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Law and Regulation of Benzene

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OSHA has created final benzene regulations after extensive rulemakings on two occasions, 1978 and 1987. These standards have been the subject of extensive litigation for nearly 20 years. This article examines in detail the conceptual underpinnings of *the Benzene Case,* (which was decided by the U.S. Supreme Court in 1980) in light of U.S. administrative law precedents that have set limits upon administrative discretion under the test for "substantial evidence" and the "hard look doctrine." This article also addresses recent developments in the wake of *the Benzene Case* and their implications for benzene regulations following the "significant risk" doctrine in that case. This article briefly describes other national, regional, and international laws governing the use of benzene. This article concludes that the revisions of the benzene regulation and subsequent rulemaking provide substantial evidence of scientific underpinnings for regulatory action and that laws from other nations reflect an international consensus that occupational exposure to benzene is a proper subject of regulation. Such regulations and policies are therefore likely to withstand scrutiny and remain enforceable as widely accepted norms.

Introduction

The carcinogenic and mutagenic characteristics of benzene have been the subject of extensive scientific research; decisions based upon these data have given rise to litigation as well as public controversy. In response to these developments around the world, benzene has been regulated in the U.S., Canada, Europe, and under international standards. In particular, benzene regulations in the U.S. have been the subject of extensive litigation and research for nearly 20 years.

The case law and regulation of benzene therefore represent an important dimension of its use. Because of the power of government to implement standards and enforce the law, legal considerations ultimately affect workers' daily exposure, despite the inherent differences between law and science. Regardless of whether future developments recognize a threshold of safety for benzene use, an industrial users of benzene need to understand these laws and regulations when designing industrial hygiene programs. In addition, there remains the potential for application of these principles to other substances or environmental laws (which are beyond the scope of this article).

Drawing upon federal statutes, case law and treaties regulating benzene, this article notes the end of the era of "unbridled discretion" for agencies that regulate the use of toxic and hazardous substances, as well as an end to the threshold question, whether occupational exposure to benzene is sufficiently dangerous to require regulation. In the U.S., the desire to regulate substances has been balanced against enhanced scientific evidence and tempered by the constraints upon economic feasibility in industry. This article therefore concludes that a far-reaching transnational trend exists, favoring cautious regulations that are unlikely to be overturned.

OSHA's Benzene Regulations

Present Standard for Occupational Exposure to Benzene

The U.S. standard for occupational exposure to benzene (*1*) was adopted under the "Occupational Safety and Health Act of 1970" ("OSH Act") (*2*). It authorizes the Secretary of Labor to promulgate "occupational safety and health standards" and established the Occupational Safety and Health Administration (OSHA) to perform the agency's mission. Such standards must be "reasonably necessary or appropriate to provide safe or healthful employment or places of employment", under s3(8) (*3*). According to traditional U.S. administrative law (*4*), agency decisions must not be "arbitrary and capricious" (*5*), and must be supported by "substantial evidence" (*6*) justifying the agency's policies, in order to meet the test set forth in s3(8).

The present permissible exposure limit, (PEL) for occupational exposure to benzene is 1 ppm (*7*), [action level of 0.5 time weighted average (TWA)], with a short-term exposure limit (STEL) of 5 ppm averaged over 15 min to a confidence interval of 95% ± 25%. Under the present rule, employers are required to establish "regulated areas" if airborne concentration can reasonably be ex-

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pected to exceed permitted exposures (*8*). In addition, the standard requires employee notification of monitoring results; establishment and implementation of a written program to reduce employee exposure with engineering and work practice controls; respiratory protection, protective clothing, medical surveillance, recordkeeping; and regularly scheduled medical examinations (including urine sample in the event of emergency exposures).

These technical provisions are identical to the earlier final rule for benzene exposure (*9*) issued by OSHA in 1978, which was subjected to extensive litigation. Because of many subtle but important minor revisions, the prior final rule was about two-thirds shorter than the present rule. The original final rule had fewer exemptions; provided detailed protection against dermal and eye contact; and required quarterly measurements unless exposure was below the action level (and "at least monthly" if in excess of the PEL), new "initial monitoring" in the event of a change in the process, and swifter examination of a urine sample in the event of emergency exposure (*10*).

The present standard provides workers with important job protections, such as Medical Removal Protection (MRP) based upon hematological findings outlined in paragraphs (i) (8) (i) and (ii) (*11*). MRP provides workers with the right to transfer and rate retention upon recommendation by a hematologist/internist. It also requires enhanced employee education and training, consistent with the requirements of OSHA's Hazard Communication standard (*12*). In addition, the present standard provides clearer definition of "representative" sample of TWA exposure; allows a longer period of time before employee notification of monitoring results; removed the requirement that notification and compliance plans be readily available to employees at the worksite; exempts from medical surveillance certain employees who face low exposures; and reduces the number of required regular medical examinations. These modifications were designed to streamline progress towards worker protection.

Regulatory History of Benzene Exposure in the U.S.

The first evidence of risk from acute or chronic effects for exposure to benzene was recognized in 1900 (*13*). According to OSHA, "the benzene-leukemia link was first identified in 1897 in a report on the leukemia death of a worker occupationally exposed to benzene" (*14*). Winslow recommended a 100-ppm exposure limit in 1927 (*15*). Benzene's long regulatory history began in 1934, when Massachusetts established a Division of Occupational Hygiene in its Department of Labor and Industries (*16*) to investigate benzene toxicity. Based upon reports by Bowditch, Hunter, Mallory, and Elkins (*17*), it set a "maximum acceptable limit" (MAC) of 75 ppm, which was soon reduced to 35 ppm.

In 1946, the American Conference of Government Industrial Hygienists (ACGIH) recommended a threshold limit value (TLV) of 100 ppm for benzene, which was lowered to 35 ppm in 1948 and 25 ppm in 1963 (*18*). In 1971, OSHA adopted the voluntary industrial limit of 10 ppm, set by the American National Standards Institute (ANSI) as part of its acceptance of "national consensus standards" (*19*). In that same year, the International Labor Office (ILO), a specialized agency of the United Nations, adopted ILO Convention number 136, "Convention Concerning Protection Against Hazards Arising From Benzene," which incorporated the ACGIH's standard and set an international ceiling of 25 ppm for occupational exposure.

The National Institute for Occupational Safety and Health (NIOSH) issued a criteria document concerning the possible link between leukemia and benzene in 1974 (updated in 1976). A request for an emergency temporary standard (ETS) to regulate occupational exposure to benzene (*20*) was filed in 1976, followed by further information from the National Academy of Sciences (NAS), which concluded that "benzene must be considered a suspect leukemogen" (*21*). These conclusions, combined with the NIOSH recommendation, prompted OSHA to issue voluntary guidelines that limited the TWA to 1 ppm in 1977 (*22*). OSHA then issued an ETS (which was defeated in the courts) followed by a proposed permanent standard (*23*). After extensive hearings that discussed scientific evidence in detail, OSHA issued its first final rule for the regulation of benzene in February 1978 (*24*).

The first final rule was challenged by labor unions and by the chemical industry, iron and steel industry, rubber manufacturers, individual companies, and the petroleum industry (*25*). The rule was vacated by the U.S. Supreme Court, in *Industrial Union Department* v. *American Petroleum Institute* (referred to as *the Benzene Case*) (*26*) in 1980. According to OSHA (*27*), the second rulemaking was initiated in response to a petition to OSHA by labor organizations in 1984, requesting a new standard to fill the void created in the wake of *the Benzene Case*.

OSHA's failure to provide a timely response to that petition gave rise to a petition in the federal courts, for a *writ of mandamus* in 1985. (If the petition before the courts had succeeded, a *writ of mandamus* would have compelled OSHA to progress with the rulemaking process under the threat of contempt of court.) Instead, OSHA set forth a proposal for a rulemaking to modify the benzene standard within 14 months (*28*) (1986), which defeated the labor union's petition. OSHA conducted its second benzene rulemaking in 1986. In September 1987, OSHA issued the present rule for benzene regulation. Ironically, this standard provides similar protections compared to the modified original rule, but became law without further court review (*28*).

Law of "Significant Risk" under *the Benzene Case*

In 1980, the U.S. Supreme Court reviewed the validity of OSHA's decision to lower benzene's PEL to 1 ppm (from the previous standard of 10 ppm) and vacated a portion of the revised standard governing the 1 ppm PEL ambient work environment (*29*). In *the Benzene Case* the

seminal issue before the Court concerned whether the evidence in the record provided a sufficient basis for more stringent protection against benzene exposure. The Court held that the standard was invalid because it was based on findings unsupported by the administrative record (*30*).

The most important feature of the Court's long and divided opinions is its quest for administrative accountability: an unanswered demand for a sound rationale based on "substantial evidence," in the agency's record. Without passing judgment upon the specific details of the scientific studies in the record, the Court found that OSHA failed to demonstrate that it had performed a "balancing test"; this rendered OSHA's presumption of "no safe level" inadequate to support modification in the pre-existing standard.

The day after the opinion was published, the *Washington Post* reported (*31*) "industrial elation and regulatory panic," because issues raised in *the Benzene Case* echoed those faced by other agencies who grapple with public health and science policy. Since then, *the Benzene Case* has been interpreted to support a wide spectrum of legal principles regarding administrative duties at the interface between law and science. It actually presented the Court with a narrow issue regarding the agency's burden of proof when changing an existing standard: What course of action is appropriate when the full extent of a risk is unknown? (*32*).

In the Court's view, such action required the agency to first establish with great certainty that there would be a major saving of lives, health care costs, or quantifiable economic costs in order to justify modification of the existing law. Although the Court imposed the requirement that OSHA make a threshold finding of "significant risk" (*33*) upon the statutory mandate to provide protection "to the extent feasible" as required by OSH Act s 6 (b) (5), this finding was not intended to be a "mathematical straightjacket" (*34*). Justice Stevens, writing for the plurality, stated that OSHA has not made a threshold finding of risk to satisfy the agency's burden of proof. The separate concurrences by Chief Justice Berger and Justice Powell address the key issue of OSHA's "burden of proof" to acertaining the "feasibility" of a standard.

OSHA's 1978 benzene regulation was based on the belief that there is "no safe level" for protection against a carcinogen or a suspected carcinogen. OSHA applied its overarching "Cancer Policy" (*35*) to justify its view that exposures must be reduced to the "lowest feasible level" (*36*). That policy creates presumption under law that there is "no safe level" of exposure for cancer-causing agents. Under this construct, the agency instituted a "risk-free" workplace policy, designed to apply "technology-forcing" standards at "the frontiers of science" (*37*), thereby instituting protections at the "lowest feasible level" even if they were expensive, unnecessary, or inappropriate for immediate application in the field. Thus, the justification for changes in existing benzene regulations was based upon another policy; not scientific evidence pertaining to harms derived from exposure to benzene at 10 ppm or less.

OSHA argued in the Supreme Court, as it did before the lower court, "that it was the agency's position that for regulatory purposes, where a safe threshold for exposure to carcinogens was not demonstrated, it would assume that none existed . . . [OSHA] cannot await scientific resolution of the issue but has a mandate to act now . . . and in the absence of . . . no-effect levels or safe levels to assume that none exist" (*38*). OSHA set forth the view that its statutory mission required fostering "technological feasibility" over economic concerns. This approach was endorsed in the lower court by the intervenors (a concerned party that was not named in the case), that "since no safe level of exposure to benzene can be determined, the Secretary properly concluded that under OSH Act's legislative policy, the PEL should be set at the lowest feasible point" (*39*) based upon the agency's statutory mandate to use the "best available evidence," and the "latest available scientific data in the field," to assure "that no employee will suffer material impairment of health . . . for the period of his working life" pursuant to s. 6 (b) (5) (*40*).

In response to the regulatory changes, industries affected by the rule maintained that OSHA's failure to demonstrate the "appreciable benefits" of the revised consensus standard rendered such revision contrary to the precepts of U.S. administrative law. In their view, the term "feasible" was limited by economic constraints, in contrast to OSHA's view that "feasible" means technologically achievable. Pointing to OSH Act's statutory language in s. 6 (b) (5), industries successfully argued that OSHA standards must be "economically feasible" for the regulated industry. Furthermore, they interpreted the term "feasible" in s. 6 (b) (5) of OSH Act to included financial costs of implementing engineering controls or new forms of protection for workers, which had not been contemplated when the statute was written (*41*). The Court was not persuaded by either view. It stated (*42*):

> [OSH Act] requires the Secretary, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a *significant risk* of material health impairment. Only *after* the Secretary has made the threshold determination that such a risk exists with respect to a toxic substance, would it be necessary to decide whether s6 (b) (5) requires him to select the most protective standard he can consistent with economic and technological feasibility . . . Because the Secretary did not make the required threshold finding in this case, we have no occasion to determine whether costs must be weighted against benefits in an appropriate case. [Emphasis added.]

The Court agreed with OSHA's critics, who charged that OSHA's "risk-free" approach to regulation was impractical and presented an undue burden upon employers, workers, and commerce. Bearing in mind that an agency's primary task is to create policies and make difficult decisions, the Court was prepared to "accord OSHA great leeway," and defer to its scientific expertise if OSHA's policy reasons proved, on balance, to be supported by substantial evidence. Thus, the Court reasoned, it was unnecessary to reach the issue of cost-benefit analysis.

Even when considered in light of OSHA's statutory purpose and the requirement of s 6 (g) to promulgate standards "with due regard to the urgency" of the risk, however, OSHA's contention that its enabling legislation required a "risk-free workplace" could not be justified (*43*) because OSHA had not shown the direct, logical correlation between the information in the record and the agency's own findings. Without such evidence in the record to provide substantial evidence for the regulations' underpinnings, this fine thread of reasoning was also absent from the agency's conclusions. In the absence of a clear nexus between the evidence in the record and the conclusions in support of agency actions, the Supreme Court declared the benzene regulations invalid.

The Supreme Court agreed with the lower court's requirement that OSHA must find, "as a threshold matter that the toxic substance in question poses a significant health risk in the workplace and that a new, lower standard is therefore 'reasonably necessary and appropriate' " (*44*) and that "the lack of substantial evidence of discernible benefits is highlighted when one considers that OSHA is unable to point to any empirical evidence documenting leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971" (*45*). It also found that the absence of sound statistical projections did not meet the test for "reasonably necessary" regulations.

Since OSHA's case was premised upon the belief that it had statutory authority to compel employers to provide a "risk-free" workplace, the Supreme Court took particular exception to the fact that "OSHA did not ask for comments as to whether or not benzene presented a significant health risk at exposures of 10 ppm or less. Rather, it asked for comments as to whether 1 ppm was the minimum feasible exposure limit" (*46*). This approach gave rise to several assumptions by OSHA regarding the absence of any safe level of exposure. In effect, the Supreme Court reasoned, "it was in fact irrelevant whether there was any evidence at all of a leukemia risk at 10 ppm" (*47*).

Without further guidance from OSHA, the Supreme Court was obliged to engage in "statutory construction", (a form of legal analysis) to interpret "feasible." Confronted with a situation where the Supreme Court could not rely upon administrative criteria to evaluate "science issues," it sought a middle ground by requiring a finding or "significant risk" to be determined by the agency itself. In the alternative, the Supreme Court could have declared the statute invalid (as Justice Rehnquist argued in his opinion, concurring in part and dissenting in part). Although the Supreme Court refused to construe the term "feasible" as requiring an economic cost-benefit analysis, it was compelled to forge a new standard of feasibility, based upon "significant risk" of harm (*48*) as measured against quantified benefits, in order to "save" the statute from "overbroad" delegation (*49*), which would have rendered it unconstitutional.

The Supreme Court therefore adopted a concept of risk assessment, which is required of other regulatory agencies, such as EPA and the FDA. It is worth noting, however, the Supreme Court did not offer the specific test in an acceptable risk assessment, as lower courts had done in the past. Nor did it offer the pretense that it should provide such criteria to an agency that was charged by law with developing the expertise to create occupational health standards. Rather, it gave a general description of the two extremes that could occur: too little protection or too much protection.

The Supreme Court's many opinions in this case revolve about a single theme that unifies the questions surrounding the accuracy of the agency's scientific findings and its legal burden of proof. They reflect the Supreme Court's underlying need to substitute its own view of the inherently vague language of the OSH Act to fill the void in administrative action. "Significant risk" and the rigors of providing valid "scientific evidence" present a secondary, albeit controversial aspect of the plurality opinion. Although the need for judges to understand science has become the subject of extensive debate, the Court is comprised of lawyers, not scientists; it therefore considered inappropriate for the Court to "review" beyond the procedural aspects of the agency's scientific "fact-finding."

The Benzene Case provides a good example of the courts' quest for substantial evidence of agency decisions when no safe level of exposure is recognized. Without strong arguments specific to the facts and circumstances, supporting the promulgation of the 1 ppm benzene standard, OSHA offered only "unclear" evidence to support its actions. Failing to demonstrate the presence of a balanced policy, the agency found itself in an untenable position from the standpoint of administrative law, which resulted in the Court's vacation of the standard.

Precedents Leading to *the Benzene Case*

In prior cases, controversy surrounding the criteria for appropriate action by an agency did not preclude further judicial inquiry, despite the traditional "presumption" of the validity of agency conclusions. As the following discussion of case law demonstrates, several substantive and procedural safeguards must be satisfied before a court will defer to an agency's exercise of its administrative discretion. This presumption of the validity of an agency's conclusions, in the face of partisan dissatisfaction with such findings can be applied to areas of scientific uncertainty, if the agency demonstrates the fairness of its proceedings and whether the information in the record is reflected in the agency's regulatory conclusions.

In *the Benzene Case*, OSHA asserted that the burden of disproving the validity of a rule must be borne by the affected industries. The "Administrative Procedure Act" (APA) (*50*), however, requires that a proponent of a rule bears the burden of proving its necessity, unless there is specific statutory language to the contrary. In such cases, the APA requirement in s556 can only be circumvented through limited means, without undermining the statute's constitutionality. For example, there was statutory language that shifted the burden of proof to the industry in the cases of *Environmental Defense Fund* v. *EPA* (*51*)

and *Certified Color Manufacturers* v. *Matthews* (*52*). In both cases, the agency's enabling legislation clearly provided that there be a presumption that a substance was unsafe unless proven otherwise. In contrast to the OSH Act, the U.S. Congress expressly required that manufacturers of pesticides certify the safety of their products before the agency could approve their regular use. OSHA, however, does not have this statutory mandate.

The statutory authority challenged in *Certified Color Manufacturers* prevents the use of new food additives, unless the agency explicitly certified to the contrary after a hearing or rulemaking. In that case, the industrial representatives brought suit challenging the FDA's actions, which terminated the provisional approval of Red Number 2 (pursuant to the transitional provisions of new food additive amendments). Finding that the Secretary did not act "in excess of statutory authority," the appellate court would not substitute its own judgment for the agency's conclusions and therefore deferred to the agency's expertise.

The court's deference was contingent upon substantial evidence that FDA had in fact met its burden of reviewing and using the evidence in the record to give full and fair consideration of the points raised by the industry. In *Certified Color Manufacturers*, this was discerned using the FDA's statutory criteria, which provided for two-step decisionmaking. First, a substance was deemed unsafe until proven otherwise. Then, the substance was listed in a national registry if proven to (the Secretary's) satisfaction that it was safe, (the so-called GRAS list).

The statutory authority is distinguishable from OSHA's policy judgment that there should be a presumption of no safe level as applied to *the Benzene Case*. Nonetheless, the FDA model is useful because it highlights the kind of information that courts request to meet a burden of proof. FDA was guided by explicit statutory criteria that guided its decisions, which included possible harm or other relevant exposure from an additive; cumulative effect of the regulated substance; safety factors appropriate for animal experimentation data; and availability of implementation of the standard. It is worth noting that the last two components of these criteria evoke an assessment of the risks and the costs of implementation. In addition, FDA was bound by, and demonstrated compliance with, its own criteria, which provided further justification for its refusal to certify the safety of the food additives in question.

When applying these criteria in *Certified Color Manufacturers*, the Agency (FDA) necessarily struck the balance for weighing the potential benefits to industry (of allowing the use of questionably safe substances) against the cost to society if the substance later proved to be hazardous. Despite this concomitant reduction in unquestioned aspects of the agency's burden of proof (when compared to vague allocation of the burden of proof under OSH Act), the Court nonetheless expressed a strong concern for the quality of the Agency's scientific record. The Court deferred to FDA only after it had examined both the content and procedures in the rulemaking record, where if found clear evidence of the risk of harm. It gave qualified deference to FDA's fact-finding, in *dicta:*

> Considering *inter alia*, that the information available to (the Secretary) indicated a statistically significant relationship between high doses of the additive and the occurrence of cancer in . . . rats, the principle study did not establish safety, notice and comment in APA were inapplicable (*53*).

One of the first decisions that demanded evidence of OSHA's administrative "expertise" held invalid an early OSHA standard that "set forth the requirement for the minimum number of lavatories in industrial establishments" *Associated Industries of New York State* v. *U.S. Department of Labor* (*54*). In *Associated Industries*, the New York court reaffirmed the long-standing concept that administrative determinations not supported by substantial evidence need not be arbitrary and capricious. Nonetheless, if found that OSHA:

> imposes a health standard upon industrial establishments that is considerably more stringent than that which apparently has been found satisfactory by many states . . . (OSHA) has an obligation to produce some evidence justifying its action. (*55*)

OSHA attempted to justify its actions in *Associated Industries* by asserting that the standard in question was valid, pursuant to OSHA's statutory authority, to require that workplaces be "free from recognized hazards" (*56*). However, without substantial evidence relating to the need for a more stringent standard, OSHA's arguments seemed simplistic, or at best, weak enough to support virtually any discretionary action by an agency (regardless of invalidity). Finding that judicial review was "exacerbated by the absence of legitimate, nonpecuniary, articulated rationale for the standard in question," the court concluded that when OSHA sought to institute a more stringent standard, "and the proposed standard has been contested on substantial grounds, the agency has the burden of offering some explanation for adopting the Standard" (*57*).

In *Society of Plastic Industries Inc.* v. *OSHA (SPI)* (*58*), the New York court considered that OSHA had assumed a legislative role because, "though the factual finger points, it does not conclude" (*59*). Citing *IUD* v. *Hodgson* (which upheld OSHA's use of administrative discretion when formulating its asbestos regulations as discussed in Part E, below), the court held that:

> where explicit factual finding of safe is not possible, and the act of decision is essentially a prediction based upon pure legislative judgment, as when a Congressman decides to vote for or against a particular bill [the Court looks to the record, to determine] . . . Whether the agency, given an essentially legislative task to perform has carried it out in a manner calculated to negate the danger of arbitrariness and irrationality. (*60*)

The Court undertook the "prodigious task" of studying the 4000 page record, which it criticized as:

> aggrevated duplications of testimony, irrelevant exhibits and letters, and almost illegible . . . and a general blunderbuss approach . . . (*60*)

Nonetheless, in *SPI*, when the court looked with "alarm" upon the "morbid" chronology of vinyl chloride exposure, unchecked by industry, even after the causal relation between occupational exposure and increased

morbidity was widely recognized, it was compelled to accept the agency's findings. Having demonstrated to the satisfaction of the court the existence of a "serious health risk" (*61*) based upon information reported to NIOSH and independent research by others, the court found OSHA's view persuasive, stating:

> it must be remembered that we are dealing here with human lives . . . it remains the duty of the Secretary . . . to act even in circumstances where existing methodology or research is deficient. (*62*)

Therefore, the urgency of the threat to worker's health combined with the Secretary's well-reasoned explanations merited deference to OSHA's action.

This theme was repeated in *American Iron and Steel Institute (AISI)* v. *OSHA ("AISI")* (*63*) where the Court took great care in distinguishing "determinations bottomed on factual matters" from "non-factual legislative-like policy decisions" (*64*). After reviewing NIOSH testimony concerning the carcinogenicity of coke oven emissions (*65*) and other data in the record, the Court employed a five-step criteria to evaluate OSHA's determinations. Of these 5 steps in this process of judicial review (which concerned procedural requirements as well as the agency's rationale), two criteria demonstrate the significance of policy considerations (*66*). OSHA satisfied its burden of proof under these criteria by offering substantial evidence that there is absolutely no safe level for toxic coke oven emissions but that the reduced PEL would have demonstrable health benefits.

There is a major distinction in OSHA's use of the term "no safe level" in *AISI* compared to *the Benzene Case*, as the harms from coke oven emissions were an undisputed fact and there was evidence in the record that occupationally induced mortality could be improved by reducing occupational exposure to coke oven emissions. In fact, acceptance of this fact, among industries as well as regulatory authorities, served as the basic rationale for enforcing a stringent performance standard. The viability of OSHA's standard, whose efficacy was established through the use of a dose-response relationship, therefore was the sole scientific question before the court.

Thus, AISI's refusal to institute occupational health protections despite an undisputed and quantified risk of cancer was far less defensible than API's contention that costly engineering controls to meet OSHA's requirements in the face of uncertain risk would "bankrupt the industry." When viewed in light of this precedent, OSHA's arguments could not withstand strict scrutiny to prevail in *the Benzene Case*.

Impact of *the Benzene Case* Upon OSHA Case Law and New Standards

The *Benzene* decision had important ramifications for all subsequent OSHA standards. Despite the Court's strict scrutiny of OSHA's decisions (which called into question OSHA' statutory authority), the findings nonetheless upheld the notion that benzene is an appropriate substance for regulation and set the tone for acceptance of similar standards in the U.S. and abroad. Additionally, the decision became the touchstone for further evaluation of the role of risk assessment in lieu of cost-benefit analysis within OSHA's regulatory process.

The ensuing debate regarding the importance of economic considerations (despite the prohibitions against cost-benefit analysis under OSH Act) has overshadowed the Court's rejection of this notion, because of a new, cost-containing regulatory outlook, and Executive Order, and increased oversight by OMB. The impact of *the Benzene Case* upon future standards promulgated by OSHA is nonetheless evident in the Agency's increased ability to demonstrate the policy rationale behind its actions.

For example, in the case of the *Building Construction Trades Dept (AFL-CIO)* v. *Brock* ("*Building Trades*") (*67*) decided in February, 1988, the Court of Appeals upheld most of OSHA's modifications to the pre-existing asbestos standard. In *Building Trades*, the DC Court of Appeals reviewed the modifications of OSHA's asbestos standard, which reduced the prior PEL to 0.2 and the STEL through work practice and engineering controls except for subgroups in the construction trades. OSHA's ban on the spraying of asbestos-containing products, however, was not upheld (*68*).

This was the second Court of Appeals case that challenged OSHA's rulemaking for asbestos; the first round of litigation began with OSHA's initial asbestos standard in 1974 (*69*). In *IUD* v. *Hodgson* (*70*), the court examined whether OSHA had authority to institute controls for occupational exposure to asbestos that were mandated by statute, (i.e., recordkeeping and medical examinations) (*71*). The court reluctantly upheld OSHA's exercise of authority to establish such controls and to set the time frame for their implementation, stating, "the record, examined closely in relation to the relevant concerns of the Act leaves nagging questions—even for the inexpert observer—as to the reasons and rationale for the Secretary's particular choices" (*72*).

In *Building Trades*, the same court reviewed the same agency's actions regarding the same substance, 15 years later. The opinion in *Building Trades* is therefore striking in its complexity and its sophisticated evaluation of scientific data (*73*). By contrast to *Hodgson's* simplistic view that "technological progress in industry appears not to have been accompanied uniformly by corresponding reductions in the health hazards" (*74*), the court in *Building Trades* made frequent references to epidemiology and discussed throughout its opinion such nonlegal concepts as odds ratios, standard mortality, and proportionate mortality (*75*). It also included in the body of its opinion a chart that shows the relative risk for smokers versus nonsmokers who are occupationally exposed to asbestos over a working lifetime. The court further stated "Even under the assumption of a 20 year working life, [OSHA] found the risk at the existing PEL to be 44 extra cancer deaths per 1000" (*76*). It therefore accepted OSHA's threshold determination that even at reduced levels there exists a significant risk, which would be measurably reduced by implementation of the modified standard.

OSHA's position regarding its threshold findings of risk

due to occupational exposure to asbestos were based upon its interpretation of *the Benzene Case*. Although the agency chose to apply a very narrow interpretation of the "significant risk" doctrine, the court was satisfied by this approach. It deferred, in large part, to the agency's findings except when the terminology used by the agency was unduly vague (*77*). The court's refusal to accept a ban on the spraying of products that contain asbestos and its desire for a clearer definition of the phrase "any kind of construction work" (*77*) when determining the scope of exemptions from the standard represent two instances where the absence of evidence in the record compelled the court to reject OSHA's policy.

The court agreed with OSHA, however, that despite the synergistic relationship between asbestos and smoking which increased the workers risk, there was no justification to require that employers institute an outright ban on smoking by all persons who face occupational exposure to asbestos (*78*).

The language used by the court throughout the *Building Trade* opinion (which concerns modified asbestos regulations) closely resembles the preamble to the present (second) final benzene regulation, issued only a few months before the *Building Trades* decision (*79*). The benzene regulations' preamble reflects a heightened awareness of technical matters to support QSHA's "determination by the Assistant Secretary that employees exposed to benzene face a significant heightened risk and that this standard will substantially reduce that risk" (*80*). The agency's use of technical language and its long discussion of whether benzene is an initiator or a promoter (*81*) is clearly derived from *the Benzene Case*, which was cited in the preamble (*82*).

For example, OSHA described the "extended and upgraded" work in studies by Infante and Rinsky (case control and retrospective studies of refinery workers) and by Aksoy (leukemia and pancytopenia among shoe workers in Istanbul (*83*), as well as major developments in new studies (*84*). These and other studies were assessed by an outside consultant for OSHA. In addition, the lengthy preamble discussed standard mortality ratios and the findings of studies on rats and mice and concluded, "the new standard creates a minimum reduction in excess risk of 90% [which will] prevent a minimum of 326 deaths from leukemia over 45 years" (*85*). This new approach indicates a concern for the evidentiary underpinnings at the heart of *the Benzene Case*.

U.S. Benzene Law Compared to Regulations Around the World

The increasing prevalence of conventions, agreements, and statutes regarding the use of benzene around the world merits close attention. Although the information currently available is sparse in contrast to the voluminous records in the U.S., the existence of such laws underscores that the U.S. is merely one among several nations that recognize the need to regulate occupational exposure to benzene and other hazardous substances. This section therefore briefly summarizes information from the International Labor Force (ILO), World Health Organization (WHO) European Region, and Canada [information from International Agency for Research on Cancer (IARC) and from developing countries will be discussed in a future article].

Probably the most widely known of the international standards regulating benzene is C.136, which was developed by the ILO. Founded in 1919 under the Treaty of Versailles (*86*), the ILO encourages dialogue between less developed and industrialized nations and promotes increased interaction and coordinated activity between employers, governments, and workers (or their representative organizations). According to the fundamental tenets of the ILO Constitution (*87*), occupational health is a human right; the amelioration of working conditions is one of the ILO's oldest goals. To foster the implementation of this goal, the ILO provides technical assistance and prepares conventions that are adopted and ratified by member nations (*88*).

C. 136 ("Convention Concerning Protection Against Hazards Arising From Benzene") provides a regulatory framework for different economic settings and covers a wide spectrum of occupational exposures. It covers all activities that give rise to occupational exposure to benzene, as well as products that contain 1% benzene by volume. Art. 2 requires substitution of products containing benzene whenever possible. Art. 4 prohibits use of benzene in certain work processes at the discretion of the competent authorities (*89*). Competent authorities may permit exception to the percentage requirements or other provisions after tripartite consultation.

Members who ratify C.136 also undertake to pass laws and regulations consistent with it and to provide appropriate inspection services and supervision to carry out the purposes of the convention, except that no nation is bound to requirements that violate their own constitutional law. Members are also free to institute more stringent protections to achieve these goals.

As in the case of many ILO standards, C. 136 Art. 5 requires occupational hygiene and technical measures to ensure effective protection, but does not specify the nature, methodology for monitoring, or extent of such protections. Presumably, engineering controls and the use of respirators may be appropriate for protection to implement this standard depending upon the circumstances at the worksite. C. 136 also requires that measures be taken to prevent the escape of benzene vapors into the air in places of employment and in Art. 6, s. 2 that the "competent authority" shall fix a "ceiling value" for exposure, which shall not exceed 25 ppm using measurements specified by that authority. The standard does not, however, list a TWA.

The standard also requires in Art. 7 that "as far as practible," workers shall have adequate means of protection against skin contact. Medical surveillance provisions include but are not limited to: preemployment medical examination, (fitness and blood test) periodic reexamination, and removal of pregnant women and nursing mothers from employment. The latter provision is probably the most controversial, insofar as it raises important ques-

tions at the interface between occupational safety and job discrimination. As in the case of all ILO standards, member states agree to report annually upon their effects to implement and comply with the convention's provisions.

Although there are no cases at the present time that pertain specifically to the benzene convention, the ILO also provides for an elaborate oversight mechanism and grievance procedure in the event of violation of a standard after it has been ratified by a nation. And, in rare cases of egregious behavior, a nation's compliance with international standards may be called into question at the annual International Labor Conference (ILC), even if the offending nation has not ratified the convention. This concept of "entry into force" is an important and highly controversial aspect of international law. For the purposes of benzene regulation, however, this concept holds greater implications for nations who have not created standards of their own, rather than to nations who have exercised their power in favor of regulation. Employers who seek to protect their employees in nations where no standards presently exist also are affected by the international benzene standard.

The European Economic Community (EEC) instituted community-wide standards for the transport and handling of toxic substances that became effective in the early 1980s. Like most EEC agreements, the standards function as a treaty but also espouse principles that many ripen into customary international law. While the transport agreement does not specify exposure limits to toxic substances, it does set forth required procedures for the safe handling and use of covered substances in a manner that closely resembles the subsequent labeling requirements under U.S. laws. By contrast, the WHO has published Air Quality Guidelines, which state, "No safe level for airborne benzene can be recommended, as . . . there is no known safe carcinogenic level" (*90*). Unlike standards, however, these guidelines are not designed to be a part of international law. Rather, they reflect the scientific consensus regarding specific substances, including benzene, following WHO's constitutional mandate to protect and promote health around the world (*91*).

Last, Canada's province of Ontario provides an example of regional benzene regulations that reflect state-of-the-art science and involvement by government, employers, and workers, consistent with the ILO's model. The pattern of consultation between these parties resembles the structure contemplated in the ILO Convention and its constitution. In addition, these benzene regulations, passed in 1984, require respirators whenever engineering controls are not available "to the lowest practible level" (*92*).

These examples highlight the growing international consensus that occupational exposure to toxic or hazardous substances is a proper subject for national, transnational, and even international regulation.

Conclusions

Benzene has become as ubiquitous in law as it is in industry due to protracted litigation and pervasive regulation. Although regulatory agencies have limited power, it is unrealistic to expect that interest in regulation will soon diminish or that the plethora of existing regulations will be reduced in their scope or rigor. Indeed, the regulatory trend is toward more stringent regulation through the adoption of more conservative, scientifically based preventative measures. Such regulations are more likely to withstand judicial scrutiny and remain enforceable as widely accepted norms before national fora and under international law.

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REFERENCES

1. The USA's standard for occupational exposure to benzene (29CFR 1910.Z1028).
2. "Occupational Safety and Health Act of 1970," 29 U.S.C. s651 et seq. (1970), ("OSH Act"). PL 91-596 (1970).
3. OSH Act s3(8); 29 U.S.C. s652(8).
4. "Administrative Procedure Act," 5 USC ss553-703 (1946) (Amend. 1966).
5. Agency decisions must not be "arbitrary and capricious" according to ss553 and 556.
6. *National Labor Relations Board, (NLRB)* v. *Universal Camera*, 190 F2d 429 (2nd Cir. 1951) Learned Hand, J. citing *Universal Camera* v. *National Labor Relations Board (NLRB)* regarding the "substantial evidence" test for administrative decisions.
7. OSHA's rationale for changing the PEL in 1987 is described in the Preamble to the (second) final rule for benzene (Henceforth Preamble B2) 52 Federal Register 34460-61-34581; the revised standard is published in 29CFR s.1910.1028 (1987). (Henceforth, FR).
8. 29 CFR s1910.1028 (A) (3) (ii). This rule does not comment, however, whether fertile or pregnant women can be banned from employer designated "restricted areas."
9. Preamble to the (first) final rule for benzene (Henceforth Preamble B1) 43 5919 (1978).
10. The old standard required testing "at least east monthly if exposure was in excess of the PEL" and testing after emergencies "at the end of the shift" s. (i) (6) (1978) instead of "within 72 hours," s. 4 (i). (1987).
11. MRP outlined in paragraphs (i) (8) (i) and (ii), 29 CFR 1910.1028. Such protections were established by OSHA under the Lead standard 29CFR 1910.1025. The MRP was upheld by the Court of Appeals in *United Steelworkers of America* v. *Marshall*, 647 F2d 1189 (D.C. Cir 1980.); *cert denied.* 453 US 913 (1981).
12. OSHA's Hazard Communication standard, 29 CFR 1910.1200 requires education and training of workers exposed to toxic and hazardous substances, as well as availability of such information contained in a Material Safety Data Sheet, (MSDS).
13. The first evidence of risk from acute or chronic effects for exposure to benzene was recognized in 1900 Preamble B2 52FR34465.
14. *Brief for the Secretary of Labor, On Consolidated Petitions to Review the Secretary's Occupational Health Standard, Nos. 78-1253, 1257, 1486, 1676, 1677, 1707, 1745 in the United States Court of Appeals for the Fifth Circuit American Petroleum Institute, (API) et al.* v. *OSHA et al.* Henceforth, *Secretary's Brief*, p. 12.
15. Preamble B2 52FR34465; Preamble B1 43FR5919; *Secretary's Brief*, p. 12.
16. Preamble B1, 43FR5918.
17. Bowditch, Hunter, Mallory, and Elkins were discussed in Preamble B2 52FR34465; Preamble B1 43FR5918.
18. Preamble B2 52FR34466.
19. "National consensus standards" includes recognized standards by the scientific community, such as ANSI, ACGIH and NSC stan-

dards which were incorporated by reference into OSHA's enforcement mechanism by statute when OSHA began its work in 1971.

20. Preamble B1 43FR5919.
21. National Academy of Sciences (NAS) report for EPA as adopted by OSHA, Preamble B2 52FR34466.
22. Preamble B1 43FR5919.
23. (First) Proposed Rule for Occupational Exposure to Benzene 42FR27452-27478 (1977). See also Benzene Emergency Temporary Standard, 42 FR 22525; 23601; (1977).
24. Preamble B1 32FR5918-5944.
25. Secretary's Brief, p. 44-45.
26. *Industrial Union Department, AFL-CIO (IUD) et al.* v. *American Petroleum Institute, (API)* (referred to as *"The Benzene Case"*) 448 US 607 (1980).
27. Preamble B2 52FR34431-2.
28. Long-delayed benzene levels set by OSHA. Chemical and Engineering News, Sept. 7: (1987).
29. 29 CFR 1910.1028. See: *The Benzene Case.*
30. *The Benzene Case,* 448 US 607 at 608, (1980); slip opinion at p. 1.
31. Omang, Joanne. Scope of Benzene Ruling Viewed as Limited. *Washington Post* July 3, 1980, P. A9.
32. McGarity, Thomas. Substantive and procedural discretion in administrative resolution of science policy questions: regulating carcinogens in EPA and OSHA. Georgetown L. J. 729: 746-747 (1979).
33. *The Benzene Case,* 448 US 607 at 652, (1980); slip opinion at pp. 40-44.
34. *The Benzene Case,* 448 US 607 (1980); slip opinion at p. 44. "It is the Agency's responsibility to determine, in the first instance, what it considers to be a 'significant risk.' "
35. "Identification, Classification and Regulation of Carcinogens," (the so-called "Cancer Policy" for generic regulation of carcinogens) 42FR54148, (1977).
36. Secretary's Brief, p. 12.
37. Secretary's Brief, p. 15.
38. *The Benzene Case,* 448 US 607 (1980); slip opinion at p. 14, footnote 19, citing Tr. 48-49. (This quote was also cited in briefs by most parties.)
39. *Brief of Intervenor, Industrial Union Department, AFL-CIO On Consolidated Petitions to Review the Secretary's Occupational Health Standard, Nos. 78-1253, 1257, 1486, 1676 1677, 1707, 1745 in the United States Court of Appeals for the Fifth Circuit American Petroleum Institute, (API) et al.* v. *OSHA et al.,* pp. 23-29.
40. OSH Act s. 6 (b) 5; 29 USC 657 (b) (5) requires that the Secretary "set the standard which most adequately assures 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 (sic) working life."
41. S. Rep. No. 91-1282, (91st Cong., 2nd Sess.) *Legislative History, Occupational Safety and Health Act of 1970,* (1971) U.S. Government Printing Office, Washington, DC.
42. *The Benzene Case,* 448 US 607 (1980); slip opinion at p. 29.
43. *API* v. *OSHA* 581 F2d 493 (1978).
44. *The Benzene Case,* 448 US 607 at 610 (1980); slip opinion at p. 4, footnote 5, citing *API* v. *OSHA,* 581 F2d 493, (1978), which characterized OSHA's position as "an assumption based only on inferences drawn from studies involving much higher exposure levels."
45. *The Benzene Case,* 448 US 607 (1980); slip opinion at p. 13.
46. *The Benzene Case,* 448 US 607 (1980); slip opinion at pp. 14-15.
47. "Statutory construction" is a form of legal analysis to "fill the gaps" in the interstices of ambiguous legislation. The two approaches are: use of the "plain meaning doctrine" (which looks at the dictionary definition or commonplace usage of the terms) and "purposive analysis" (which looks beyond the plain meaning to discern the legislative intent when the statute was written).
48. *The Benzene Case,* 448 US 607 (1980); slip opinion at p. 9.
49. *Schechter Poultry Corp.* v. *United States, 295 US 495, 539 and Panama Refining Co.* v. *Ryan, 293 US 388 (1935).*
50. "Administrative Procedure Act," 5 USC s556.
51. *Environmental Defense Fund* v. *EPA,* 548 F. 2d 998 (D.C. Cir. 1976); 179 US App. DC 43 (1979) cert. denied, 431 US 925 and *Certified Color Manufacturers* v. *Matthews,* 543 F. 2d, 284 (1976).
52. *Certified Color Manufacturers* 548 F2d. 284 at 293 (1976).
53. *Certified Color Manufacturers* 548 F2d. 284 at 287.
54. *Associated Industries of New York State* v. *U.S. Department of Labor ("Associated Industries")* 487 F2d 342 (1973).
55. *Associated Industries,* 487 F2d 342 at 344 (1973).
56. Each employer is required to provide a workplace that is free from "recognized hazards," OSH Act s. 5 (a) 1; 29 USC 665 (a) l.
57. *Associated Industries,* 487 F2d 342 at 347.
58. *Society of Plastic Industries Inc.* v. *OSHA (SPI)* 509 F2d 1301 (1975).
59. *SPI,* 509 F2d at 1308 (1975).
60. *SPI,* 509 F2d at 1304, Citing 74. *Industrial Union Department, AFL-CIO (IUD)* v. *Hodgson,* 499 F2d 467 (DC Cir. 1974).
61. *SPI,* 509 F2 at 1305.
62. *SPI,* 509 F2d at 1308.
63. *American Iron and Steel Institute* v. *OSHA (AISI)* 577 F2d 825 (1978).
64. AISI 577 F2d at 831.
65. AISI 557 F2d 831 at 831 and 832.
66. AISI 577 F2d at 833.
67. *Building Construction Trades Dept, (AFL-CIO)* v. *Brock, (Building Trades)* consolidated cases No. 86-1359; No. 86-1360; No. 86-1410; No. 86-1411. Decided February 2, 1988. 838 F2d 1258 (DC Cir. 1988).
68. *Building Trades,* 838 F2d 1258; slip opinion at pp. 21-22.
69. 29 CFR 1910.1001 (1987) and 29 CFR 1926.58 (1987); proposed new rule for asbestos 40FR47652 (1975).
70. *Industrial Union Department, AFL-CIO (IUD)* v. *Hodgson,* 499 F2d 467 (DC Cir. 1974).
71. OSHA's authority to establish such controls. 29 USC.
72. *Hodgson,* 499 F2d 467 at 488 (DC Cir. 1974).
73. *Building Trades* 838 F2d 1258.
74. *Hodgson,* 499 F2d 467 at 470 (DC Cir. 1974).
75. *Building Trades* 838 F2d 1258; slip opinion at pp. 11-13.
76. *Building Trades,* 838 F2d 1258; slip opinion at p. 9.
77. *Building Trades,* 838 F2d 1258; "Part III", slip opinion at pp. 26-43.
78. *Building Trades,* 838 F2d 1258; slip opinion at pp. 11, 22.
79. Preamble B2 52FR344; compare Preamble B1 43FR5919.
80. Preamble B2 52FR34460
81. Preamble B2 at 52FR34491
82. Preamble B2 at 52FR34460-1
83. Preamble B2 at 52FR34468
84. Preamble B2 at 52FR34462
85. Preamble B2 at 52FR34461
86. Chapter XIX, The Treaty of Versailles (1919).
87. The preamble to the ILO Constitution reads in part: "Whereas Universal and lasting peace can be established only if it is based upon social justice; And whereas conditions of labor exist involving such injustice; hardship and privation to large numbers of people so as to produce unrest so great that the peace and harmony of the world are imperiled and an improvement of those conditions is urgently required; as for example by the provision of adequate living wage; the protection of the worker against sickness, disease and injury arising out of his employment . . ."
88. Articles IV through XII of the ILO Constitution.
89. C.136 This convention was presented to member nations for ratification in 1971. ILO convention concerning protection against hazards arising from benzene.
90. WHO Air Quality Guidelines, European Region. p. 54.
91. World Health Organization, (WHO) Constitution, Article I, in Basic Documents, WHO Geneva Switzerland, 1917. "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."
92. Benzene is subject to regulation in Canada (Revised Statutes of Ontario, 1980 Chapter 321), and under laws concerning the regulation of a "designated substance." Revised statutes of Ontario provide an "objective" of a PEL of 1 ppm, with a TWA of 5 ppm and a ceiling of 15 ppm. The regulations also require participation by Joint safety committees, (comprised of management, labor and government). Benzene is a "designated substance" under its regulatory authority. Under this system, workers who are occupationally exposed to such substances must be granted special protections.