imposing strict liability on an actor gives an incentive to experiment with methods of preventing accidents by refusing to excuse him from liability because he was unable to avoid harm with exercise of greater care).

20. See G.J. Leasing Co. v Union Elec. Co., 825 F. Supp. 1363, 1373 (S.D. Ill. 1993) (stating that the "determination of whether an activity is an abnormally dangerous activity is a question of law for the court"); see also Amland Properties, 711 F. Supp. at 804; Edwards v. Post Transp. Co., 228 Cal. App. 3d 980, 984 n.2 (Ct. App. 1991) (noting that all authorities agree that determining whether an activity is abnormally dangerous is "a question of law, and not to be submitted to a jury").

21. See G.J. Leasing, 825 F. Supp at 1374 (stating that "whether or not an activity should be deemed abnormally dangerous is not tested by the substance itself, but by the activity alleged to be abnormally dangerous"); see also Indiana Harbor, 916 F.2d at 1181 (stating that "abnormal dangerousness is, in the contemplation of the law at least, a property not of substances, but of activities").

22. See Kenney, 497 A.2d at 1320 (noting that "the potential for calamity lurking in an abnormally dangerous substance is precisely what justifies the imposition of absolute liability").
Although the *Restatement* does not define the term “abnormal dangerousness,” it establishes six factors which are intended to guide the court in a determination of whether an activity is abnormally dangerous:

a) existence of a high degree of risk of some harm to the person, land or chattels of others;

b) likelihood that the harm that results from it will be great;

c) inability to eliminate the risk by the exercise of reasonable care;

d) extent to which the activity is not a matter of common usage;

e) inappropriateness of the activity to the place where it is carried on; and

f) extent to which its value to the community is outweighed by its dangerous attributes.24

Although the *Restatement* states that each of these factors is important and should be considered by the court, it also indicates that all of them need not be present.25 However, an activity’s risk of harm and magnitude of exposure will always be relevant to the court’s analysis, as these factors are critical to the central issue of whether an activity is abnormally dangerous.

The first three *Restatement* elements require an evaluation of factual information, as they involve risk and exposure characteristics of the activity itself.26 However, unless an activity may be characterized as abnormally dangerous based on common knowledge or judicial precedent, the court is generally unable to evaluate the danger of the activity without reliance upon the advice of experts.27 This judicial reliance on data submitted by subjective experts poses a potential for abuse, as judges may sometimes be misled by the “expert-for-hire.”28

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23. See *Restatement* (Second), *supra* note 5, § 520 cmt. f.
24. *Id.* § 520.
25. *Id.* § 520 cmt. f.
27. *Id.* at 984. While certain activities “may be subject to characterization based upon common knowledge, it is obvious that other activities involve danger which can be appraised only upon the advice and education of experts.” *Id*; see also Allied Corp. v. Frola, 730 F. Supp. 626, 633 (D.N.J. 1990) (noting that “in light of today’s knowledge about the pernicious effects of carcinogens such as PCBs, the disposal of such compounds is abnormally dangerous”); Amland Properties Corp. v. Aluminum Co. of Am., 711 F. Supp. 784, 807 (D.N.J. 1989) (if the facts at hand are “factual congruent” with case law precedent which found an activity to be abnormally dangerous, “an independent re-weighing of the Restatement factors” may be precluded).
The Restatement factors which address the extent to which the activity is not a matter of common usage, and the inappropriateness of the activity in relation to its location, require judicial evaluation of public policy. In considering these factors, the court often draws upon its own knowledge of the community.29

The last Restatement factor requires the court to perform a risk-utility balancing test, addressing the extent to which an activity's value to the community is outweighed by its dangerous attributes.30 Thus, even though an activity presents a serious risk of harm which cannot be eliminated with reasonable care, a court might ultimately find that it is not abnormally dangerous if the community derives a large part of its prosperity from the activity.31 Courts have interpreted this factor as requiring a judicial determination that the substance at issue is "so necessary to society that we would insulate its users from strict liability."32

Judicial evaluation of the Restatement factors has been described as determining the dangers of the activity and the magnitude of the risks in view of the locality, followed by a policy determination of whether the dangers and inappropriateness of the activity are so great as to require the actor to pay for resulting harm, in spite of the activity's value to the community.33

In summary, a judicial finding of an activity's abnormal dangerousness reflects the court's determination of the level at which a health risk is unreasonable. Analysis of the Restatement factors involves data-intensive factual determinations of an activity's magnitude.

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29. See Edwards, 228 Cal. App. 3d at 986.
30. See Restatement (Second), supra note 5, § 520 cmt. k; see also Notstein, supra note 3, at 323 (the extent of the risk and magnitude of harm must be weighed against the value of the activity to the community).
31. See Restatement (Second), supra note 5, § 520 cmt. k.
32. Edwards, 228 Cal. App. 3d at 985-86 (noting that while sulfuric acid is "unquestionably a useful and beneficial chemical," it is not so necessary that users should be insulated from strict liability).
33. See Ahrens v. Pacific Gas & Elec. Co., 197 Cal. App. 3d 1134, 1145 n.9 (Ct. App. 1988). Consideration of the Restatement factors involves an evaluation of whether the dangers of the activity are inappropriate for the locality, the magnitude of the risks, and the ultimate policy issue whether the dangers and inappropriateness of the activity are so great as to require the enterprise engaged in the activity to pay for any harm it causes, despite any usefulness to the community.

Id.
of harm, risk and the inability to reduce the risk to a reasonable level, as well as policy-based judgmental evaluations of the toxicity and risk of the activity compared to its value to the community. In practice, courts often make these findings without evaluating all six Restatement factors.\textsuperscript{34}

III. THE TOXIC SUBSTANCES CONTROL ACT

TSCA's emphasis on toxic harm prevention is evident in the comprehensive scope of the EPA's regulatory authority.\textsuperscript{35} This regulatory authority commences before a substance or mixture is manufactured and continues for as long as the substance exists in the marketplace.\textsuperscript{36}

If the EPA determines that existing data is insufficient to determine the health effects of a pre-manufactured substance, either because a substance "may present an unreasonable risk of injury to health or the environment" or because of production in substantial quantities, the EPA must issue a testing rule.\textsuperscript{37} Issuance of such a rule requires the manufacturer or processor to develop specific data necessary for further evaluation of the substance's risk.\textsuperscript{38} This testing data becomes part of an extensive EPA database which is used for subsequent risk assessment and risk management decisions. Additionally, if the EPA has a reasonable basis for determining that a substance already in the marketplace presents or will present an unreasonable risk of injury, TSCA empowers the EPA to impose the least burdensome of an array of statutory permanent controls in order to reduce the risk to a reasonable level.\textsuperscript{39}

\textsuperscript{34} See Edwards, 279 Cal. App. 3d at 986 (finding that the factor relating to inappropriateness of the activity to its locality is not "of significant importance in our analysis"); see also State Dep't of Envtl. Protection v. Ventron, 468 A.2d 150, 159-60 (N.J. 1983) (declining to discuss or consider whether the activity was a matter of common usage).

\textsuperscript{35} See H.R. REP. No. 1341, supra note 13, at 6-7. TSCA mandates the development of a comprehensive data system which focuses on "the totality of human or environmental exposure" in order to remedy the deficiencies in federal environmental statutes which did not consider the cumulative impact of all sources of exposure. Id; see also O'REILLY, supra note 9, at 9-25 (noting that TSCA is unique among the environmental laws because it focuses attention on the "particular characteristics of particular chemicals, rather than to the types of [chemical] releases").


\textsuperscript{39} 15 U.S.C. § 2605(a)(1)-(7) (1988); see J. CLARENCE DAVIES ET AL., DETERMINING UNREASONABLE RISK UNDER THE TOXIC SUBSTANCES CONTROL ACT 25 (1979). Upon determining that a substance presents or will present an unreasonable risk of injury, the EPA is
TSCA therefore creates a two-tiered system for the evaluation and regulation of substances to protect against unreasonable risks. The level of certainty of risk required for EPA action against pre-manufactured substances is lower than that required for regulatory controls of substances already in the marketplace.

A. Characteristics of the Unreasonable Risk Standard

The threshold standard which triggers all regulatory action under TSCA is an EPA finding of unreasonable risk. This standard contains four components: “regulation of risk instead of actual harm, a regulatory goal of less than complete safety, facilitation of cost-risk-benefit balancing [and] implementation through case-by-case determinations.” Congress intentionally adopted each of these components in order to address perceived deficiencies in existing federal environmental statutes.

The EPA’s statutory mandate to regulate risk rather than actual harm is intended to focus prospectively on toxic harm prevention. The “unreasonableness” element of TSCA’s risk standard indicates that Congress was not willing to assume that a risk-free society is attainable. This congressional assumption that a risk of toxic expos...
sure is not necessarily equivalent to an "unreasonable" risk has successfully survived judicial scrutiny.\textsuperscript{47} The required element of "unreasonableness" also indicates that this standard is one of risk management as well as risk assessment.\textsuperscript{48} The "unreasonableness" of a substance's risk is not an inherent quality of a substance. It is a conclusory finding based on EPA balancing of the cost, risk and benefit of any regulatory action.\textsuperscript{49} Although the balancing process involved in determining whether a risk is "unreasonable" does not require an assignment of monetary value to both the benefits and costs of EPA action, the EPA is required to balance

the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society.\textsuperscript{50}

Congress intentionally chose not to define the term "unreasonable risk" in the statute, as the value-laden balancing process required for such a determination implicitly mandates exercise of the EPA's dis-

\textit{\textsuperscript{47}} See Environmental Defense Fund v. EPA, 636 F.2d 1267, 1278 n.30 (D.C. Ct. App. 1980) (describing plaintiff's attempts to equate a risk of PCB exposure with an unreasonable risk as "misguided," the court noted that although the EPA "has determined that no level of [PCB] exposure can be considered safe, and that therefore, any exposure should be considered 'significant,' that determination does not imply that the exposure is unreasonable").

\textit{\textsuperscript{48}} See Applegate, supra note 10, at 277-79. The risk assessment process is described as "measuring the probable health effects of toxic substances" and providing an "objective evaluation of the risk posed by a chemical." Risk management requires evaluation of policy and economic considerations to determine the "unreasonableness" of a risk. \textit{Id.; see also Davies, supra note 39, at 4 (noting the distinction between the "essentially scientific question of 'risk' and the political-economic-philosophical question of 'unreasonableness'").}

\textit{\textsuperscript{49}} See 15 U.S.C. § 2601(o) (1988) (the EPA "shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take"); \textit{see also} 45 Fed. Reg. 48,524 (1980) (to be codified at 40 C.F.R. § 773); Applegate, supra note 10, at 274 (noting that "[t]he unreasonable risk standard expressly incorporates cost-risk-benefit balancing to answer the question raised by relative safety").

\textit{\textsuperscript{50}} H.R. Rep. No. 1341, supra note 13, at 13; \textit{see Davies, supra note 39, at 13. Whether a regulated chemical can be replaced by a nonregulated chemical is "a crucial factor in determining the cost of regulation." Evaluation of the costs and benefits of proposed regulatory action should compare pre-regulation costs and benefits with costs and benefits post-regulation. \textit{Id.}
cretionary judgment, rather than an objective factual determination.\textsuperscript{51}

Although these general criteria apply to any EPA finding of unreasonable risk under TSCA, the statute enumerates specific additional factors which must be considered by the EPA prior to regulatory action under certain specific sections.\textsuperscript{52} For example, before issuance of a testing rule under Section 4, the EPA must consider the costs of the various tests required, as well as the availability of facilities and personnel needed to perform the tests.\textsuperscript{53} Similarly, regulatory action under Section 6 must be substantiated by a published statement demonstrating EPA consideration of specific factors.\textsuperscript{54} Although these various statutory mandates will be discussed in detail, it should be apparent that implementation of TSCA's unreasonable risk standard necessarily varies depending upon the nature of the proposed EPA action.\textsuperscript{55} A toxic tort plaintiff in a strict liability action cannot persuasively argue the evidentiary relevance of regulatory actions and EPA findings of unreasonable risk without understanding the components of the "unreasonable risk" standard. Additionally, in order to persuade the court that a specific regulatory action should either be accorded conclusive weight or treated as a rebuttable presumption, an understanding of the statutory context pursuant to which the EPA made its finding of unreasonable risk is essential.

\textbf{B. Implementation of Unreasonable Risk Standard for Testing Rules}

Section 4 authorizes the EPA to require the manufacturer and/or processor of a pre-manufactured substance to conduct specific tests of the substance's health and environmental effects if the EPA finds a

\textsuperscript{51} See H.R. REP. NO. 1341, supra note 13, at 13-14; see also DAVIES, supra note 39, at 1 (noting that "TSCA makes it quite clear that EPA must consider conflicting values in making a determination of unreasonable risk"); Baram, supra note 28, at 3 (determining the appropriate risk limit, or "how safe is safe enough," is within the province of agency judgement and judicial review).

\textsuperscript{52} See DAVIES, supra note 39, at 4.

\textsuperscript{53} 15 U.S.C. § 2603(b)(1) (1988) (stating that the EPA's considerations "shall include the relative costs of the various test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing").

\textsuperscript{54} 15 U.S.C. § 2605(e) (1988) (requiring that the EPA consider and publish a statement regarding the effects and magnitude of exposure on health and the environment, the benefits of the substance, availability of substitutes and "reasonably ascertainable economic consequences of the rule").

\textsuperscript{55} See H.R. REP. NO. 1341, supra note 13, at 14 (noting that "implementation of the standard will of necessity vary depending on the specific regulatory authority which the Administrator seeks to exercise").
legitimate basis of concern. A testing rule must identify the substance to be tested, the standards to be used in the development of test data and the duration of the time period during which test data must be submitted. TSCA changed existing practice by imposing the cost of testing on the substance’s manufacturer or processor rather than on the government agency which required the testing.

The statutory trigger for issuance of a testing rule is an EPA finding of three factors, involving the substance’s risk potential, the insufficiency of existing data and the need for testing to develop the data. First, the EPA must find either that a) “the manufacture, distribution in commerce, processing, use or disposal of a chemical substance . . . may present an unreasonable risk of injury to health or the environment,” or that b) the substance “is or will be produced in substantial quantities” with potentially significant human exposure or substantial environmental release of the substance. Second, the EPA must find that there is insufficient data on which to evaluate the health and environmental effects of the substance. Third, testing must be necessary to develop the requisite data. Both the second and third factors are requisite components of any EPA determination to issue a testing rule, whether based upon a finding of potentially

56. 15 U.S.C. § 2603(a) (1988); see also 45 Fed. Reg. 48,524, supra note 49, at 48,527. To fulfill the statute’s intent under Section 4, the EPA’s goals are “(1) to require testing of selected high priority chemicals to determine reliably whether or not such substances pose an unreasonable risk to health or the environment; and (2) to make such testing requirements as efficient and cost effective as possible.” Id.

57. 15 U.S.C. § 2603(b)(1) (1988); see also 45 Fed. Reg. 48,524, supra note 49, at 48,525 (noting that certain health effects for which test standards may be required include “carcinogenesis, mutagenesis, teratogenesis and behavior disorders”).

58. 15 U.S.C. § 2601(b)(1) (1988) (providing that “adequate data should be developed with respect to the effect of chemical substances . . . and that the development of such data should be the responsibility of those who manufacture and those who process” such substances); see also H.R. REP. NO. 1341, supra note 13, at 6 (noting that “since present laws require regulatory agencies to bear the cost of testing, regulatory action often does not occur until adverse effects of a chemical become evident in the population or in the environment”); Ausimont U.S.A., Inc. v. EPA, 838 F.2d 93, 98 (3d Cir. 1988) (stating that “Congress obviously had serious concerns about toxic substances and made a policy judgment to place the expense of testing on manufacturers who ultimately can transfer the cost to consumers”).


62. 15 U.S.C. § 2603(a)(1)(B)(ii) (1988); see 45 Fed. Reg. 48,524, supra note 49, at 48,529 (noting that the EPA reviews existing information to determine if there is sufficient data to provide “the basis for defining the hazard component of a decision whether the chemical does or does not present an unreasonable risk”).

unreasonable risk or upon a finding of substantial exposure.  

An exposure-based finding is appropriate when testing of a substance is required because of the potential for significant human exposure to a chemical whose hazards have not yet been determined. Because an exposure-based finding of unreasonable risk is not based on a substance's suspected toxicity, a testing rule may be issued even in the absence of evidence that the substance may be hazardous. This subtle distinction between the basis of a risk-based and exposure-based EPA finding under Section 4 would be relevant to a toxic tort plaintiff's argument that a risk-based finding which underlies issuance of a testing rule should be accorded greater evidentiary weight than an exposure-based finding.

A risk-based finding requires an EPA determination that the substance may present a hazard, may present a risk and may present an unreasonable risk. The phrase "may present an unreasonable risk" explicitly indicates that implementation of the unreasonable risk standard in this statutory context will result in EPA findings of unreasonable risk which are not based on definitive scientific data. Courts have upheld EPA interpretation of "may present an unreasonable risk" as requiring a "substantial (i.e., more than theoretical) probability" of unreasonable risk of injury to health. Although this standard requires findings of both toxicity and exposure, the EPA generally applies a "see-saw" approach which considers the strength of evidence on both factors.

64. See 45 Fed. Reg. 48,524, supra note 49, at 48,529 (noting that insufficiency of available data is a requisite element common to both risk-based and exposure-based findings because Congress wanted to ensure that the EPA would not impose unnecessary or duplicative testing rules).

65. Id.

66. See 58 Fed. Reg. 28,736, 28,740-41 (1993) (articulating the following criteria for exposure-based findings of unreasonable risk under Section 4: a 1 million pound threshold for "substantial production"; a 1 million pound threshold for "substantial release into the environment"; and thresholds of 1,000 workers, 10,000 consumers and 100,000 persons in the general populace for "substantial exposure").


68. See 45 Fed. Reg. 48,524, supra note 49, at 48,528 (determining the potential health effects of a substance in a Section 4 regulatory context will necessarily be not based on "definitive scientific data"); see also H.R. REP. NO. 1341, supra note 13, at 17-18. Section 4 does not require the EPA to find that a substance causes or will cause an unreasonable risk of injury, as such a requirement "would defeat the purpose of the section." Such a determination would justify regulatory action to protect against the risk, rather than additional testing. Id.


70. Id. at 983-84 n.7 (noting that although weak evidence of exposure and weak evi-
The hazard potential of a chemical will necessarily involve scientific assumptions and extrapolations, since the substance is evaluated upon a prerequisite finding of insufficient data. The "risk" component of a risk-based finding includes evaluation of both toxicity and exposure potential. Although the potential for exposure is a requisite element of both a risk-based and exposure-based finding, the threshold of exposure in a risk-based finding is much lower. Therefore, if the EPA has information that a chemical may be highly toxic even at low levels of exposure, the required amount of exposure to justify a toxicity or risk-based finding will be minimal. In order to determine that a substance may present a risk, the EPA need only establish that in view of strong evidence of toxicity, "there is a reasonable likelihood that exposure may arise."

The EPA must additionally find that the substance may present an "unreasonable" risk. This determination requires balancing the potential severity of the substance's harm against the effects of the proposed testing rule on the availability of benefits from the sub-

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71. See 45 Fed. Reg. 48,524, supra note 49, at 48,528. Factors which indicate that a potential health hazard may exist include knowledge of a substance's physical and chemical properties, structural relationships to other substance's with demonstrated adverse effects, data from inconclusive tests, and case history data. Id.

72. Id.; see also Ausimont U.S.A. Inc. v. EPA, 838 F.2d 93, 96 (3d Cir. 1988). Recognizing that "risk" is a critical factor underlying Section 4 testing rules, the court noted that risk "implies two concepts—toxicity and exposure. In each instance, quantity is important." Id.

73. See 45 Fed. Reg. 48,524, supra note 49, at 48,528. Toxicity without human exposure is of little concern to the EPA. A risk-based finding requires a scientific basis for suspecting potential toxicity, so there is an inverse relationship between hazard and exposure. The more significant the risk potential, the less exposure is needed to support a finding of risk and vice versa. Id.

74. See 52 Fed. Reg. 21,412, 21,416-17 (1987) (to be codified at 40 C.F.R. § 707 & 766) (In justifying a testing rule for dibenzo-p-dioxins ("HDDs") and dibenzofurans ("HDFs"), the finding of unreasonable risk was based on the highly toxic nature of HDDs and HDFs even at trace levels. The requisite amount of exposure information was therefore "even less definitive" than for other toxicity-based findings.; see also Ausimont, 838 F.2d at 97 (refusing to support petitioners' conclusion that the number of persons potentially exposed to fluoroalkenes is "insignificant," the court upheld the EPA's finding of unreasonable risk even though the issue of human exposure was a question of degree).

75. See 52 Fed. Reg. 21,412, supra note 74, at 21,416-17.
stance.\textsuperscript{76} In implementation, this cost-risk-benefit analysis often results in a determination that the societal impact of the proposed testing rule is not significant enough to outweigh the benefits of testing, since this regulatory action occurs before the substance is manufactured.\textsuperscript{77} Although TSCA requires the EPA to consider the specific costs of the tests required by a testing rule,\textsuperscript{78} the economic component of the cost-risk-benefit analysis generally involves only the cost of testing and the availability of facilities and personnel needed to conduct the tests.

EPA implementation of the unreasonable risk standard under Section 4 has been described as follows:

If there is substantial evidence that exposure to a chemical may lead to a serious health effect or increase in mortality and that people may be exposed to the chemical, EPA will presume that the activities in question . . . "may present an unreasonable risk" unless the rule is likely to result in a significant loss to society of the benefits of the substance.\textsuperscript{79}

Because the EPA is required to perform the above-described analysis for each health effect for which it is proposing a testing rule, the rule-making record for Section 4 regulatory action contains extensive data on the potential risks of a substance.\textsuperscript{80}

The chemical industry has judicially challenged EPA implementation of the unreasonable risk standard regarding the degree of uncertainty in toxicity and exposure data needed to justify issuance of a testing rule.\textsuperscript{81} The EPA's implementation of the unreasonable risk

\textsuperscript{76} See H.R. Rep. No. 1341, supra note 13, at 14.
\textsuperscript{77} See 45 Fed. Reg. 48,524, supra note 49, at 48,529 (noting that the EPA must weigh the potential adverse impact of testing costs on the manufacturer against the benefits of testing); see also H.R. Rep. No. 1341, supra note 13, at 14. A testing rule will not ordinarily deprive the public of the benefits of a substance because at most it will only delay the commercial availability of a new substance. \textit{id.}
\textsuperscript{78} 15 U.S.C. § 2603(b)(1) (1988) The EPA's considerations "shall include the relative costs of the various test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule". \textit{id.}
\textsuperscript{79} 45 Fed. Reg. 48,524, supra note 49, at 48,529. If the EPA's analysis indicates that "the costs of testing may cause manufacturers or processors to cease or severely restrict their commercial activities, the EPA will weigh this potential adverse impact against the benefits of testing before presuming that the chemical may present an unreasonable risk." \textit{id.}
\textsuperscript{80} \textit{id.} at 48,537-38.
\textsuperscript{81} See Ausimont U.S.A. Inc. v. EPA, 838 F.2d 93 (3d Cir. 1988); see also Chemical Mfrs. Assoc. v. EPA, 899 F.2d 344 (5th Cir. 1990); Chemical Mfrs. Assoc. v. EPA, 859 F.2d 977 (D.C. 1988).
standard for testing rules was judicially evaluated under TSCA’s stricter standard of judicial review and was upheld. In *Ausimont U.S.A., Inc. v. EPA*, the court recognized that even though a prerequisite for issuance of a testing rule is insufficiency of data, the EPA cannot require expensive experimentation based only on speculation or “mere scientific curiosity.” In *Chemical Mfrs. Assoc. v. EPA*, the court upheld EPA implementation of the unreasonable risk standard under Section 4 as requiring evidence of a “more than theoretical probability” that some exposure occurs and that the substance is toxic enough at that level of exposure to present an unreasonable risk of harm.

These decisions clearly establish that the unreasonable risk standard under Section 4 is satisfied by substantial probability of toxicity at a demonstrated level of exposure and less than definite scientific certainty of harm. However, the decisions also demonstrate that the EPA is still required to show that its findings satisfy those criteria of the “unreasonable risk” standard which are common to all findings, regardless of statutory context. Thus, the weight of the elements balanced by the EPA may vary between Section 4 and Section 6, but the methodology of risk assessment is the same. Regulatory action under Section 4 is driven by a substance’s hazard and risk, balanced

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82. See *Ausimont*, 838 F.2d at 98; *Chemical Mfrs.*, 859 F.2d at 992. But see *Chemical Mfrs.*, 899 F.2d at 360 (declining to stay the EPA’s testing rule for health effects of cumene which was based on an exposure-based finding of unreasonable risk, but remanding for EPA articulation of the criteria used to find “substantial” human exposure and “substantial” quantities entering the environment).

83. *Ausimont*, 838 F.2d 93 (3d Cir. 1980).

84. *Id.* at 97. Although the necessity for testing depends on lack of knowledge, the EPA is bound by TSCA’s directive to “carry out this chapter in a reasonable and prudent manner.” 15 U.S.C. § 2601(e) (1988). While this prevents issuance of a testing rule “based on little more than scientific curiosity,” the EPA is authorized to act “when an existing possibility of harm raises reasonable and legitimate cause for concern.” *Ausimont*, 838 F.2d at 97.

85. 859 F.2d 977 (D.C. 1988).

86. *Chemical Mfrs.*, 859 F.2d at 987. Evaluating a testing rule for 2-ethylhexanoic acid, the court held that the EPA’s interpretation of “substantial” evidence in the record as requiring a more than theoretical probability of harm was “a reasonable accommodation of the conflicting policies Congress committed to its care—specifically, the need to gather information about suspect chemicals without mandating expensive tests based on little more than a hunch.” *Id.*

87. 15 U.S.C. § 2601(b)-(c) (1988). The EPA must be able to demonstrate that the environmental economic and social impact of all regulatory actions was considered, that the exercise of EPA authority does not unduly impede or create economic barriers to technological innovations in the substance, and that TSCA is administered in a reasonable and prudent manner.
against the economic impact of the regulatory action. These same
criteria are evaluated by a court when determining if an activity is
abnormally dangerous. Testing rules and their underlying findings of
unreasonable risk represent an evidentiary source which is relevant to
a toxic tort plaintiff’s strict liability action for abnormally dangerous
activity. These findings and regulatory actions should therefore create
a rebuttable presumption on the issue of the substance’s and activity’s
risk. 88

C. Implementation of Unreasonable Risk Standard for Regulatory
Actions Under Section 6

Section 6 of TSCA requires the EPA to regulate the production,
use, commercial distribution or disposal of a substance if there is a
“reasonable basis to conclude” that the activity “presents or will pres-
ent an unreasonable risk of injury.” 89 Upon making such a finding,
the EPA must impose the least burdensome regulatory control of
among seven statutory options which would reduce the risk to a rea-
sonable level. 90

These options range from the most onerous, a total ban of the
substance, to the least onerous, labeling or quality control. 91 Each
option may be limited in application to “specified geographic ar-

88. See Ladd, supra note 16, at 288. Although legal scholars are not in agreement on
whether a rebuttable presumption shifts the burden of persuasion, it clearly imposes a burden
on the adverse party to produce rebutting evidence in order to burst the bubble of the pre-
sumption. Id.
90. Id.
91. Id. § 2605(a)(1)-(7) (1988). These regulatory options present varying degrees of bur-
den to a manufacturer and include: 1) either a total prohibition or a limit on manufacturing,
processing or distribution in commerce of a substance; 2) a prohibition or limit on manufactur-
ing for a particular use or a use in excess of a specified level of concentration; 3) a re-
quirement that the chemical or any product containing the substance be labeled with clear
and adequate warnings as prescribed by the EPA; 4) a requirement that manufacturers and
processors make and retain records of the production processes; 5) a prohibition or regulation
of the manner or method of commercial use; 6) a prohibition or regulation of the manner or
method of disposal; and 7) a requirement that manufacturers or processors give notice of the
unreasonable risk of injury to persons possessing or exposed to the substance, give public
notice of the risk and replace or repurchase the substance.
92. Id.
additionally requires the EPA to publish a statement of its findings on each of the requisite factors it. These EPA risk and economic analyses demonstrably are more extensive than those conducted by a court in determining an activity’s abnormal dangerousness.

Section 6 implicitly provides that factual certainty regarding the existence of an unreasonable risk of injury is not required. This section has been judicially interpreted as demanding somewhat less than the more-probable-than-not standard of tort law. In rejecting a zero-risk policy, TSCA requires the EPA to distinguish between risk and unreasonable risk. This mandates consideration of the general factors common to all unreasonable risk findings under TSCA: toxicity evidence, predicted health effects, predictions as to the magnitude of human exposure, and the economic and social impact of the proposed action.

Although Section 6 identifies specific factors which must be considered by the EPA in implementing the unreasonable risk standard, it does not address how much weight these factors should be given in the requisite balancing process.

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EPA prohibition of the manufacture and sale of asbestos under TSCA's “more rigorous” standard of judicial review, the court noted that TSCA’s “least burdensome requirement” imposes a heavier burden on the EPA when it “seeks a partial or total ban of a substance than when it merely seeks to regulate that product.” Id.; see also 56 Fed. Reg. 49,863, supra note 1, at 49,869 (considering and rejecting alternative regulatory options to a total ban of acrylamide grout).


95. See H.R. Rep. No. 1341, supra note 13, at 32 (noting that since regulatory action is intended to prevent the occurrence of future harm as well as to protect against presently known harm, regulatory action must often be based on scientific theories, projections of trends from available data, reasonable assumptions and extrapolations); see also 56 Fed. Reg. 21,802, 21,806 (1991) (codified at 40 C.F.R. § 744) (in finding that uncontrolled land application of paper mill sludge containing specific toxic substances presents an unreasonable risk of injury, the EPA noted that Section 6 does not require a factual certainty before regulatory action may be taken).

96. See Chemical Mfrs. Assoc. v. EPA, 859 F.2d 977, 986 (D.C. 1988) (noting that the legislative history of Section 6 does not indicate a requirement of certainty and the “reasonable basis” requirement suggests a less demanding standard than the more-probable-than-not standard); see also H.R. Rep. No. 1341, supra note 13, at 32 (noting that an EPA finding of “a reasonable basis must include adequate reasons and explanations” but does not require “the factual certainty of a ‘finding of fact’ . . . associated with adjudication”); 56 Fed. Reg. 21,802, supra note 95, at 21,806.

97. See 56 Fed. Reg. 21,802, supra note 95, at 21,806. The unreasonable risk standard is “highly judgmental in the case of health and environmental risks” and requires a “weighing of the risks to be reduced by Agency action and the consequences of the action.” Id.


99. 15 U.S.C. § 2605(c)(1)(A)-(D) (1988). The EPA must consider the health and environmental effects of the substance, the magnitude of human and environmental exposure, the
Every unreasonable risk finding under TSCA involves balancing the probability of harm and severity of risk against the economic impact of regulatory action. In the context of Section 6 regulatory actions which affect substances already on the market, the economic analysis of the proposed rule must include the impact of the rule on the economy, technological innovation, the environment and the public health. This analysis must also include the economic savings to society which result from the removal of an unreasonable risk.

In evaluating the positive effect of regulatory action on the development of substitutes, the EPA must consider the costs of switching from a regulated substance to a substitute non-risk substance.

The EPA's analysis underlying the proposed ban on acrylamide grout is an example of how the "unreasonable risk" standard is implemented under Section 6. The EPA's risk analysis of the grout focused on specific health effects such as neurotoxicity, carcinogenicity, and reproductive and developmental effects. Both human and animal studies were conducted to correlate the exposure of grouters to these health effects. The EPA concluded that there was sufficient weight of evidence on these health effects to indicate serious concern.

EPA analysis of the magnitude of exposure focused on dermal and inhalation exposure during various applications of the grout. The EPA collected data during monitoring studies at four sites and concluded that dermal exposure is virtually unavoidable. The mag-

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101. Id. at 35. Analysis of the reasonably ascertainable economic consequences should include consideration of the "major effects of the rule on the national economy and the rule's effect on technological innovation, the environment, and the public health." Id.
102. Id.
103. See 56 Fed. Reg. 49,863, supra note 1, at 49,866. A total ban on acrylamide and N-methylolacrylamide ("NMA") grout for manhole sealing and phased delay in banning NMA grout in sewer line repair was proposed. The EPA found that health risks from the grout out-weighed the benefits of continued use, effective substitute grouts were available at less risk, and a delay in the ban of NMA grout for sewer line repair lessened the economic burden of compliance. Imposition of the rule was therefore justified. Id.
105. Id. at 49,866-68.
106. Id.
107. Id. at 49,863. Grout applications included sewer line sealing, manhole sealing, and processes like mixing, testing, equipment disassembly and clean-up of the grout.
108. Id. (concluding that "it is virtually impossible for grouting workers who use acrylamide grout not to be exposed dermally").
nitude of exposure, even with personal protective equipment, placed all grouters at very high neurotoxic risk and the estimated lifetime risk of cancer ranged from 1 in 100 to 1 in 1000.  

TSCA also requires the EPA to consider the benefits of a substance and the availability of substitutes. Acrylamide grout was found to be the most popular grout for rehabilitation of sewer systems because of its low cost, reliability, low viscosity and ease in use. After examination of available substitutes, the two most promising were found to be used for almost all major commercial applications. An essential component of the analysis of available substitutes is the possible hazards they might present, however the EPA found that none of the substitutes presented a potential risk as great as acrylamide grout.

The EPA then weighed the economic effects of the proposed ban against these findings of serious neurotoxic and carcinogenic effects from worker exposure, and the existing availability of effective substitutes in the marketplace which posed less potential risk to grouters. In estimating the cost of switching from acrylamide grout to a substitute, the EPA individually examined the costs of using a substitute grout in each of the grout applications discussed above. The EPA concluded that the total compliance costs of the proposed ban ranged from $4.4 million to $7.4 million, depending on the substitute used. This converted to a cost per worker of $2,500 to $4,000 per year to protect against serious individual neurotoxic and carcinogenic risks. In view of the magnitude and severity of the risks associated with use of acrylamide grout, the EPA concluded that the estimated costs of the ban, which would have an impact on the chemical grouting industry, would not outweigh the beneficial impact of the regulatory action.

However, the EPA's unreasonable risk analysis under Section 6 was not yet complete. TSCA requires the EPA to impose the least burdensome regulatory option which will reduce the risk to a reason-
able level. The EPA therefore considered various less onerous regulatory options such as banning the grout for manhole sealing only or banning the grout only at non-OSHA work sites. However, it determined that a total ban of acrylamide grout was warranted. The significant individual cancer risks and serious neurotoxic risks from worker exposure, even with protective equipment, outweighed the cost to society of the proposed regulation.

D. Indicia of Reliability for EPA Regulatory Actions

In addition to understanding the components of the “unreasonable risk” standard and its implementation in the context of temporary testing rules and permanent regulatory actions, a toxic tort plaintiff should understand TSCA’s administrative processes which ensure the reliability of EPA findings. TSCA creates three methods of public oversight. First, proposed regulatory actions, in addition to EPA findings of unreasonable risk, must be published in the Federal Register. No EPA regulatory action can be implemented until expiration of the public comment period and the EPA is required to publicly respond to any received comments, unless an imminent hazard exists. All EPA findings and proposed rules are therefore subject to the rigors of public scrutiny.

Second, TSCA authorizes citizen participation in the regulatory effort to deter toxic risk creation by providing that any person may petition the EPA for issuance, amendment or repeal of an EPA regulatory action. If the EPA denies a petition, the petitioner may commence a civil action in district court to compel compliance with petitioner’s request. The court shall consider the petition in a “de novo proceeding” and shall determine if petitioner’s submitted evidence satisfies the preponderance of the evidence standard. This citizens’ petition process therefore reduces potential bureaucratic lethargy in enforcing TSCA and encourages the EPA to sufficiently document its’ regulatory actions in the rule-making record in order to

118. See 56 Fed. Reg. 49,863, supra note 1, at 49,870.
119. Id.
121. Id. § 2605(c)(2) (1988).
122. Id. § 2606 (1988).
123. Id. § 2620(a) (1988).
124. Id. § 2620(b)(4)(A) (1988).
125. Id. § 2620(b)(4)(B) (1988).
successfully defend against a citizen’s petition.

Third, EPA findings of unreasonable risk in the context of Section 4 testing rules and Section 6 regulatory actions are subject to a stricter standard of judicial review. The Administrative Procedure Act ("APA") usually applies the "arbitrary and capricious" standard of judicial review to administrative rulemaking. TSCA however, imposes a more rigorous standard of review which requires "substantial evidence in the rulemaking record" to support EPA regulatory action.

This stricter level of judicial scrutiny, as well as the scrutiny of EPA actions by industry and the public during the requisite comment period, demonstrate the reliability and objectivity of EPA findings of unreasonable risk and regulatory actions. These indicia of reliability persuasively support a toxic tort plaintiff’s argument that Section 4 EPA findings of risk and testing rules should be treated as rebuttable presumptions and Section 6 findings and actions should be given conclusive weight as irrebuttable presumptions.

IV. DETERMINATION OF EVIDENTIARY WEIGHT OF EPA REGULATORY ACTIONS AND UNREASONABLE RISK FINDINGS

There are several similarities in underlying policy and risk analysis between EPA findings of unreasonable risk and judicial findings of abnormal dangerousness. Judicial determination of an activity’s abnormal dangerousness must be considered on a case-by-case basis, as the relation among the Restatement factors will vary with the circumstances. Similarly, EPA findings of unreasonable risk are necessarily made on an ad hoc basis, since the agency is required to balance several factors which differ depending on the statutory context. Whether the finding of risk is made in a judicial or regulatory context, the decision-maker must exercise its discretionary judgment. Additionally, imposition of strict liability reflects a public poli-

128. Id. § 706(2)(D); see also Ausimont U.S.A. Inc. v. EPA, 838 F.2d 93, 96 (3d Cir. 1988).
129. 15 U.S.C. § 2618(c)(1)(B)(i) (1988); see also Ausimont, 838 F.2d at 96 (interpreting "this standard of review as more demanding than the arbitrary and capricious test often applied to administrative rulemaking").
130. See Amland Properties Corp. v. Aluminum Co. of Am., 711 F. Supp. 784, 804 (D.N.J. 1989); see also RESTATEMENT (SECOND), supra note 5, § 520 cmt. f.
131. See Applegate, supra note 10, at 276.
cy that the party responsible for creating a toxic hazard should be responsible for any resulting harm, regardless of the exercise of reasonable care.\textsuperscript{132} Similarly, TSCA imposes the cost of developing adequate data for potentially toxic substances on the manufacturers and processors of the substance.\textsuperscript{133}

In the toxic tort context of a strict liability action, the court must determine what level of risk is unreasonable by evaluating an activity's abnormal dangerousness. In the absence of common law precedent on a specific activity, the court is guided in its "risk limit" analysis by the six \textit{Restatement} factors.\textsuperscript{134} However, the \textit{Restatement} does not require that the risk be one that no conceivable exercise of care could eliminate.\textsuperscript{135} TSCA also establishes a non-zero risk threshold of "unreasonable risk" for regulatory action, reflecting Congress' assumption that a risk-free society is not attainable.\textsuperscript{136}

EPA findings of unreasonable risk generally involve a balancing of the probability that harm will occur and the magnitude and severity of the harm against the economic and social effect of the proposed regulation.\textsuperscript{137} The Court of Appeals for the District of Columbia has likened this balancing process performed by the EPA in making a finding of unreasonable risk to the balancing process conducted in tort law.\textsuperscript{138} The "unreasonable" component of the "unreasonable risk" determination involves discretionary judgments of economic and policy considerations such as the balance between cost, risk and benefit.\textsuperscript{139} This balancing process reflects the EPA's analytical methodology of quantitative risk assessment which balances qualitative objective risk data against subjective quantitative nonhealth-related factors.\textsuperscript{140}

Similarly, the six \textit{Restatement} factors can be generally catego-

\begin{itemize}
\item \textsuperscript{134} \textit{RESTATEMENT (SECOND)}, supra note 5, and accompanying text.
\item \textsuperscript{135} \textit{Id.} § 520 cmt. f. The factor requiring inability to eliminate the risk with reasonable care does not mean that "the risk be one that no conceivable precautions or care could eliminate. What is referred to here is the unavoidable risk remaining in the activity." \textit{Id.}
\item \textsuperscript{136} See H.R. REP. NO. 1341, supra note 13, at 15.
\item \textsuperscript{137} \textit{Id.} at 14.
\item \textsuperscript{138} See Environmental Defense Fund v. EPA, 636 F.2d 1267, 1276-77 n.24 (D.C. Cir. 1980) (noting that an administrative balancing of "the severity of the injury that may result from the product, factored by the likelihood of the injury [and] the harm the regulation itself imposes upon manufacturers and consumers" is derived from tort law).
\item \textsuperscript{139} See Applegate, supra note 10, at 279.
\item \textsuperscript{140} \textit{Id.} at 277-78.
\end{itemize}
rized as either factors requiring toxicity and risk data on the activity itself or factors related to questions of public policy.\footnote{141} The existence of a high degree of risk of harm, the likelihood that magnitude of harm will be great and the inability to eliminate risk with reasonable care require data-intensive evaluations of toxicity and risk. The extent of the activity’s common usage, inappropriateness to the locality and extent to which its value is outweighed by its risk are policy-related factors requiring discretionary and more subjective judgments. In evaluating these two categories of factors, the court essentially performs qualitative and quantitative risk assessments closely analogous to those performed in the regulatory context.

A. Variations in Statutory Implementation of Unreasonable Risk Standard Produce Variations in Evidentiary Weight

The materiality and relevance of EPA regulatory actions and underlying findings of unreasonable risk to a judicial determination of abnormal dangerousness is supported by the similarities in risk assessment analysis discussed above. However, the evidentiary weight to be judicially accorded EPA regulatory actions and findings of risk on the issue of an activity’s abnormal dangerousness is determined by the differences in risk analyses required for testing rules as opposed to regulation of existing substances.

The EPA is statutorily required to consider certain general criteria for every finding of unreasonable risk under TSCA.\footnote{142} These factors include hazard data on toxicity, risk data on magnitude of harm and exposure, and the economic and social impact of a proposed regulatory action.\footnote{143} Additionally, every EPA finding or action must satisfy the overarching statutory mandate to carry out TSCA’s provisions in a reasonable and prudent manner, to develop substantial evidence in the rule-making record to justify regulatory actions and to expose all regulatory actions and findings of risk to public scrutiny and comment.\footnote{144} In the context of a Section 6 permanent regulatory action, the EPA is also required to publish a statement containing its findings on each of the specific factors considered.\footnote{145} The Restatement however, explicitly provides that a court is not required to con-

\footnote{143}{Id.; see also H.R. REP. NO. 1341, supra note 13, at 14.}
\footnote{144}{15 U.S.C. §§ 2603, 2605 (1988).}
\footnote{145}{15 U.S.C. § 2605(c) (1988).}
sider all six factors in its determination of an activity's abnormal dangerousness. This judicial flexibility in application of the factors often results in decisions in which one factor becomes determinative.

The EPA's requisite analysis of economic consequences under TSCA's Section 6 has been shown to be more extensive than any economic analysis performed in the toxic tort context. The sixth Restatement factor states that a court should consider the extent to which the value of an activity to the community is outweighed by the activity's risk. However, the economic component of this factor is essentially limited to the extent to which an activity's risk may be offset by the community prosperity derived from the activity. In contrast, the EPA's economic analysis under Section 6 addresses not only the cost of the proposed regulatory control on the industry, but the economic consequences of the rule on the national economy, on the development of substitute substances, and on technological innovation. The cost involved in using available substitutes, the potential health risk posed by these substitutes, and the economic savings to society from removal of an unreasonable risk are also requisite factors for consideration.

The unreasonable risk standard for Section 6 requires the EPA to find that a substance or activity "presents or will present" an unreasonable risk of injury. The level of certainty implicit in this standard is higher than that required for a Section 4 testing rule, as Congress recognized that the economic impact of the permanent regulation of an existing substance is more extensive than a testing rule for a pre-manufactured substance. The statutory indicia of reliability and the extensive scope of the EPA's risk analysis indicate that a court should adopt a rule of decision which gives conclusive weight to Section 6 regulatory actions and underlying findings of risk. California has adopted a more liberal position by mandating judicial notice of federal regulations and documents contained in the Federal Register.

146. See Restatement (Second) of Torts, supra note 5, § 520 cmt. f.
147. Id. § 520 cmt. k.
148. Id.
150. Id.; see also H.R. Rep. No. 1341, supra note 13, at 35.
The unreasonable risk standard under Section 4 requires a lower level of certainty of risk than a Section 6 finding, as a finding of actual risk would mandate regulation of the substance rather than testing. Implementation of the “unreasonable risk” standard under Section 4 requires a finding that a substance “may” present an unreasonable risk, thus implicitly focusing EPA attention on substances which raise a legitimate basis for concern, but for which adequate data has not yet been developed. As previously discussed, this standard has been judicially interpreted as less demanding than the “more-probable-than-not” standard of common law. A finding of unreasonable risk for testing rules therefore requires a legitimate and more than theoretical scientific basis for suspicion that a substance is sufficiently toxic to present potential risk in the event of exposure.

EPA consideration of the availability of substitutes and the potential economic, technological and social impact of depriving the public of the benefits of a substance in the marketplace are obviously not included in a Section 4 risk-based finding. However, EPA findings of hazard, risk and unreasonable risk are embodied in the issuance of every testing rule. Section 4 regulatory actions are therefore supported by evidence of risk and exposure which outweigh the potentially adverse effects of expensive testing and delay in commercial availability of the substance. EPA regulatory actions and findings of unreasonable risk under Section 4 might not be sufficiently definite to merit conclusive weight in a toxic tort context, however they should create a rebuttable presumption of the substance’s inherent risk.

154. 15 U.S.C. § 2603 (1988). The EPA must find that the manufacture, processing, distribution in use, or disposal of a substance “may present an unreasonable risk of injury.” Id.


156. Id.

157. See Chemical Mfrs. Assoc. v. EPA, 859 F.2d 977, 986 (D.C. Cir. 1988) (interpreting the “may present” language of Section 4 as demanding less than a more-probable-than-not finding).

158. Id. at 988.

159. See Ausimont U.S.A. Inc. v. EPA, 838 F.2d 93, 97 (3d Cir. 1988). If the EPA justifies an unreasonable risk finding with only the remote possibility of potential exposure, “the statutory directive for ‘reasonable and prudent’ agency action would counsel against expensive testing.” Id.
B. Judicial Recognition of EPA Findings Minimizes Reliance on Experts

Courts must generally rely on the data submitted by the parties' experts, because the risk assessment decision-making process is information intensive and the judicial system is institutionally ill-equipped to generate or validate relevant data. The admissibility of expert testimony on the risks of a substance is subject to the discretion of the court, and inevitably leads to nonuniformity in judicial treatment of expert testimony.\(^{160}\) Judicial dependence on expert testimony for essential toxicity and risk data presents a potential for abuse.\(^{161}\) One suggested alternative to this system of judicial reliance on biased experts is the use by the courts of "court-commissioned studies by government agencies or impartial experts."\(^{162}\) The extensive studies and tests conducted in the regulatory context to justify EPA findings of unreasonable risk and regulatory actions represent, in effect, impartial scientific studies by a government agency. EPA findings and risk assessments are used to determine the risk limit in standard-setting regulatory actions, and as such they are extremely relevant in the toxic tort context to judicial determinations of whether an activity is abnormally dangerous.\(^{163}\)

The EPA adopted quantitative risk assessment as the analytical methodology to justify implementation of its standard of unreasonable risk.\(^{164}\) The EPA adopted this methodology for unreasonable risk decision-making in the 1980s in reaction to judicial treatment of agency regulation of toxic substances.\(^{165}\) Courts moved from judicial

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160. See Baram, supra note 28, at 45 (noting that this "discretion, which is exercised on a case-by-case basis by different judges in different states, inevitably leads to variability in the treatment of expert testimony and opinions"). A discussion of the admissibility of expert testimony is beyond the scope of this Note.

161. Id. at 47. Judge Jack Weinstein has written that an expert can be found to testify to the truth of almost any factual theory. An expert's testimony can be used to obfuscate what would otherwise be a simple case, as judges "can be, and sometimes are, misled by the expert-for-hire." Id.

162. Id. at 48.

163. Id. at 49.

164. See Applegate, supra note 10, at 277 (noting that "quantitative risk assessments" have been developed by the EPA to "determine whether the risk posed by a substance is unreasonable"). Additionally, this methodology reflects "risk management" by considering policy issues like the acceptable level of risk and "non-health factors like economic and technological feasibility." Id. at 279.

165. Id. at 282-83 (describing the "hard look" doctrine as a characterization of judicial review which "emphasized rigorous examination of agency rationales"); see also Bernard D. Goldstein, Risk Assessment and the Interface Between Science and Law, 14 COLUM. J.
deference to a requirement of objectivity in agency judgments and quantification of the regulatory risk assessment process.\textsuperscript{166}

During the 1980s, the inherent potential for abuse in judicial reliance on subjective expert testimony for essential risk data was publicly recognized as a matter of concern.\textsuperscript{167} The objective and quantifiable risk assessments of the EPA have not been recognized as an evidentiary solution to this continuing judicial need for impartial studies of risk. Thus, the inherently problematic judicial reliance on subjective experts in toxic tort cases still exists. A possible solution is to recognize EPA findings of risk and regulatory actions as irrebuttable or rebuttable presumptions on the issue of a substance’s and an activity’s risk.

V. CONCLUSION

Human and environmental exposure to toxic substances is a widespread concern for all members of society. As improvements in scientific methodology increase the certainty of identifiable risks from specific substances, society’s ability to control these risks should also increase. However, this correlation between knowledge and toxic risk control depends upon the flow of toxicity information among the scientific, legal and regulatory communities.

TSCA focuses EPA efforts on toxic harm prevention through data generation and on toxic regulation through risk management. These statutory goals are implemented through regulatory actions triggered by findings of unreasonable risk. In the context of toxic tort litigation, judicial attention is focused on determining the point at which an activity becomes abnormally dangerous by posing an unreasonable health risk. This goal is implemented through judicial evaluation of the activity’s risk components.

The EPA’s analytical methodology of quantitative risk assessment provides objective data which frames the cost-risk-benefit analyses required by TSCA. The data-intensive risk analysis performed by a court in determining if an activity is abnormally dangerous is typical--

\textsuperscript{166} \textit{ENVTL. LAW} 343 (1989) (noting that another explanation for the EPA’s adoption of quantitative risk assessment was a political need to develop a methodology for providing scientific and technical information which was “free from the inference of bias”).

166. \textit{See} \textit{Applegate, supra} note 10, at 283. Hard look review involves “aggressive analysis of agency evidence in toxic substances cases.” \textit{Id}.

167. \textit{See supra} notes 161, 162 and accompanying text (discussing Judge Jack Weinstein’s recognition of the problems inherent in reliance on expert testimony furnished by litigants and his recommended suggestions).
ly based upon subjective expert testimony. Although independently generated EPA data constitutes a relevant, reliable and persuasive evidentiary source, toxic tort plaintiffs tend to overlook the evidentiary potential of these findings and regulatory actions.

Hopefully, the preceding discussion of TSCA’s “unreasonable risk” standard and its implementation in the context of EPA testing rules and permanent regulatory controls demystified the regulatory process. A clearer understanding of the demonstrable similarities between the regulatory and judicial “risk limit” analyses, should make the applicability of EPA findings to a toxic tort strict liability action more apparent.

Judicial creation of a rebuttable presumption for EPA regulatory actions and findings of risk under TSCA’s Section 4 is justified by the following factors: 1) implementation of the unreasonable risk standard requires the same balancing analysis required for all findings, even though the economic component of a Section 4 analysis is limited to consideration of the cost of testing and delay in commercial availability of the substance; 2) the risk standard is satisfied by a finding of insufficient data and a less than factual certainty of risk, however the probability of risk must be sufficiently demonstrable to outweigh the cost of testing.

Judicial creation of an irrebuttable presumption for regulatory actions under Section 6 is supported by the following factors: 1) findings of unreasonable risk reflect consideration of extensive economic data which far exceeds the scope of a judicial risk analysis; 2) EPA findings on each evaluated component of the standard must be published and substantially documented in the rule-making record; 3) the finding of unreasonable risk requires a higher level of certainty of risk than that required for Section 4 findings, since the EPA must find that the substance presents or will present an unreasonable risk of injury.

By failing to give evidentiary weight to these regulatory actions, courts have produced an unpredictable and inconsistent framework for toxic tort injury compensation. If efforts to deter toxic risk creation remain segregated within individual institutional contexts, their effectiveness will be minimized. TSCA adds a powerful data-intensive weapon to the federal statutory arsenal against toxic risk. Judicial recognition of EPA regulatory actions and findings of unreasonable risk as either rebuttable or irrebuttable presumptions of a substance’s
and an activity's abnormal dangerousness therefore represent an important and necessary step in the battle against toxic risk creation.

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