

“ADVERSE EFFECTS” AND SIMILAR TERMS IN U.S. LAW

A Report Prepared by the  
Duke Center for Environmental Solutions  
for the  
Dose Response Specialty Group  
of the  
Society for Risk Analysis (SRA)

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## 1. OVERVIEW

The Dose Response Specialty Group of the Society for Risk Analysis (SRA) requested research to characterize and compare the uses of the term “adverse effect” and similar terms in the laws of the United States. A grant from the SRA supported research by two Duke University students to survey the uses of these terms. This report summarizes that research.

We surveyed the uses of 19 specific search terms, grouped into 5 general types, across all U.S. federal statutes, federal agency regulations, and federal judicial opinions issued since 1970. We did not survey the uses of these terms in the laws or regulations of the 50 states and the state courts, nor in international legal texts.

The 19 specific terms used in our searches are listed in Table 1, grouped into 5 basic types: “adverse effect,” “adversely affect,” “risk,” “endanger,” and “threat.” These terms are ubiquitous: they appear in almost every title of the United States Code.<sup>1</sup> As indicated in Table 2, the majority of the U.S. Code Titles use at least one of the specific search terms. Some Titles of the U.S. Code use the terms significantly more than others. Cumulating across all the 19 search terms, they are used most often in Titles 7, 10, 15, 16, and 42, which (as shown in Table 3) are the Titles covering Agriculture, Armed Forces, Commerce and Trade, Conservation, and Public Health and Welfare,

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<sup>1</sup> Statutes enacted by the United States Congress (“Acts of Congress”) are then organized into the United States Code (abbreviated “U.S.C.”), which groups federal statutes into “titles” by subject matter. For example, Title 5 governs Government Organization and Employees, and includes the Administrative Procedure Act; Title 33 governs Navigable Waters, and includes the Clean Water Act; and Title 42 governs Public Health and Welfare, and includes numerous environmental laws such as the Clean Air Act and the Comprehensive Environmental Responsibility, Compensation and Liability Act (CERCLA). See Table 3. Usually a new statute is codified entirely within one Title, but it is possible for different provisions of a statute to be codified in different Titles. Statutory provisions are cited by title number and section number; for example, the Clean Air Act begins with section 101, codified at 42 U.S.C. 7401.

respectively. The most frequent uses of the specific term “adverse effect” appear in Title 42, which contains many of the nation’s environmental laws.

Different federal statutes employ many different variations on the search terms we surveyed. As indicated in Table 1, the term “adverse effect” appears over 300 times in federal laws, and the term “risk” nearly 2,000 times. The text of this report focuses its discussion on the uses of the terms in statutes that address health, safety and environmental risks, because those are the statutes of greatest interest to the SRA. Many of the uses of these terms in federal laws relate to other topics, such as financial risks and national security risks.

Our major finding is that the federal statutes themselves give little or no definition or guidance regarding the precise meanings or intended interpretations of “adverse effect” and related terms. Though some statutes purport to define these terms, the definitions are often circular and of little value because they include the term being defined as part of its definition. The statutes generally do not speak to the scientific methods to be used to calculate adverse effects. Agency regulations and judicial interpretations add some clarity, but still leave basic questions of meaning and methodology unaddressed. (One area of further research might be to investigate the legislative history of the terms, though not all courts look to legislative history to interpret statutes.)

The lack of precise definitions of “adverse effect” and similar terms leaves their interpretation and application largely in the hands of agency staff (in particular, agency scientists). This may be appropriate, because agency staff are more expert than members of Congress or their staff, or judges, in assessing adverse effects. But the lack of definitions or guidance on what constitutes an “adverse effect” may result in

determinations lacking transparency and in inconsistencies across agencies and statutes. At the same time, this situation may offer an opportunity for expert groups such as the SRA to contribute helpful insights and guidance to improve “adverse effect” determinations by legislative, administrative and judicial actors.

Our report offers both descriptive statistics and textual examples of the uses of these terms by federal legislative, administrative, and judicial bodies. Part 2 of the report examines Congressional statutes, Part 3 addresses agency regulations, and Part 4 studies judicial decisions. Part 5 compares the frequencies of legislative (statutory) and judicial uses of different terms. In Part 6, we discuss the implications of these findings for risk assessment science. Part 7 suggests further avenues of research.

## **2. LEGISLATIVE USES OF THE TERMS**

The U.S. Congress has used “adverse effect” and related in a wide variety of statutes. As might be expected, terms relating to “health” appear most often (though not exclusively) in public health and welfare statutes, while terms relating to the “environment” appear most often in pollution control and land management statutes. As shown in Table 3, search terms such as “adverse environmental effect,” “adversely affect /2 environment!,” “risk /2 environment!,” “threat! /2 environment!,” and “threat! /2 species” occur most commonly in titles of the Code that deal with land management and pollution control. The titles dealing with agriculture (Title 7), conservation (Title 16), navigable water (Title 33), and public welfare (Title 42) are all examples of such parts of the Code.

Similarly, search terms that include the word “health” occur mostly in those statutes dealing with the public welfare or the welfare of specific groups of people. Such statutes include those concerning the armed forces (Title 10), commerce and trade (Title 15), criminal procedure (Title 18), education (Title 20), foreign relations (Title 22), labor (Title 29), and public welfare (Title 42), as shown in Table 3.

More general search terms such as “adverse effect,” “adverse /2 effect,” “adversely affect,” and “endanger” show up in a multitude of statutes addressing everything from the public welfare to copyright, from national security to intoxicating liquors. The most general search terms containing only one key word, such as “risk” and “threat!”, occurred in thousands of statutes throughout the United States Code.

Though the term “adverse effect” and similar terms are used very often in the statutes, they are rarely defined within the actual language of the Code. Where the term is defined in the statute, the definition is often circular, using the term to define itself. For example, the definition in the Hazardous Air Pollutants provision of the Clean Air Act, section 112, codified at 42 U.S.C. § 7412(a)(7), provides that “[t]he term ‘adverse environmental effect’ means any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.” This attempt to define the term “adverse environmental effect” is largely circular. It defines the term “adverse environmental effect” using the terms “significant and widespread adverse effect” and “adverse impacts.” The term “significant degradation” is not defined. Thus the language

of the definition does little to explain what truly constitutes an adverse effect, environmental or otherwise, or how the word “adverse” modifies “effect.”

Meanwhile, section 108(a)(1)(A) of the Clean Air Act calls on EPA to list substances “which may reasonably be anticipated to endanger public health or welfare,” and section 108(a)(2) asks EPA to issue “criteria” for listed substances, reflecting “the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air,” including any “adverse effect” on health or welfare. 42 U.S.C. 7408. But nowhere does section 108 or the Clean Air Act define the meanings of “endanger,” “identifiable effects,” or “adverse effect.”

Likewise, § 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4322(2)(C), provides that major federal actions “significantly affecting the quality of the human environment” must be accompanied by an environmental impact statement (EIS) that evaluates the environmental impact, and any unavoidable adverse environmental effects, of the action. However, NEPA does not go further to define these terms.

Often the terms of interest are qualified by additional adjectives. The word “unreasonable” is often used, such as in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136d, which says, “...continued use of the pesticide would pose an unreasonable adverse effect on the environment.” Another commonly used modifier is the word “potential.” The language of 12 U.S.C. § 635i-5 discusses the use of goods that “mitigate potential adverse environmental effects....” Statutes also use the word “significantly” quite often to modify and further explain the term “adverse

environmental effect.” However, like the terms themselves, these qualifiers are rarely defined in the language of the statutes.

### **3. AGENCY INTERPRETATIONS OF THE TERMS**

As shown in Table 4, federal agencies use the terms frequently: “adverse effect” and “adversely affect” each appears in the Code of Federal Regulations (CFR) more than 1,000 times, while “risk” appears more than 5,000 times and “threat!” more than 2,000 times.

Agencies using the selected terms do so with varying degrees of specificity. While the agencies offer more definitions than the statutes themselves, many of these agency definitions suffer from the same problems as statutory definitions. For example, the Council on Environmental Quality, in its regulations interpreting the phrase “significantly affecting the quality of the human environment” in NEPA 102(2)(C), defines “affecting” as “will or may have an effect on.” 40 C.F.R. § 1508.3. At other times, agency regulations have offered much more detailed definitions of certain terms. In 40 C.F.R. § 1508.27, CEQ undertakes twelve paragraphs to describe what factors constitute “significance” when determining if an agency action has “significant impact” on the environment. The CEQ regulations are also concerned with impact over time, noting that, “Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts,” *id.*, and that “Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.” 40 C.F.R. § 1508.7. However, there is no mention of

specific time horizons or discount rates in the CEQ regulations. And while the CEQ regulations are very concerned with significance, their occasional mentions of “adverse effects” are not discussed as thoroughly, although the regulations do note that “Effects and impacts as used in these regulations are synonymous,” as part of a two paragraph discussion of “effects” in 40 C.F.R. § 1508.8. That section also notes that any significant environmental impact must be reported in the EIS, even if the benefits of the proposed action outweigh its (environmental) costs.

By contrast, the EPA regulations that govern pesticide registration under FIFRA explicitly define “unreasonable adverse effects” as being determined by a “risk/benefit balance.” 40 C.F.R. § 159. Section 6(a)(2) of FIFRA requires the submission of information regarding pesticide effects on the environment. Because of the qualifier “unreasonable,” which has long been understood in American law to invoke a balance of benefits and harms, EPA’s FIFRA regulations appear less concerned with significance per se and to focus on the net effect. For example, when determining if a pesticide has “unreasonable adverse effects,” EPA considers “information concerning the benefits of pesticide use.” 40 C.F.R. § 159.188. Thus, potential pesticide registrants are required to submit reports of incidents in which the pesticide in question failed to perform as claimed, in addition to incidents in which negative effects were noted. *Id.* And EPA considers even a casual observation of an adverse effect reportable:

For example, where someone develops tremors shortly after using a pesticide, common sense would suggest a link between pesticide exposure and the effect. Such an event would be reportable, even if it were not brought to the attention of a trained professional. 40 C.F.R. § 159.158.

Most of the adverse effects that FIFRA is concerned with are based on both human factors and environmental factors. Generally, the two are mentioned simultaneously in

the text of the regulations. For example, when defining the “water reference level” of a pesticide in order to maintain consistency with the Clean Water Act, FIFRA sets the limit at either an amount based on what is harmful to humans, or the level that is harmful to aquatic life, whichever is *lower*. 40 C.F.R. 159.153 (emphasis added).

#### **4. JUDICIAL INTERPRETATIONS OF THE TERMS**

As noted above, the selected phrases are ubiquitous yet often ambiguous. Federal judicial opinions employing the phrases are similar in this regard. As shown in Table 5, the terms arise in judicial texts quite frequently, indeed hundreds or thousands of times since 1970. Federal court opinions dealing with “adverse effects” and similar phrases span a vast range of topics, including but not limited to environmental law, criminal law, drug safety regulations, national security law, privacy law, family law, antitrust and other economic regulation, as well as disability and antidiscrimination law.

Generally speaking, federal judicial use of the terms falls into four broad categories. First, courts have interpreted “adverse effect” and variations thereof when considering plaintiffs’ “standing to sue.” Second, the courts have interpreted “adverse effect” and similar terms when an agency is challenged in court regarding the agency’s action (or inaction) under a statutory instruction to list or regulate substances or activities that may affect public health, welfare, or the environment. Third, the courts frequently grapple with what constitutes “adverse effects” when reviewing EIS filings under NEPA. Fourth, the terms are often quoted by courts in passing, without interpretive discussion, simply because the terms were used in the factual findings of regulatory agencies supporting a rulemaking that is being litigated for other reasons.

#### 4.1 Standing to sue

Establishing an “adverse effect” is an important element of standing to sue in federal court. When citizens sue to challenge federal agency actions (usually under the Administrative Procedure Act, 5 U.S.C. § 702 et seq.), or sue private polluters for failure to comply with federal pollution control laws that authorize “citizen suits” (such as the Clean Water Act, 33 U.S.C. §§ 1365(a), (g)), then the plaintiffs must establish that they have “standing to sue” before the federal courts will hear their claims. This requirement stems in part from Article III of the Constitution, which limits the jurisdiction of the federal courts to “cases or controversies,” and which the U.S. Supreme Court has interpreted to require that plaintiffs show that they have suffered some “injury in fact.” Sierra Club v. Morton, 405 U.S. 727 (1972). And it arises from the Administrative Procedure Act, which provides that a person may bring suit if he or she is “adversely affected or aggrieved by agency action within the meaning of a relevant statute.” 5 U.S.C. § 702.

In general, the courts have not required any particular kind of scientific evidence to establish such injury in fact or adverse effect. Judicial discussions of these tests are typically narrative and qualitative, and turn on judges’ impressions of the concreteness, severity, and immediacy of the alleged injury or effect. In a series of cases through the 1970s and 1980s, the Supreme Court eased its criteria for standing, enabling suits to enforce federal laws to be brought by plaintiffs with increasingly attenuated or uncertain causal chains flowing from the agency or private action to the alleged harm. This trend was interrupted by prominent Supreme Court decisions in the 1990s rejecting

what the Court saw as inadequate claims of injury in fact or adverse effect. For example, in Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992), the Court rejected as insufficiently concrete and immediate a plaintiff's allegation that she planned to travel to observe an endangered species and that she would be injured if the species were harmed by agency action. But the Court appeared to return to its eased standing criteria in Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc., 528 U.S. 167 (2000). There the plaintiffs claimed to be adversely affected under the Clean Water Act, which gives standing to "a person or persons having an interest which is or may be adversely affected." 33 U.S.C. §§ 1365(a), (g). In that case, the alleged adverse effect consisted of affidavits asserting the plaintiffs' diminished desire to swim, canoe, camp, and fish in areas where they were concerned about defendant's mercury discharges. *Laidlaw* at 181. Although the defendant's mercury discharges were in excess of their allowed permit levels, the Court noted that "there had been no demonstrated proof of harm to the environment," but nonetheless the Court held that the relevant showing of an adverse effect was "not injury to the environment, but injury to the plaintiff." *Id.* at 182 (internal quotes omitted). In general, the Court concluded, even without proof of actual environmental damage, "environmental plaintiffs adequately allege injury in fact when they aver that they use the affected area and are persons for whom the aesthetic and recreational values of the area will be lessened by the challenged activity." *Id.* at 183 (internal quotes omitted). The *Laidlaw* court distinguished the facts in *Lujan* without overruling it (*Laidlaw* at 180), even though plaintiffs alleged similar "adverse effects" in the two cases, perhaps because the plaintiffs in *Laidlaw* were actually physically present at the site whereas the plaintiffs in *Lujan* expressed only a future intention to visit

the site. That basis for reconciling the cases suggests that the Court may view an adverse effect as too remote to constitute an injury in fact if the plaintiff's loss is prospective; but such a distinction has been criticized on the ground that many health and environmental statutes are intended to prevent prospective harm.

#### **4.2 Judicial review of agency action**

The second category of cases involves judicial review of an agency decisions under a statute instructing the agency to list a substance or activity that may have “adverse effects” on, may “adversely affect,” or may “endanger,” the public health, welfare, or the environment. Under such statutes, the term “adverse effect” or similar is rarely if ever defined in precise scientific terms, leaving the agency considerable discretion to interpret the term and to apply its own understanding to its risk assessment methods. This discretion typically receives deference from the courts, both because the generalist judiciary usually defers to the expertise of agency technical staff on questions of science, see Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103 (1983) (when an agency “is making predictions, within its area of special expertise, at the frontiers of science ... a reviewing court must generally be at its most deferential”), and also because the judiciary usually defers to an agency’s reasonable interpretation of an ambiguous statutory term which the agency is charged with administering, under Chevron, USA, Inc. v. NRDC, Inc., 467 U.S. 837 (1984).

For example, in 1976 the U.S. Court of Appeals deferred to EPA’s application of “endanger” in section 108 of the Clean Air Act: the court held that the agency had no discretion not to list a substance under section 108 once the agency had made a

determination that the substance would “endanger” public health, but that the agency had essentially unfettered discretion in the scientific matter of *how* it came to the determination that the substance would or would not endanger public health. NRDC v. Train, 545 F.2d 320 (D.C. Cir. 1976). More recently, the Supreme Court deferred to the Secretary of Interior’s interpretation of the term “harm” in the Endangered Species Act (where “harm” is used in the statute as one of several words defining the statutory term “take”). The Secretary had defined “harm” to a species to include “habitat modification that resulted in actual injury or death.” The Court held that this interpretation was reasonable, even though other terms in the statute had defined “take” to mean actual killing or capture of an individual animal. Babbitt v. Sweet Home Chapter of Communities for a Great Oregon, 515 U.S. 687, 708 (1995). The Court placed emphasis on “the degree of regulatory expertise necessary” to make policy decisions under the Endangered Species Act. *Id.* at 703.

But the courts do not always defer to agency interpretations about adverse effects. For example, the courts have held that “adverse modification of critical habitat” could occur when sufficient critical habitat is lost so as to threaten a species’ “recovery” instead of only when it threatens the species’ “survival,” rejecting a contrary agency view. Gifford Pinchot Task Force v. United States Fish & Wildlife Serv., 378 F.3d 1059, 1069-1071 (9th Cir. 2004). And the D.C. Circuit rejected EPA’s argument that, when regulating under Clean Air Act sections 108 and 109, the agency could consider only the harmful effects of a pollutant and could ignore the potential beneficial effects of the pollutant (in this case, tropospheric ozone, which is harmful when inhaled but potentially beneficial if it screens out some incoming ultraviolet radiation). The court held that CAA

section 108 requires EPA to consider “all identifiable effects” of the pollutant, encompassing both adverse and benign effects. American Trucking Ass’ns v. EPA, 175 F.3d 1027 (D.C. Cir. 1999), rehearing granted in part and denied in part, 195 F.3d 4 (D.C. Cir. 1999), affirmed in part and reversed in part sub nom. Whitman v. American Trucking Ass’ns, 531 U.S. 457 (2001).<sup>2</sup>

### 4.3 Judicial review under NEPA

Related to these interpretations of statutory terms during judicial review of agency actions is a distinct set of court cases on environmental impact assessment under NEPA. § 102(2)(c) of the National Environmental Policy Act of 1969 (NEPA) provides that where a federal action has a significant impact on the human environment, an environmental impact statement (EIS) must be provided that evaluates the environmental impact and any unavoidable adverse environmental effects of the action. Yet NEPA does not go further to define these terms. In Metropolitan Edison Co. v. People Against Nuclear Energy (PANE), 103 S.Ct. 1556 (1983), the question was raised whether public fear of nuclear power and associated mental health impacts were the kind of “adverse environmental effect” covered by NEPA. The Court wrote that this provision “does not require the agency to assess *every* impact or effect of its proposed action, but only the impact or effect on the environment.” The opinion went on to say:

The statute's context shows that Congress was talking about the physical environment. Although NEPA states its goals in sweeping terms of human health and welfare, these goals are *ends* that Congress has chosen to pursue by *means* of protecting the physical environment. NEPA does not require agencies to evaluate

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<sup>2</sup> This part of the D.C. Circuit’s opinion, regarding EPA’s obligation to assess the beneficial as well as adverse effects of the pollutant, was not appealed by EPA and thus remains in force. On remand, EPA assessed the benefits of ozone in screening out UV, and found them to be too small to affect the ambient air quality standard being set.

the effects of risk, *qua* risk. The terms "environmental effects" and "environmental impact" in § 102(C) should be read to include a requirement of a reasonably close causal relationship between a change in the physical environment and the effect at issue. *PANE*, 103 S.Ct. at 1557-58.

The Court therefore ruled that the psychological effects of a nuclear power plant were not covered by NEPA § 102(2)(c), because an "adverse environmental effect" is limited to effects on the physical environment, not encompassing all adverse effects. *PANE*, 103 S.Ct. at 1563. This of course leaves the terms "significant impact" and "adverse effect" yet to be defined. While 40 C.F.R. 1508.27 attempts to define "significantly" under NEPA, the explanations also employ terms like "significance" and "adverse effects." The Seventh Circuit has lamented that "[t]he statutory concept of 'significant' impact has no determinate meaning." *River Rd. Alliance, Inc. v. Corps of Engineers of United States Army*, 764 F.2d 445, 449 (7th Cir., 1985), cert. denied 475 U.S. 1055 (1986). Still, one federal district court has ruled "that it was arbitrary and capricious [of the U.S. Fish and Wildlife Service] to hold that the loss of 20% of optimal habitat in the action area, on top of previous losses of 20.6% of optimal habitat in the action area since the species was listed, would have no significant impact on the species." *Sierra Club v. Norton*, 207 F. Supp. 2d 1310, 1336 (D. Ala. 2002).

#### **4.4 Passing references**

Some judicial uses of "adverse effect" or similar terms appear to be passing references that are not interpretations of phrases at issue in litigation. For example, in explaining the history of a case, sometimes the courts quote agency documents using these terms even though there is no dispute that turns on these terms. Meanwhile, sometimes the terms have been employed by the courts even when Congress did not write

the terms into statutes. For example, Table 1 shows no results for a search using “endanger” near any variation of “environment,” yet Table 5 indicates that 18 judicial opinions have used this term.

## **5. COMPARING TERMS, AND COMPARING LEGISLATIVE WITH JUDICIAL USES**

Overall, the 19 specific terms were used 4,278 times the current federal statutes, and 314,319 times in federal court cases since 1970. (These numbers count multiple hits within the same document as distinct hits. For example, a case that used the phrase “adverse environmental effect” in addition to the phrase “unreasonable risk” would be counted twice.)

The term “health” was used more often than the term “environment,” both in statutes and in judicial opinions, as is evident from Tables 1 and 5. There are 16.4 uses of “health” in federal statutes for each use of “environment” in such statutes, suggesting a greater legislative focus on “health” than on the “environment.” Although the courts also used “health” more often than “environment,” the judicial emphasis on “health” is less pronounced than the legislative emphasis: there are only 2.5 uses of “health” in federal court cases for each use of “environment” in such cases. (And in either setting, the term “health” could relate to ecological health as well as to human health.) It may be that “health” is legislated more often but that “environment” is litigated more often; or it may be that the current stock of statutory uses does not reflect the historical uses that gave rise to the accumulation of judicial uses since 1970.

There is some corroboration for the inference that “environment” terms are raised in litigation more often than are “health” terms. Each statutory hit using the term “health” corresponds to, on average, 22 court cases using the term “health.” In contrast, each statutory occurrence of the term “environment” corresponds to, on average, 39 judicial occurrences. It appears that “environmental” effects, although addressed less often by Congress than “health” effects, garner more judicial attention than “health” effects, relative to the legislative effort expended.

One small anomaly caught our attention: the frequently litigated 6 uses of unidentified permutations of “adverse /2 effect.” The broad term “adverse /2 effect” was used 389 times in statutes and 16,136 times in federal court cases (for 41.48 judicial uses per statutory use). The included phrase “adverse effect” accounts for almost all of those hits: 340 of the 389 statutory uses and 14,168 of the 16,136 judicial uses (for 41.67 judicial uses per statutory use). In addition, the included phrases “adverse environmental effect” and “adverse health effect” occur 20 and 23 times in the statutes, respectively, as well as 849 and 484 times in court cases (yielding 42.45 and 21.04 judicial uses per statutory use, respectively). Thus, the three included terms “adverse effect,” “adverse environmental effect,” and “adverse health effect” together account for 383 of the statutory uses and 15,501 of the judicial uses (for 40.47 judicial uses per statutory use). This implies that the remaining 6 statutory uses of some other terms matching “adverse /2 effect” (out of the 389 total) account for the remaining 635 uses by courts of those other terms comprised by “adverse /2 effect,” or far more judicial attention to those 6 statutory phrases than to either “environmental” or “health” (105.83 judicial uses per statutory use).

## **6. IMPLICATIONS FOR RISK ASSESSMENT SCIENCE**

The main finding of our survey is that although the term “adverse effect” and similar terms are used widely in U.S. federal law, they are rarely defined or constrained by statutory text or judicial interpretation. The statutes typically do not attempt to dictate any specific scientific methodology for determining whether an effect is adverse. Nor do they grapple with possible differences in scale: for example, whereas society tends to treat any individual human injury as an adverse effect, the loss of every individual non-human organism is not usually deemed an adverse effect, on the ground that many changes in nature are both adverse and benign, or of ambivalent normative import, because they injure some members of an ecological system while benefiting others. The statutes did not speak to such questions, though they seem fundamental to an understanding of “adverse effect.” Nor did the statutes address the more tractable but still elusive question how serious an effect must be to count as adverse or significant. That question probably admits of no simple numerical expression, but could be guided by phrasing about the relative importance of an impact to the factors involved in making a decision. The judiciary typically defers to agency science, and to agency interpretations of ambiguous statutory terminology, though as noted above the courts have occasionally rejected agency attempts to ignore beneficial effects of pollutants (where the statute required analysis of “all identifiable effects”), and to find that large effects were not “significant.”

Thus, the interpretation and calculation of terms like “adverse effect” is largely in the hands of agency staff. The choices made by each agency may or may not be

consistent across agencies or statutes. The choices may not be transparent. The particular scientific methods used to assess “adverse effects” – such as hazard identification, dose-response assessment (including linear, threshold, or hormetic low-dose extrapolations), and exposure assessments – appear to be largely within the discretion of agency scientific staff and their supervisors.

Only one statute we surveyed appeared to dictate an exposure assumption: the Occupational Safety and Health Act (OSHAct), which in section 6(b)(5) requires OSHA to ensure “to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity *even if such employee has regular exposure to the hazard ... for the period of his working life.*” 29 U.S.C. 655(b)(5) (italics added). This provision does not address a term like “adverse effect,” but we mention it because it is an unusual example of a statute specifying a methodology for risk assessment.<sup>3</sup>

One possible avenue for increased judicial scrutiny of terms like “adverse effect” is the inclusion of statutory phrases requiring agencies to look to the “best available science” in determining adverse effects. Clean Air Act section 108(a)(2) and Clean Water Act section 304(a)(1) require the use of the “latest scientific knowledge” in setting air and water quality standards, respectively. Section 4(b)(1)(A) of the Endangered Species Act requires the use of the “best scientific ... data” in listing species. Section 1412(b)(3)(A) of the Safe Drinking Water Act requires EPA to use the “best available,

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<sup>3</sup> And note that unrealistic exposure assumptions may be rejected by the courts. See, e.g., Leather Industries v. EPA 40 F.3d 392 (D.C. Cir. 1994) (in a challenge to EPA’s regulations under CWA 405 of sewage sludge disposal, the court remanded EPA’s selenium content standard because it viewed the exposure assumption in the risk assessment – that children would eat sludge on highway median strips year-round -- as not credible).

peer-reviewed science” in setting Maximum Contaminant Level Goals (MCLGs), which must be set at the level of “no known or anticipated adverse effects.” In a recent decision, the U.S. Court of Appeals for the D.C. Circuit held that the phrase “best available science” in the SDWA requires EPA at least to use its *own* scientists’ best science in setting MCLGs; the court vacated the MCLG set for chloroform (a byproduct of chlorination to disinfect drinking water) because it was based on a scientific assumption - - a linear no-threshold low dose extrapolation - - that the agency scientific arm itself had almost simultaneously disavowed by publishing a threshold which it found to be the “no observed adverse effect level” for chloroform. Chlorine Chemistry Council v. EPA, 206 F.3d 1286 (D.C. Cir. 2000). The court did not specifically interpret the phrase “adverse effect,” but it did hold that the agency cannot use old science to determine adverse effects – that is, to draw the dose-response function at low doses -- when newer, better science is available.

This decision can be seen as deferential to agency science, because the court held only that EPA could not issue an MCLG based on science that EPA itself had just disavowed; the court did not say that EPA must adhere to scientific research performed outside the agency. Thus, *Chlorine Chemistry Council* speaks again for the discretion and authority of agency scientists to determine the scientific methods for evaluating “adverse effects.” Supporting that view, in another case addressing similar language, the D.C. Circuit held that EPA’s expert judgment to rely on epidemiological data to find that particulate matter “contributes” to “endangering” public health -- despite absence of proof of a causal mechanism -- was sufficient to satisfy the requirement of the “latest

scientific knowledge” in Clean Air Act sections 108(a)(2) and 109(d)). American Trucking Ass’ns v. EPA, 175 F.3d 1027, 1055-56 (D.C. Cir. 1999).

The absence of clear definitions of “adverse effect” and related terms, and the typical deference shown by the judiciary to agency expertise, may mean that the identification of adverse effects is subject to non-transparent considerations and inconsistencies across agencies and staff. On the other hand, they may appropriately leave the interpretation and identification of adverse effects in the hands of the most expert institution in the government: agency staff (especially agency scientists) are surely far more expert on these questions than members of Congress or their staff, and than generalist judges. At the same time, the lack of precise definitions of “adverse effect” and similar terms may offer an opportunity for expert groups such as the SRA (which include members from academia, industry, and the agencies themselves) to contribute helpful insights and guidance to help agency staff and legislative and judicial actors bring greater coherence to these matters.

## **7. OTHER POSSIBLE SEARCHES**

Although this study identified the use of 19 terms similar to “adverse effect,” there are still other terms that could be researched. There are many synonyms for the words already researched that might be used in the Code. Though we have discussed the use of the words “effect,” “risk,” “threat,” and “endanger,” other possibilities that we have not yet surveyed include “hazard,” “harm,” “exposure,” “chance,” “impact,” “injury,” and “consequence.” There are also other terms that can be used to describe an impact on the environment, such as “ecosystem,” “species,” “ecology,” “ecological,”

“air,” “atmosphere,” “water,” “soil,” and “earth.” Most of the uses of a general term like “risk” appear to be about topics other than human health and the environment, because (as shown in Table 1) 1,933 statutes use the term “risk,” but more specific searches using the term “risk” in combination with “health,” “environment” and “unreasonable” yielded a total of only 169 statutes, meaning that there are at least 1,764 statutes using “risk” in other contexts.

Statutes may employ these different terms to imply carefully chosen different meanings, but it may also be the case that the terms were used without a carefully crafted linguistic intent. Finding the meaning behind each term might be informed by researching the intentions of the enacting legislatures, in addition to the specific language adopted in the statute. But some or many terms may have been chosen without any legislative history to bear on intent; and some jurists argue that a statute’s meaning should be drawn from its text without resort to legislative history.

## Tables

Table 1. – Occurrence of search terms in United States statutes (Westlaw, July 2004)

<b>Phrase (Search Term)</b>	<b>Library (Database)</b>	<b>Hits (Documents)</b>
1. adverse /2 effect	USC	389
1a. “adverse effect”	USC	340
1b. “adverse environmental effect”	USC	20
1c. “adverse health effect”	USC	23
2. “adversely affect”	USC	360
2a. “adversely affect” /2 environment!	USC	3
2b. “adversely affect” /2 health	USC	24
3. risk	USC	1933
3a. risk /2 environment!	USC	13
3b. risk /2 health	USC	87
3c. “unreasonable risk”	USC	69
4. endanger	USC	177
4a. endanger /2 environment!	USC	0
4b. endanger /2 health	USC	34
5. threat!	USC	1419
5a. threat! /2 environment!	USC	12
5b. threat! /2 health	USC	45
5c. threat! /2 ecosystem	USC	1
5d. threat! /2 species	USC	52

Table 2. – Title numbers of statutes using a given search term

<b>Phrase (Search Term)</b>	<b>Title Numbers of USC</b>	<b>Number of Titles</b>
“adverse effect”	5, 7, 8, 10, 11, 12, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 26, 27, 28, 29, 30, 31, 33, 38, 41, 42, 43, 45, 46, 47, 48, 49, 50	33
adverse /2 effect	5, 7, 8, 10, 11, 12, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 26, 27, 28, 29, 30, 31, 33, 38, 41, 42, 43, 45, 46, 47, 48, 49, 50	33
“adverse environmental effect”	7, 12, 16, 22, 30, 33, 42, 49	8
“adverse health effect”	10, 15, 21, 22, 38, 42	6
“adversely affect”	5, 7, 8, 10, 11, 12, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 26, 28, 29, 30, 31, 32, 33, 35, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 49, 50	37
“adversely affect” /2 environment!	33, 42	2
“adversely affect” /2 health	10, 15, 19, 29, 30, 33, 42	7
risk		
risk /2 environment!	7, 33, 42, 43	4
risk /2 health	5, 7, 10, 15, 16, 18, 20, 21, 22, 26, 29, 33, 38, 42, 46, 50	16
“unreasonable risk”	7, 8, 15, 16, 20, 21, 29, 33, 42, 49	10
endanger	5, 7, 8, 10, 12, 14, 15, 16, 17, 18, 19, 21, 22, 25, 28, 29, 30, 31, 33, 42, 43, 45, 46, 47, 49, 50	26

endanger /2 environment!		
endanger /2 health	5, 7, 15, 18, 29, 30, 33, 42, 50	9
threat!		
threat! /2 environment!	5, 16, 22, 25, 42	5
threat! /2 health	5, 6, 10, 18, 20, 21, 22, 25, 26, 29, 31, 33, 42	13
threat! /2 ecosystem	16	1
threat! /2 species	7, 10, 16, 22, 33, 42, 49	7

Table 3. – Phrases used in specific titles of the U.S. Code

USC Title	Phrases (Search Terms) Used
GOVERNMENT ORGANIZATION AND EMPLOYEES (5)	“adverse effect”, adverse /2 effect, “adversely affect”, risk /2 health, endanger, endanger /2 health, threat! /2 health
AGRICULTURE (7)	“adverse effect”, adverse /2 effect, “adverse environmental effect”, “adversely affect”, risk /2 environment!, risk /2 health, “unreasonable risk”, endanger, endanger /2 health, threat! /2 species
ALIENS AND NATIONALITY (8)	“adverse effect”, adverse /2 effect, “adversely affect”, “unreasonable risk”, endanger
ARMED FORCES (10)	“adverse effect”, adverse /2 effect, “adverse health effect”, “adversely affect”, “adversely affect” /2 health, risk /2 health, endanger, threat! /2 health, threat! /2 species
BANKRUPTCY (11)	“adverse effect”, adverse /2 effect, “adversely affect”
BANKS AND BANKING (12)	“adverse effect”, adverse /2 effect, “adverse environmental effect”, “adversely affect”
COAST GUARD (14)	endanger
COMMERCE AND TRADE (15)	“adverse effect”, adverse /2 effect, “adverse health effect”, “adversely affect”, “adversely affect” /2 health, risk /2 health, “unreasonable risk”, endanger, endanger /2 health
CONSERVATION (16)	“adverse effect”, adverse /2 effect, “adverse environmental effect”, “adversely affect”, risk /2 health, “unreasonable risk”, endanger, threat! /2 environment!, threat! /2 ecosystem, threat! /2 species
COPYRIGHTS (17)	“adverse effect”, adverse /2 effect, “adversely affect”, endanger
CRIMES AND CRIMINAL PROCEDURE (18)	“adverse effect”, adverse /2 effect, “adversely affect”, risk /2 health, endanger, endanger /2 health, threat! /2 health
CUSTOMS DUTIES (19)	“adverse effect”, adverse /2 effect, “adversely affect”, “adversely affect” /2 health, endanger
EDUCATION (20)	“adverse effect”, adverse /2 effect,

	“adversely affect”, risk /2 health, “unreasonable risk”, threat! /2 health
FOOD AND DRUGS (21)	“adverse effect”, adverse /2 effect, “adverse health effect”, “adversely affect”, risk /2 health, “unreasonable risk”, endanger, threat! /2 health
FOREIGN RELATIONS AND INTERCOURSE (22)	“adverse effect”, adverse /2 effect, “adverse environmental effect”, “adverse health effect”, “adversely affect”, risk /2 health, endanger, threat! /2 environment!, threat! /2 health, threat! /2 species
HIGHWAYS (23)	“adverse effect”, adverse /2 effect, “adversely affect”
INDIANS (25)	“adverse effect”, adverse /2 effect, “adversely affect”, endanger, threat! /2 environment!, threat! /2 health
INTERNAL REVENUE CODE (26)	“adverse effect”, adverse /2 effect, “adversely affect”, risk /2 health, threat! /2 health
INTOXICATING LIQUORS (27)	“adverse effect”, adverse /2 effect
JUDICIARY AND JUDICIAL PROCEDURE (28)	“adverse effect”, adverse /2 effect, “adversely affect”, endanger
LABOR (29)	“adverse effect”, adverse /2 effect, “adversely affect”, “adversely affect” /2 health, risk /2 health, “unreasonable risk”, endanger, endanger /2 health, threat! /2 health
MINERAL LANDS AND MINING (30)	“adverse effect”, adverse /2 effect, “adverse environmental effect”, “adversely affect”, “adversely affect” /2 health, endanger, endanger /2 health
MONEY AND FINANCE (31)	“adverse effect”, adverse /2 effect, “adversely affect”, endanger, threat! /2 health
NATIONAL GUARD (32)	“adversely affect”
NAVIGATION AND NAVIGABLE WATERS (33)	“adverse effect”, adverse /2 effect, “adverse environmental effect”, “adversely affect”, “adversely affect” /2 environment!, “adversely affect” /2 health, risk /2 environment!, risk /2 health, “unreasonable risk”, endanger, endanger /2 health, threat! /2 health, threat! /2 species
PATENTS (35)	“adversely affect”
PAY AND ALLOWANCES OF THE UNIFORMED SERVICES (37)	“adversely affect”
VETERANS' BENEFITS (38)	“adverse effect”, adverse /2 effect,

	“adverse health effect”, “adversely affect”, risk /2 health
POSTAL SERVICE (39)	“adversely affect”
PUBLIC BUILDINGS, PROPERTY, AND WORKS (40)	“adversely affect”
PUBLIC CONTRACTS (41)	“adverse effect”, adverse /2 effect, “adversely affect”
THE PUBLIC HEALTH AND WELFARE (42)	“adverse effect”, adverse /2 effect, “adverse environmental effect”, “adverse health effect”, “adversely affect”, “adversely affect” /2 health, risk /2 environment!, risk /2 health, “unreasonable risk”, endanger, endanger /2 health, threat! /2 environment!, threat! /2 health, threat! /2 species
PUBLIC LANDS (43)	“adverse effect”, adverse /2 effect, “adversely affect”, risk /2 environment!, endanger
PUBLIC PRINTING AND DOCUMENTS (44)	“adversely affect”
RAILROADS (45)	“adverse effect”, adverse /2 effect, “adversely affect”, endanger
SHIPPING (46)	“adverse effect”, adverse /2 effect, “adversely affect”, risk /2 health, endanger
TELEGRAPHS, TELEPHONES, AND RADIOTELEGRAPHS (47)	“adverse effect”, adverse /2 effect, “adversely affect”, endanger
TERRITORIES AND INSULAR POSSESSIONS (48)	“adverse effect”, adverse /2 effect
TRANSPORTATION (49)	“adverse effect”, adverse /2 effect, “adverse environmental effect”, “adversely affect”, “unreasonable risk”, endanger, threat! /2 species
WAR AND NATIONAL DEFENSE (50)	“adverse effect”, adverse /2 effect, “adversely affect”, risk /2 health, endanger, endanger /2 health

Table 4. – Occurrence of search terms in federal agency regulations (Westlaw, July 2005)

<b>Phrase (Search Term)</b>	<b>Library (Database)</b>	<b>Hits (Documents)</b>
1. adverse /2 effect	CFR	1,112
1a. “adverse effect”	CFR	990
1b. “adverse environmental effect”	CFR	62
1c. “adverse health effect”	CFR	44
2. “adversely affect”	CFR	1,280
2a. “adversely affect” /2 environment!	CFR	21
2b. “adversely affect” /2 health	CFR	58
3. risk	CFR	5,219
3a. risk /2 environment!	CFR	44
3b. risk /2 health	CFR	153
3c. “unreasonable risk”	CFR	186
4. endanger	CFR	607
4a. endanger /2 environment!	CFR	0
4b. endanger /2 health	CFR	68
5. threat!	CFR	2,478
5a. threat! /2 environment!	CFR	16
5b. threat! /2 health	CFR	81
5c. threat! /2 ecosystem	CFR	1
5d. threat! /2 species	CFR	210

Table 5. – Occurrence of search terms in federal judicial opinions since 1970 (Westlaw, June 2005)

<b>Phrase (Search Term)</b>	<b>Library (Database)</b>	<b>Hits (Documents)</b>
1. adverse /2 effect	Allfeds	16,136
1a. “adverse effect”	Allfeds	14,168
1b. “adverse environmental effect”	Allfeds	849
1c. “adverse health effect”	Allfeds	484
2. “adversely affect”	Allfeds	12,307
2a. “adversely affect” /2 environment!	Allfeds	68
2b. “adversely affect” /2 health	Allfeds	154
3. risk	Allfeds	138,837
3a. risk /2 environment!	Allfeds	544
3b. risk /2 health	Allfeds	2349
3c. “unreasonable risk”	Allfeds	3719
4. endanger	Allfeds	5764
4a. endanger /2 environment!	Allfeds	18
4b. endanger /2 health	Allfeds	567
5. threat!	Allfeds	141,275
5a. threat! /2 environment!	Allfeds	391
5b. threat! /2 health	Allfeds	1057
5c. threat! /2 ecosystem	Allfeds	11
5d. threat! /2 species	Allfeds	806