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## Law and Science Policy in Federal Regulation of Formaldehyde

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Formaldehyde, one of the more widely used chemicals in modern industry, has recently become one of the more controversial as well. A plethora of lawsuits, congressional hearings, and scholarly analyses have centered on formaldehyde, and more particularly on federal agency responses to new data indicating that it may be a carcinogen. These devel-

opments were sparked by an October 1979 report from the Chemical Industry Institute of Toxicology (CIIT) that formaldehyde causes cancer in rats.

On receiving the CIIT findings, the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission

(CPSC), and other agencies undertook several joint actions, the most important of which was to form the Federal Panel on Formaldehyde. The panel was composed of top scientists from the federal government and was directed to evaluate all available information on the long-term effects of exposure to formaldehyde and to assess the human health risks. In November 1980 the panel presented its report to the agencies. Based on its review of the available data, the panel concluded that "formaldehyde should be presumed to pose a carcinogenic risk to humans" (1). Thereafter, CPSC issued a ban against the use of urea-formaldehyde foam insulation. EPA and OSHA, however, declined to take regulatory action against formaldehyde.

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## Framework for Evaluating the Formaldehyde Decisions

The great weight of judicial authority suggests that the appropriate legal standard by which to evaluate agency decisions is whether the agency engaged in "reasoned decision-making" (2). As recently articulated by the D.C. Circuit Court (3), an agency practices reasoned decision-making when it (i) takes a "hard look . . . at the relevant issues," (ii) deliberates "in a manner calculated to negate the danger of arbitrariness and irrationality," (iii) violates "no law," and (iv) provides an "articulated justification" that makes a "rational connection between the facts found and the choice made."

Applying the concepts of reasoned decision-making as an analytical tool requires a clear understanding of what a particular agency has and has not done. With health risk determinations, this understanding often requires a technical knowledge of the underlying data and methodologies. Further, it requires an ability to distinguish between purely technical determinations and those based on the more subjective, science policy determinations.

The term "science policy" denotes issues that are grounded in scientific analysis but for which technical data are insufficient to support an unequivocal scientific conclusion. The ultimate resolution of these issues depends on determinations of social policy. Distinguishing science policy determinations from those of a truly technical nature is a central step in evaluating the adequacy of an agency's assessment of human health risks. Simply deferring to agency expertise on all determinations that appear to be "scientific" overlooks the subjective determinations at the heart of the agency's decisions. Such an approach frustrates any effort to measure agency decisions against the standard of reasoned decision-making.

Acknowledging that science policy will often play a major role in agency assessments of human health risks, it must then be determined whether an agency has abided by the principles of reasoned decision-making. These principles impose three primary responsibilities on an agency assessing health risks: (i) it must adequately evaluate the technical data, (ii) it must follow proper administrative procedures, and (iii) it must correctly carry out its statutory mandate. In practice, these functions overlap. An agency's interpretation of its statutory mandate, for example, can influence both the nature of the technical

data it examines and the manner in which it makes that examination. When completed agency decisions are analyzed, however, the three elements are separable and provide a logical framework.

*Treatment of technical data.* In evaluating the technical data relevant to determining health risk, an agency must delve deeply into scientific issues. The agency will ordinarily engage in two levels of scientific analysis. On one level, it will address "hard" scientific issues that can be resolved with currently available

tries and interested members of the general public. As a matter of administrative procedure, an agency must adhere to its policy guidelines or identify and explain any change in, or departure from, those guidelines. To develop policy guidelines in the area of health risk assessment, the agency must adopt positions on science policy issues. In the absence of formal announcements of changes in these positions, recognizing policy departures will require that one first identify and understand the underlying science policy issues.

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*Summary.* An examination of the way in which the Environmental Protection Agency, Occupational Safety and Health Administration, and Consumer Product Safety Commission each responded to evidence of formaldehyde's carcinogenicity in animal systems reveals the interplay between politics and science policy in regulatory determinations. In some cases there were significant and unjustified departures from reasoned decision-making. Agency decisions not to take action deserve special attention by citizens, the Congress, and the judiciary to ensure that federal regulatory agencies take the necessary steps to protect the public from significant health, safety, and environmental risks.

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methodologies. On a second level, the agency will confront various science policy issues that cannot be answered solely on a technical basis. Thus a meaningful critique of an agency's treatment of technical data requires both an understanding of the relevant technical methodology and an ability to distinguish between "hard" science and science policy determinations.

In appropriate circumstances, of course, the agency may depart from scientific opinion on science policy issues. These issues do, after all, involve policy determinations, and accordingly should be made by the governmental entity charged with reflecting the will of the people through the execution of a congressional mandate. Nonetheless, they are also determinations that should be properly based on a sufficient understanding of the underlying scientific evidence. When a majority position on a science policy issue has evolved within the scientific community, we believe the agency should not depart from that position without acknowledging and justifying the departure.

*Adherence to procedural requirements.* Science policy issues may also arise in the context of procedural matters. Agencies often develop general policy guidelines for their regulatory actions, in the form of either formal generic standards, such as OSHA's, or informal statements of procedure, such as the Regulatory Council's. These guidelines not only promote regulatory continuity but also provide notice to affected indus-

*Execution of statutory mandates.* Finally, the agency must act in accordance with its statutory mandate. This responsibility has two elements. The agency must carry out the specific duties of the particular statutory provisions under which it is considering regulatory action. At the same time, it must faithfully adhere to the more general aspects of the congressional mandate underlying its enabling legislation.

Any analysis of agency decision-making must carefully consider both of these elements. In evaluating health risk determinations, particular attention must be given to the ways in which assessments of science policy issues reflect an agency's interpretation of its statutory mandate. In close cases, for example, should the agency tip the balance in favor of finding a human health risk or in favor of deferring such a finding until additional data are available?

In developing a general analytical framework, we are not unmindful of the judicial deference traditionally afforded agency decisions not to act. In the past, legal challenges to agency decisions on health and safety have come primarily in response to specific regulatory actions. An agency's implementation of a statutory provision was challenged as either too zealous or insufficiently protective. In the present antiregulatory climate, challenges to agency decisions not to act may assume greater significance.

Judicial deference to agency discretion in such situations is based largely on respect for agency expertise in matters

of resource allocation and technical evaluation. Such deference is misplaced, however, where the cloak of expertise serves to disguise inadequate technical analysis, improper decision-making procedures, or statutory misinterpretation. An analysis of the formaldehyde decisions demonstrates why, before deferring to an agency's decision not to take regulatory action to protect human health, the courts should first study the agency's decision to determine whether such deference is, in fact, warranted.

## **EPA's Decision Not to Designate**

### **Formaldehyde a Section 4(f) Chemical**

In March 1981 EPA's deputy assistant administrator for toxic substances, in consultation with other EPA officials, concluded that the agency was obligated to begin consideration of formaldehyde under section 4(f) of the Toxic Substances Control Act. Section 4(f) provides that once EPA receives information indicating that there "may be a reasonable basis to conclude" that a chemical poses a significant cancer risk, the agency has 180 days to either "initiate appropriate regulatory action" or publish an explanation of why the risk "is not unreasonable" (4).

When newly confirmed EPA administrator Anne Gorsuch assumed office in May 1981 she delayed action on formaldehyde pending additional review. Finally, on 10 February 1982, EPA released a memorandum, written by new assistant administrator John Todhunter, that analyzed the available evidence on formaldehyde carcinogenicity and exposure and concluded that section 4(f) had not been triggered.

In a sense, any discussion of EPA's decision-making process may be superfluous. Considerable evidence suggests that the incoming EPA officials had determined their policy on formaldehyde long before any "decision-making process" had been completed (5, 6). Assuming, however, that the Todhunter memorandum does represent the culmination of a lengthy decision-making process, this process was nonetheless flawed in numerous respects.

*Analysis of technical data.* An agency decision must evidence a "rational connection between the facts found and the choice made" (3). Health risk assessments thus require a careful analysis of the relevant technical data regarding both a substance's toxicity and the extent of human exposure. Unquestionably, an agency is properly accorded some discretion in its treatment of tech-

nical data. Nonetheless, the agency's analysis must be free of overt errors in technical methodology or reasoning. EPA's treatment of the formaldehyde data aroused significant criticism. A review of the agency's technical analysis reveals several examples of questionable scientific reasoning.

The Todhunter memorandum appears to contain significant lapses in hard science. In many cases it seems simply to ignore empirical data contrary to EPA's conclusions, or to rely on controversial factual assumptions without offering evidence in support of these assumptions. As has been discussed elsewhere (7), the questionable aspects of Todhunter's technical analysis include his reliance on methodologically inadequate epidemiologic studies, his presumption of site specificity and species specificity for formaldehyde carcinogenicity, his argument that the irritant properties of formaldehyde are the basis of its carcinogenicity, his assumption that humans will avoid formaldehyde exposures above 2 ppm, and his conclusion that formaldehyde exposure levels in homes with urea-formaldehyde foam insulation are no higher than those in other homes.

In his reliance on the epidemiologic studies and his assumption of site and species specificity, Todhunter also departed from the science policy conclusions of a scientific panel convened by the Interagency Regulatory Liaison Group (IRLG). Indeed, EPA's formaldehyde deliberations reflected science policy positions that represent the views of a minority in the scientific community (7). While these positions may not be "wrong" in a purely technical sense, they demand justification. EPA neither acknowledged the need for such justification nor supplied any.

*Procedural aspects.* The principle of reasoned decision-making further requires that an agency deliberate "in a manner calculated to negate the dangers of arbitrariness and irrationality" (3). Depending on the particular agency action under review, courts have enumerated various specific procedural requirements for reasoned decision-making. EPA's treatment of formaldehyde raises procedural questions.

Several of these questions concern a possible bias of EPA with respect to industry. With the advent of the Gorsuch administration, EPA embarked on a decision-making process for formaldehyde that served to maximize input from the formaldehyde industry and to minimize input from other sectors. Regardless of the ultimate substantive validity of the agency's section 4(f) determination, the

appearance of its decision-making process lends credence to claims of impropriety.

The EPA held three meetings with representatives of the formaldehyde industry in summer 1981. The initial impetus for the meetings apparently came from industry. Although EPA has subsequently characterized these meetings as having been "exclusively scientific in nature," the rosters of those present reveal that the sessions were dominated by the perspective of the formaldehyde industry. With the exception of one or two "neutral" scientists at each meeting, the Formaldehyde Institute selected all the non-EPA participants.

Rather than solicit a variety of viewpoints, EPA closed the meetings to the public. Conspicuous by their absence were scientists representing groups that might be expected to oppose the formaldehyde industry's position. Also absent were representatives of other regulatory agencies and the IRLG. Indeed, the agency reportedly refused to admit two scientists who requested permission to attend: Andrew Ulsamer of CPSC and Han Kang of OSHA, both members of the IRLG formaldehyde group.

As other observers have suggested, these meetings may also have violated the Federal Advisory Committee Act (FACA) (8). That statute recognizes that agencies have come to rely on technical "advisory committees" as an aid to decision-making, and establishes specific procedural requirements for such committees. The Act requires that advisory committees be formally chartered, be composed of a "fair balance" among opposing viewpoints, give notice of their meetings and open them to the public, and maintain accurate and detailed minutes of those meetings.

The deputy administrator of EPA, John Hernandez, has written that the primary function of those sessions was to allow him to meet with "scientific and technical experts" to "discuss the scientific merits of the available information." The meetings, he indicated, "were designed . . . to explore fully the scientific and technical issues." He later testified that the purpose of the meetings was to "get all the scientific information pertaining to the exposure and toxicity of these substances out in the open." If this characterization is accurate, the meetings would probably fall within FACA's purview. EPA departed from the Act's procedural requirements in numerous particulars. Certainly, the narrow range of viewpoints represented at the industry meetings is inconsistent with the "fair balance" requirement of the Act.

A substantial amount of evidence indicates that before releasing his 10 February memorandum, Todhunter met on several occasions with John Byington, attorney for the Formaldehyde Institute, and Len Guarraia, then a director of the American Industrial Health Council and director for government relations for the Synthetic Organic Chemical Manufacturer's Association. Although the precise nature and scope of these gatherings are difficult to deduce, it seems that Todhunter did meet with formaldehyde interests before drafting EPA's position paper on the section 4(f) determination. As the D.C. Circuit Court has noted, "[t]he inconsistency of the *ex parte* contacts with reasoned decision-making and fairness to the public has been increasingly recognized in recent years" (9).

Shortly after they took office the new EPA administrators ceased to cooperate with the other federal agencies that were assessing formaldehyde carcinogenicity. EPA also isolated itself from its own science advisory board. On 29 October 1981 the board's executive committee recommended that EPA submit the formaldehyde issue to the National Academy of Sciences before it concluded its section 4(f) determination. EPA instead permitted Todhunter to draft his technical memorandum on formaldehyde without such assistance.

Other procedural questions concern the explanation given by EPA for its decision on formaldehyde. The courts have long required agencies to "articulate with reasonable clarity their reasons for a decision" (2). In the words of an oft-cited opinion (10), "the orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained." EPA's formaldehyde deliberations fell far short of this standard.

The most troublesome procedural problem lies in Todhunter's failure to acknowledge his departure from prior agency positions on many of the science policy issues involved. Where an agency has changed a previously articulated policy or departed from a relevant agency precedent, the courts have required the agency to provide a detailed rationale. Although EPA never promulgated a formal cancer policy, it published informal cancer guidelines in 1976, endorsed the IRLG risk assessment document in 1979, and participated in the Regulatory Council's September 1979 policy statement on regulation of chemical carcinogens (11). Being most recent, the Regulatory Council's statement was the logical foundation for EPA's approach to formalde-

hyde, yet Todhunter's positions differ from the council's in several areas.

The guidelines specify that (i) negative epidemiologic studies will not be presumed to indicate that a substance is not carcinogenic, (ii) sites exposed by routes other than those tested will be presumed to be at risk, (iii) negative bioassay results for some animal species, even in well-conducted tests, will not be said to detract from well-established positive evidence for other species, and (iv) a no-effect threshold level will not be assumed to exist for carcinogenic substances. Todhunter adopted a contrary position on each of these points.

Todhunter also suggested that positive data on more than one species at more than one dose level should be a prerequisite to a determination of human risk. The Regulatory Council's guidelines require only positive data in a single species at one dose level. Similarly, Todhunter discounted findings of benign tumors in bioassay data and considered only verifiably malignant tumors, while the council concluded that benign tumors should be considered evidence of potential malignancy. The council statement also indicates that agencies will attempt to estimate the maximum risk that could reasonably be expected. Todhunter consistently assumed policy positions that minimized estimated risks. In its failure to explain or even acknowledge these policy reversals, EPA fell short of its procedural responsibility.

Finally, Todhunter's memorandum was not reviewed by his scientific peers inside or outside the agency. The failure to garner peer review, especially on matters so controversial, ran counter to the professed goal of the new EPA administrators to improve the scientific basis of the agency's regulatory decisions. It may also have violated internal EPA procedures. In January 1982 EPA implemented a new internal policy governing the review of scientific, informational, and educational materials. The policy, which applies to "any material prepared for distribution to anyone outside the agency," requires that at least two specialists review all such materials (12). Nonetheless, the Todhunter memorandum was released to the public without prior peer review.

*Statutory mandate.* Congress designed section 4(f) as a mechanism for early identification and regulation of those chemicals that were of particular concern because they are likely carcinogens, mutagens, or teratogens. EPA's current interpretation of that section, however, will frustrate this scheme.

As noted, section 4(f) requires agency

action if there "may be a reasonable basis" to conclude that a risk of harm exists. In both common usage and judicial interpretation, "may" indicates the possibility of occurrence. Under the plain language of section 4(f), then, EPA cannot delay its threshold determination until a risk has become certain or probable, but rather must take action on learning of a credible possibility of such risk.

Todhunter's memorandum is particularly noteworthy in this respect. In summarizing the formaldehyde data, Todhunter noted that "there may be human exposure situations . . . which may not present carcinogenic risk which is of significance." He thus stated the required statutory finding in the negative. The logical converse of this statement—that there may be human exposure situations that do present significant carcinogenic risk—is precisely the finding that requires EPA to proceed under section 4(f). The agency's failure to do so reflects misinterpretation of statutory language.

The agency's assessment of the kind of risk that it is to consider under section 4(f) may also be inaccurate. Once again, the statute itself provides relatively clear guidelines. Congress dealt with both short-term and long-term risk in 4(f), which addresses chemical substances that either "present" or "will present" a significant risk of harm. The Toxic Substances Control Act does not define the phrase "significant risk," but the context suggests that "significance" pertains to the likelihood of occurrence. By providing that the risk that may exist must be significant, the Act seems to require only the possibility of a probable occurrence. Evidence indicating the possibility of a significant risk thus triggers the threshold determination that compels EPA to assess the risk more precisely.

In its risk assessment, the agency must consider both "serious" and "widespread" harm. By specifically distinguishing between these two categories of harm in section 4(f), Congress clearly indicated that either one will trigger a threshold determination. One element focuses on the extent to which the chemical may pose a risk of serious harm. Here the concern is not so much the number of people who may be affected, but how severely they may be affected. A low incidence of a debilitating cancer, then, would suffice. The other element is the extent to which the chemical may pose a risk of widespread harm. Here a higher incidence is required, but the harm need not be as severe.

After making a threshold determination of possible significant risk, EPA

must decide, within a prescribed time period, whether regulatory action is appropriate. If the agency determines that the risk is not unreasonable, it must subject this finding to public scrutiny by publishing it in the *Federal Register*. If, on the other hand, the agency does not conclude that the potential risk is not unreasonable, it must "initiate appropriate action . . . to prevent or reduce to a sufficient extent such risk." While we express no opinion here as to the appropriate regulatory response to formaldehyde under the Toxic Substances Control Act, it appears that section 4(f) requires something more of EPA than the agency's actions to date.

### OSHA's Decision Not to Issue an Emergency Temporary Standard

After receiving the results of the preliminary CIIT bioassay in late 1979, both OSHA and the National Institute for Occupational Safety and Health began preparing a joint current intelligence bulletin (CIB) on formaldehyde. A pre-publication version was made available to the public in December 1980. The CIB recommended that "formaldehyde be handled as a potential occupational carcinogen and that appropriate controls be used to reduce worker exposure."

In March 1981 Thorne Auchter assumed office as assistant secretary of labor for OSHA. Soon thereafter he withdrew OSHA's sponsorship of the CIB.

In October 1981 the United Auto Workers and 13 other major labor unions petitioned OSHA to set an emergency temporary standard (ETS) for formaldehyde under section 6(c) of the Occupational Safety and Health Act (13). Section 6(c) specifies that OSHA shall promulgate an ETS if it determines that employees are exposed to "grave danger" from exposure to a hazard and that an ETS is "necessary to protect employees from such danger." In a letter dated 29 January 1982, Auchter denied the petition. He stated that OSHA assessments indicated that risks at the current permissible exposure level of 3 ppm were not sufficient to warrant a finding of grave danger, and that current employee exposure levels were below 3 ppm.

Auchter's decision to deny the union's ETS petition was apparently based on two evaluations performed by agency personnel after Auchter took office. The first is a review of a formaldehyde risk assessment prepared by scientists at the Massachusetts Institute of Technology, and the second, the agency's preliminary

risk assessment. Positions expressed in each of these documents found their way into Auchter's ultimate statement of rationale, although the extent to which they contributed to the ETS decision is not altogether clear.

In many ways, OSHA's deliberations on formaldehyde mirrored EPA's. Although OSHA's departures from sound technical reasoning and established administrative procedure were perhaps less troublesome than EPA's, they were nonetheless significant. OSHA's treatment of science policy issues provides an excellent example of how such issues can cut across all three levels of an agency's administrative responsibility.

*Analysis of technical data.* The review of the MIT study inappropriately relies on the formaldehyde epidemiologic studies, on arguments of species specificity, and on arguments of minimum exposure. The review also assumes that workers are exposed only to low levels of formaldehyde, avoiding exposures above 3 ppm because of their irritating effects. Like the Todhunter memorandum, the OSHA review cites no empirical evidence for this assumption and apparently ignores data on exposures above the 3 ppm level.

Furthermore, the review departs from prevailing scientific opinion on science policy. As previously noted, the review presumes species specificity and relies on negative epidemiologic data. In an even more striking departure, the review does not merely question the way results of animal bioassays are extrapolated to humans, but rather argues that such extrapolation is meaningless: "Because of the vast uncertainties in extrapolating from experimental rodent studies to man, such experiments do not and cannot predict or measure human risks." At best, this sweeping denunciation of accepted science policy represents a controversial minority opinion.

*Procedural aspects.* Perhaps the most significant procedural deficiency in OSHA's deliberations was the agency's failure to adhere to its own policy on cancer risk assessment. Although that policy was promulgated as a formal agency regulation, which is still in effect, Auchter's denial letter does not acknowledge it. Indeed, Auchter's treatment of the rat data and the agency's failure to consider benign tumor data conflict with the policy's plain language. The OSHA review of the MIT report also departs significantly from the agency's cancer policy, again without acknowledging or explaining the departure.

Although the Auchter letter contains a statement of rationale, that statement

does not identify the agency "risk assessments" on which it says it relies. Does it refer only to the OSHA assessment made after the ETS petition was filed, or does it refer also to the agency's earlier review of the MIT study? Indeed, the OSHA assessment appears to have been prepared in written form sometime after Auchter's letter was delivered to the unions. This fact, along with the conclusory nature of Auchter's analysis, calls into question the letter's adequacy as a "statement of reasons." The possibility of post hoc rationalization looms large here.

A final procedural problem with OSHA's formaldehyde deliberations is that the agency disregarded and mischaracterized the advice of its own scientists. Although Auchter publicly stated that the agency withdrew its support of the formaldehyde CIB because it "lacked confidence in the data" on which the CIB was predicated, all the technical personnel in OSHA's carcinogenicity assessment group supported both the CIB and the underlying data. Later, when Peter Infante, director of OSHA's Office of Carcinogen Identification and Classification, wrote to the International Agency for Research on Cancer (IARC) recommending that formaldehyde be classified as an animal carcinogen, the agency took steps to have him dismissed. The matter became the focus of a congressional hearing. Subsequently, the dismissal proceedings were canceled.

*Statutory mandate.* The issuance of an ETS for a workplace chemical under section 6(c) depends on a finding that "employees are exposed to grave danger from exposure" to that chemical. A review of OSHA's formaldehyde decision indicates that the agency may have adopted a more limited interpretation of section 6(c) than the statute will permit.

Clearly, cancer is a "grave" illness. The question is what degree of cancer risk constitutes a "grave danger" under section 6(c). The Third Circuit Court provided guidance in a 1973 opinion (14), stating that "[w]hile the Act does not require an absolute certainty as to the deleterious effect of the substance on man, an emergency temporary standard must be supported by evidence that shows *more than some possibility* that a substance *may cause cancer in man*" [italics added].

A review of OSHA records shows that such evidence was available during the formaldehyde deliberations. Extrapolating from the CIIT rat bioassay results, the agency's own risk analysis indicates that four formaldehyde-related cancer deaths per 1000 exposed workers would

be expected at the currently permitted exposure level of 3 ppm. Because OSHA estimated that the average occupational mortality rate for manufacturing workers, from all reported occupationally related causes, is also four per thousand, Auchter concluded that formaldehyde does not pose a grave risk of danger. This comparison misses the mark. The question is not how the risk from formaldehyde compares with the aggregate of all other risks, but how many lives can be saved by regulating formaldehyde exposure. Furthermore, if the agency's estimate of average aggregate risk is valid, the fact that exposure to formaldehyde alone presents a risk of comparable magnitude should give rise to considerable concern.

This evidence of carcinogenic potency appears sufficient to warrant the issuance of an ETS, assuming that a determination of "grave danger" under section 6(c) may be made by extrapolating from animal data. Dicta from the Third Circuit Court again provide substantial guidance (13): "Extrapolation from animal experiments may in appropriate cases be used to establish a sufficient probability of harm to man." Moreover, the courts have indicated that evidence of animal carcinogenicity is by itself sufficient to justify a permanent standard. A greater burden would hardly seem appropriate for a temporary standard. In addition to contravening its own cancer policy and the IRLG guidelines on this issue, OSHA contravened its section 6(c) mandate as well.

The remaining inquiry is whether the evidence of worker exposure to formaldehyde is sufficient to warrant issuing an ETS. In a recent decision involving ethylene oxide, the D.C. Circuit Court declined to compel OSHA to issue an ETS where the evidence indicated that only "some" workers are exposed to ethylene oxide at levels that present a "significant risk" of "grave danger." On the basis of this finding, however, the court ordered OSHA to expedite ongoing procedures to set a permanent standard to reduce worker exposure to ethylene oxide. The data on formaldehyde exposure appear to be stronger than the data on ethylene oxide, both in the detail and reliability of the exposure information and in the number of workers exposed. Indeed, the D.C. Circuit's approach in the case of ethylene oxide may also be appropriate for formaldehyde. An order to commence a procedure to set a permanent standard for formaldehyde would set the stage for an objective appraisal of the cancer risk and of the need for further worker protection.

## **CPSC's Decision to Ban**

### **Urea-Formaldehyde Foam Insulation**

The Consumer Product Safety Commission received the results of the preliminary CIIT bioassay in late 1979. By this time, the commission had already begun to study the health problems associated with the use of urea-formaldehyde foam insulation (UFFI). In March 1980, when the need for further study became apparent, CPSC organized the Federal Panel on Formaldehyde. In June 1980 CPSC proposed a rule requiring UFFI manufacturers to inform prospective buyers of UFFI health effects. The commission received the panel report in November 1980, and in February 1981 it proposed to ban UFFI altogether. Ultimately it promulgated a final rule banning UFFI as of August 1982.

On 12 April 1982 the Formaldehyde Institute filed a suit to challenge the CPSC ban. On 10 August of that year a federal judge refused to issue a temporary injunction, and the ban took effect on that date. The Fifth Circuit Court vacated the UFFI ban on 7 April 1983 and has recently reaffirmed its decision.

Especially when viewed in contrast to the EPA and OSHA deliberations, CPSC's formaldehyde deliberations might be considered a model of reasoned decision-making. The commission was subject to more stringent statutory requirements than were EPA and OSHA. However, it not only met these requirements, but exceeded them.

*Analysis of technical data.* During the notice and comment rule-making period for the UFFI ban, CPSC responded to many comments that specifically questioned its technical risk analysis. A search of the commission's stated rationale, background documents, and comment responses reveals no clear errors in scientific reasoning.

The commission conformed to prevailing scientific opinion on science policy issues. For example, it extrapolated animal results to humans and high-dose results to low doses.

*Procedural aspects.* In promulgating its UFFI ban, CPSC was subject to the procedural provisions of the Consumer Product Safety Act, which require an opportunity for notice and comment. In addition, as a commission headed by a "collegial body," CPSC must comply with advance notice and open meeting requirements of the government in the Sunshine Act. CPSC appears to have conformed to these requirements and to have comported with the principles of reasoned decision-making. It established and maintained a decision-making frame-

work that allowed for input from all interested parties.

The commission's UFFI science policy decisions were consistent with the Regulatory Council's policy on the regulation of carcinogens, which CPSC explicitly endorsed. The commission also provided a detailed statement of reasons for its decision to ban UFFI. That statement explains the basis of the ban, cites specific sources of data, and responds to numerous comments.

## **The Fifth Circuit Court Opinion**

### **Overturning the UFFI Ban**

The Fifth Circuit Court does not share our sanguinity regarding the CPSC cancer risk assessment. The court criticized two aspects of the commission's risk assessment: the manner in which homes were selected for measurements of in-home formaldehyde levels and the use of the CIIT data on rats to project human carcinogenic risk. The court indicated that CPSC's handling of either of these factors would be sufficient to warrant reversal of the UFFI ban. We disagree.

The CPSC based its estimate of likely formaldehyde exposure levels on 1164 measurements from homes insulated with UFFI and on laboratory tests on UFFI panels. Of the in-home measurements, 827 were conducted in residences whose occupants had complained about UFFI-related health problems and 337 in homes selected for other reasons. In concluding that these in-home measurements were an improper basis for the commission's risk assessment, the court points to two "significant omissions" (15):

The Commission does not explain its reliance on a data base comprised largely of complainant houses. Nor does the agency justify its failure to conduct a study of randomly selected UFFI homes before issuing the product ban.

In truth, however, the agency did explain its willingness to rely on the in-home data. According to the final risk assessment, all the in-home measurements (for both "complaint" and "non-complaint" homes) were grouped according to the time that had elapsed between the date that UFFI had been installed and the date that the measurement had been taken. The groupings were by 10-week periods over a period of 9 years. Average measurements for complaint homes were compared with average measurements for noncomplaint homes within each of these 10-week periods, but no statistically significant differences were found. Thus, the agency con-



cluded, there is no reason to believe that formaldehyde levels in the complaint homes were significantly higher than those in other homes insulated with UFFI. While the statistical comparison employed by the agency does not rule out the possibility that use of complaint homes did influence the data to a certain degree, the data indicate that the effect of any such influence on the ultimate cancer risk projection would be relatively small.

The failure to use a randomized sample is perhaps a closer question. Although selecting a study population through random sampling would be scientifically preferred, failing to do so does not necessarily vitiate the value of a study. The obvious source of potential bias in the CPSC data—and the only one cited by the court—is the possibility that formaldehyde levels were appreciably higher in the complaint homes than in other homes. As noted, however, comparisons between complaint and non-complaint homes revealed no statistically significant differences in formaldehyde levels.

There remains a possibility that the lack of randomization allowed some other source of bias to influence the results. As the in-home measurements were largely consistent with the results of the laboratory tests, this possibility seems slight. Nonetheless, some uncertainty remains. In choosing to take regulatory action in the face of this uncertainty, CPSC implicitly made a policy determination that the potential risk to human health from continued use of UFFI insulation did not permit it to delay action until a large randomized study of UFFI homes could be completed. In vacating the UFFI ban, the court has substituted its own policy judgment for that of the agency. As a matter of administrative law, a court may reverse an agency's policy determination when that determination conflicts with the statutory mandate. It may also remand the issue to the agency for reconsideration if it finds procedural irregularity. It may not, however, merely replace the agency's policy with its own.

Does the Consumer Product Safety Act require the commission to conduct a controlled test from a randomly selected study population before imposing a product ban? Clearly the statute itself contains no explicit direction in this regard. Rather, both the statutory language and the legislative history indicate that con-

siderable discretion is to be afforded the commission in its choice of study designs, so long as it bases its conclusions on generally reliable data.

Declaring that "it is not good science to rely on a single experiment," the court also found the commission's "exclusive reliance" on the CIIT rat bioassay in its projection of human cancer risk to be "unsupportable" (14). The extrapolation of animal data to predict human cancer risk is ultimately an issue of policy; "good science" is simply unable to provide a precise calculation of formaldehyde's carcinogenicity in humans. Consistent with the federal cancer policy set forth in the Regulatory Council statement, CPSC based its projections on a single, well-conducted animal bioassay. Although the court makes no mention of the Regulatory Council statement in its review of the commission's action, its rejection of that action is an implicit repudiation of carefully established federal administrative policy. All indications are that the court did not base this position on its reading of the commission's statutory mandate, but rather on its own understanding of scientific methodology. As such, the court has confused science with science policy, and has once again substituted its policy judgment for that of the agency.

In sum, though we must emphasize that we express no opinion as to the other aspects of the commission's decision, nor of the court's review thereof, we find the Fifth Circuit's analysis to be unpersuasive in its evaluation of CPSC's cancer risk assessment for formaldehyde.

## Conclusion

Reasoned decision-making has evolved as a common standard for judicial review of agency action, and is a particularly appropriate criterion by which to evaluate the conduct of agencies responsible for protecting public health by regulating exposure to toxic substances. Although it was initially applied to decisions to take regulatory action, this standard has been increasingly applied to decisions not to act as well. This is a welcome development. In these antiregulatory times, decisions not to act are becoming more numerous, and adequate review is needed to ensure that the agencies adhere to their statutory mandates.

This review of the OSHA and EPA actions demonstrates the need to examine scientific determinations carefully, lest social policy decisions be hidden in alleged assessments of technical or scientific fact.

Finally, the formaldehyde case raises important questions about the proper status for an environmental agency. Of the three agencies examined here, only the one structured as a commission acted responsibly. Recent concern over the political manipulation of environmental agencies has prompted proposals to convert EPA into a "hybrid commission." Although structural changes can help insulate an agency from political influence, continued judicial and congressional scrutiny of Executive Branch agencies may—at least for the short term—provide the most practical check on agency impropriety. The courts and Congress thus must take a "hard look" to ensure that agencies exercise reasoned decision-making in their approach to toxic substance control.

## References and Notes

1. Federal Panel on Formaldehyde, *Environ. Health Perspect.* **43**, 139 (1982).
2. *Greater Boston Television Corp. v. Federal Trade Commission*, 444 Fed. Rep. 2nd ser. 841, 852 (D.C. Circuit Court, 1970), certiorari denied, 403 U.S. 923 (1971). See also: *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, *U.S. Law Week* **51**, 4953 and 4960 (1983), where the Supreme Court held that an agency must perform a "reasoned analysis."
3. *W.W.H.T., Inc. v. Federal Communications Commission*, 656 Fed. Rep. 2nd ser. 807 and 817 (D.C. Circuit Court, 1981).
4. 15 U.S. Code, §2603(f) (1976).
5. J. Todhunter himself has testified that when he arrived at EPA in July 1981 he was informed that the agency would take no regulatory action on formaldehyde.
6. N. A. Ashford, C. W. Ryan, C. C. Caldart, *Harv. Environ. Law Rev.* **7**, 297 (1983).
7. *ibid.*, pp. 329–333; U.S. Congress, Committee on Science and Technology, *Review of the Scientific Basis of the Environmental Protection Agency's Carcinogenic Risk Assessment of Formaldehyde* (98th Congress, 1st Session, 1983); F. Perera and C. Petito, *Science* **216**, 1285 (1982).
8. 5 U.S. Code, appendix 1 (1976).
9. *United States Lines, Inc. v. Federal Maritime Commission*, 584 Fed. Rep. 2nd ser. 519 and 540, note 8 (D.C. Circuit Court, 1978).
10. *Securities and Exchange Commission v. Chenery Corp.*, 318 U.S. 80 and 94 (1943).
11. Regulatory Council, *Fed. Regist.* **44**, 60,038 (1979).
12. "Review process for scientific, informational, and educational documents" (Order 2200, Environmental Protection Agency, Washington, D.C.), p. 3.
13. 28 U.S. Code, §655(c) (1976).
14. *Dry Color Manufacturers Association, Inc. v. Department of Labor*, 486 Fed. Rep. 2nd ser. 98 and 104 (Third Circuit Court, 1973).
15. *Gulf South Insulation v. Consumer Product Safety Commission*, 701 Fed. Rep. 2nd ser. 1137 (Fifth Circuit Court, 1983).
16. All the primary source material referred to in this article was cited in full in our detailed treatment of this topic (6). For convenience, we included citations here only where we quoted directly from the source material, or where we felt the citation to be particularly important.