United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 7, 1997 Decided August 1, 1997

No. 96-5188

TROY CORPORATION,
APPELLANT

v.

CAROL M. BROWNER,
ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND
ENVIRONMENTAL PROTECTION AGENCY,
APPELLEES

Consolidated with
Nos. 96-5203 & 96-5204

Appeals from the United States District Court
for the District of Columbia
(No. 95cv00980)
(No. 95cv01673)
(No. 95cv01910)

William K. Rawson argued the causes for appellants Chemical Manufacturers and Troy Corporation, with whom *Claudia M. O'Brien, David F. Zoll,* and *John C. Marchese* were on the briefs.

Cynthia A. Lewis argued the cause for appellant NMP Producers Group, with whom *Alec I. Ugol* and *Karl S. Bourdeau* were on the briefs.

Ellen J. Durkee, Attorney, United States Department of Justice, and *Timothy Burns,* Attorney, United States Environmental Protection Agency, argued the cause for appellee, with whom *Lois J. Schiffer,* Assistant Attorney General, *Scott J. Jordan, Mary F. Edgar,* and *John A. Bryson,* Attorneys, United States Department of Justice, were on the brief.

Before: GINSBURG, SENTELLE and TATEL, *Circuit Judges.*

Opinion for the Court filed by *Circuit Judge* SENTELLE.

SENTELLE, *Circuit Judge*: Appellants, chemical manufacturers and associations of chemical manufacturers, appeal from the district court's grant of summary judgment in favor of the Administrator of the United States Environmental Protection Agency ("EPA" or "the Administrator") in actions appellants brought seeking to invalidate the Administrator's rulemaking which had culminated in the addition of 286 chemicals to the Toxic Release Inventory ("TRI") under the Emergency Planning and Community Right to Know Act of 1986 ("EPCRA" or "the Act"), 42 U.S.C. § 11001 *et seq.* Appellants had asserted error on the Administrator's part both as to the adoption of the list of new chemicals as a whole, and as to specific chemicals on the list. Finding only specific error, we affirm the judgment of the district court in large part, but remand for further proceedings with regard to two chemicals.

I. Background

In 1986, Congress enacted EPCRA, which provides, *inter alia,* that manufacturers, processors, and users of certain toxic chemicals must file annual reports of environmental releases of those chemicals with the EPA and state environ-

mental agencies. The EPA and the state agencies, in turn, make the information available to federal, state, and local governments and the public, including the citizens of communities surrounding covered facilities. *See* 42 U.S.C. § 11023(h). The requirements for the report are rather detailed. It must include, as to each facility at which the chemicals are manufactured, processed, or used, the name, location, and principal business activities of the facility; a certification of accuracy by responsible management officials; and, as to each covered toxic chemical known to be present at the facility:

> (i) Whether the toxic chemical at the facility is manufactured, processed, or otherwise used, and the general category or categories of use of the chemical.
>
> (ii) An estimate of the maximum amounts (in ranges) of the toxic chemical present at the facility at any time during the preceding calendar year.
>
> (iii) For each wastestream, the waste treatment or disposal methods employed, and an estimate of the treatment efficiency typically achieved by such methods for that wastestream.
>
> (iv) The annual quantity of the toxic chemical entering each environmental medium.

42 U.S.C. § 11023(g)(1)(C)(i)-(iv).

The reporting requirement of the Act applies to chemicals listed in a document titled "Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986," now known as the TRI. 42 U.S.C. § 11023(c). The original list, compiled by the Senate Committee on Environment and Public Works and incorporated by reference in the statute, included 309 individual chemicals and twenty categories of chemicals. Congress did not, however, limit the coverage of the Act to the original list, but stated that "the Administrator may by rule add or delete a chemical" based on statutory criteria, providing specifically that the Administrator may add a chemical when "in his

judgment, ... there is sufficient evidence to establish any one of the following":

> (A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous or frequently recurring, releases.
>
> (B) The chemical is known to cause or can reasonably be anticipated to cause in humans—
>
> (i) cancer or teratogenic effects, o
> (ii) serious or irreversible—
>
> (I) reproductive dysfunctions,
> (II) neurological disorders,
> (III) heritable genetic mutations, or
> (IV) other chronic health effects.
>
> (C) The chemical is known to cause or can reasonably be anticipated to cause, because of—
>
> (i) its toxicity
> (ii) its toxicity and persistence in the environment, of
> (iii) its toxicity and tendency to bioaccumulate in the environment,
>
> a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section [with qualifications].

42 U.S.C. § 11023(d)(2). EPCRA further provides that listing decisions shall be based on "generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies." *Id.*

Between 1986 and 1994, the Administrator made little use of the statutory power to revise the list, adding only sixteen chemicals and deleting twelve. In 1994, the EPA put forth a proposed rule adding 313 chemicals and chemical categories to the TRI. *Addition of Certain Chemicals: Toxic Chemical Release Reporting; Community Right-to-Know,* 59 Fed. Reg. 1788. After receiving comments, the EPA determined that there was insufficient evidence to include three of the chemicals. The EPA also deferred action on 40 chemicals and one chemical category for a future rulemaking and added a category containing 20 chemicals, three of which had been proposed for listing individually. With these revisions, the EPA issued a final rule adding 286 chemicals to the TRI. *Addition of Certain Chemicals: Toxic Chemical Release Reporting; Community Right-to-Know,* 59 Fed. Reg. 61,432.

II. Analysis

We review a grant of summary judgment *de novo* applying the same standards as those that govern the district court's determination. *Doe v. Gates,* 981 F.2d 1316, 1322 (D.C. Cir. 1993). Those standards require us to "determine whether there is on the record 'no genuine issue as to any material fact.' " *Id.* (quoting FED. R. CIV. P. 56(c)). In cases like the present one, where the district court was reviewing an agency rulemaking under the Administrative Procedure Act ("APA"), this means that we "review the administrative record directly." *Gas Appliance Mfrs. v. Dep't of Energy,* 998 F.2d 1041, 1045 (D.C. Cir. 1993). In so doing, we must determine whether the agency has complied with the APA; specifically, whether its actions have been arbitrary or capricious, including whether it has acted consistently with its own procedures; and whether its applications of its governing law have been reasonable. The present appeals call upon us to apply those tests to a complex of issues.

Prior to the administrative proceedings leading to the present litigation, the EPA established guidelines for the evaluation of chemicals which were candidates for addition to (or for that matter, deletion from) the TRI, known as the "HAZARD ASSESSMENT GUIDELINES FOR LISTING CHEMICALS ON THE TOXIC RELEASE INVENTORY," May 26, 1992 ("Guidelines"). In the proceedings which we review, the Administrator, at times acting through a contractor, generally applied the Guidelines. The Guideline-mandated analysis involves two steps: (1) "screening" and (2) "hazard evaluation."

In the initial screening stage, the EPA makes what it calls a "rapid initial assessment." Guidelines at 1. In this assess-

ment, the EPA seeks to evaluate whether the subject chemical is handled in a volume that can be expected to cross the statutory threshold for reporting, and to provide an initial categorization of the sufficiency of the toxicological effect of the chemical to be included in the inventory. *Id.* at 3. In the toxicological categorization, the EPA seeks to classify the candidate chemicals into three categories. Initially, the Guidelines named these categories "sufficient for listing," "may be sufficient for listing," and "insufficient for listing." *Id.* However, the EPA received comments on the Guidelines pointing out that this nomenclature was misleading and tended to confuse the screening process with the ultimate listing determination. Crediting the comments, the EPA, in the proposed rule, adopted the category titles of "high, medium, and low priority." 59 Fed. Reg. 1788, 1790.

In the second or "hazard evaluation" step, the Administrator undertook a chemical-specific review to determine whether the hazards presented by the specific candidate were in fact sufficient to support listing. Those chemicals classified in the low priority screening category at step one were no longer considered for listing. Guidelines at 3. As to the high and medium categories, the EPA conducted a review of the existing data to determine whether the chemical met one of the three criteria for listing established in EPCRA § 313: that is, whether the chemical "is known to cause or can reasonably be anticipated to cause" (1) significant adverse acute health effects in humans; (2) any of the following effects in humans: "cancer, teratogenic effects, or serious or irreversible reproductive dysfunctions, neurological disorders, hereditable genetic mutations, or other chronic health effects;" or (3) "a significant adverse effect on the environment." 42 U.S.C. § 11023(d)(2).

After subjecting its long list of chemicals to the two-step process, the Administrator came forward with the new list of 286 chemicals giving rise to the present controversy. Representatives of the chemical industry filed four lawsuits in the district court seeking to set aside and enjoin enforcement of all or part of the final rule. The district court, in a single memorandum opinion, granted summary judgment in favor of

the EPA in all four claims. In three of the cases, plaintiffs appealed to us for review. In this proceeding, we review those consolidated appeals.

In addition to several chemical-specific exceptions to the EPA's listing, Chemical Manufacturers Association ("CMA"), supported by the NMP Producers Group ("NPG") and Troy Corporation ("Troy"), raises four exceptions which are applicable to the entire list of additional TRI chemicals. First, appellants contend that the EPA acted contrary to law by basing its final listing decisions on toxicity criteria inconsistent with the criteria specified in EPCRA § 313. Second, in an argument intertwined with the first, they contend that the EPA acted arbitrarily and capriciously by listing chemicals without complying with its own guidelines and without presenting sufficient evidence and explanation to establish that the chemicals meet the statutorily listed criteria. Third, they contend that the EPA acted contrary to law by failing to consider the potential for human exposure from environmental releases for any of the chemicals which it listed based on chronic health effects. Finally, they argue that the EPA abused its discretion and acted arbitrarily and capriciously by failing to establish criteria for the consideration of exposure and failing to make adequate chemical-specific findings. Before considering the chemical-specific objections raised by appellants, we will dispose of each of the general objections.

A. *The General Objections.*

1. *The alleged inconsistency with statutory criteria and EPA guidelines.*

First, appellants argue that the EPA based its final listing decisions on toxicity criteria inconsistent with the criteria specified in EPCRA § 313. They point out that Congress set a high evidentiary standard for listing. In the subsection relevant to appellants' specific objection, the statute specifies that the EPA may add a chemical to the TRI based on chronic health effects only where there is "sufficient evidence" to establish that the chemical "is known to cause or can reasonably be anticipated to cause ... serious or irre-

versible ... chronic health effects" in humans. 42 U.S.C. § 11023(d)(2)(B)(ii)(IV). In urging that the EPA did not comply with these criteria, appellant CMA acknowledges the EPA's claim in its final rule that its senior scientists conducted a thorough hazard evaluation in determining by the weight of the evidence whether each chemical met the listed criteria. However, appellants go on to remind us that "[s]tating that a factor was considered ... is not a substitute for considering it." *Getty v. Federal Sav. & Loan Ins. Corp.,* 805 F.2d 1050, 1055 (D.C. Cir. 1986). They argue that we should not accept at face value the EPA's claim to have conducted the evaluation, but should make a "searching and careful inquiry" to determine if the agency did in fact consider the necessary factors. *Id.* (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe,* 401 U.S. 402, 416 (1970)). Appellants contend that our review of the record in the present case will reveal no support for the proposition that the EPA actually did conduct the hazard evaluation or weight-of-the-evidence assessment. They argue that this case is analogous to *AFL-CIO v. OSHA,* 965 F.2d 962 (11th Cir. 1992), in which the Eleventh Circuit considered an Occupational Safety and Health Administration rulemaking that established permissible exposure limits ("PELs") for 428 chemicals. In that case the Eleventh Circuit vacated all the PELs because OSHA inadequately articulated its reasons for their promulgation, merely "cit[ing] a few studies and then establish[ing] a PEL without explaining why these studies mandated" the agency's choice. *Id.* at 976.

CMA joins its argument that the EPA failed to comply with statutory standards with a contention that the Administrator also arbitrarily and capriciously failed to comply with the Guidelines. While this is conceptually separate from the statutory argument, CMA almost makes the two arguments one by contending that the Administrator telescoped the two-step Guideline analysis into the first step and made its decision to list a chemical based solely on what CMA calls the "overly broad toxicity criteria" applied in the first step of the Guidelines without either determining whether the toxicity of the chemical met the more demanding standards of the statute, or conducting the hazard analysis required in step

two of the Guidelines. Whether this is viewed as a failure to comply with the statute, or an arbitrary and capricious disregard of its own procedures, or both, if CMA is correct, then the district court erred in granting summary judgment in favor of the Administrator, and we must reverse. However, we hold that CMA is not correct.

In reaching this conclusion, we are guided by one of the cases relied upon by CMA. In *Citizens to Preserve Overton Park,* the Supreme Court held that a reviewing court is not "to substitute its judgment for that of the agency." 401 U.S. at 416. Instead, we only determine whether the decision was arbitrary and capricious, or otherwise contrary to law. In so doing, we examine whether the decision was based on the relevant factors and was not "a clear error of judgment." *Id.* In conducting this review, we show considerable deference, especially where the agency's decision rests on an evaluation of complex scientific data within the agency's technical expertise. *See, e.g., New York v. Reilly,* 969 F.2d 1147, 1152 (D.C. Cir. 1992). As we have said, we review scientific judgments of the agency "not as the chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality." *Ethyl Corp. v. EPA,* 541 F.2d 1, 36 (D.C. Cir.), *cert. denied,* 426 U.S. 941 (1976). This review of the factual determinations and policy decisions of an agency is governed by the APA, which directs us to set aside an agency's decision only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Moreover, insofar as the agency's determination amounts to or involves its interpretation of EPCRA, a statute entrusted to its administration, we review that interpretation under the deferential standard of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837 (1984). Under that standard, in order to hold erroneous the EPA's application of EPCRA in assessing the hazard risk, we would have to conclude that its interpretation either ran athwart a clear mandate of Congress, or was an unreasonable one. On the present record, we agree with the district court that appel-

lants have established neither unlawfulness, arbitrariness, capriciousness, nor a misinterpretation of the statute.

CMA's combined statutory/Guidelines argument begins with the proposition that the EPA departed from the high evidentiary standard set by Congress for listing and instead relied on the less demanding toxicity criteria at the first step of the Guidelines. Those criteria are broader than the statute's, and therefore, allowing them to govern is inconsistent with the statute. This argument would be a colorable one if the EPA had done just what appellants set forth and then listed chemicals based on the results of that activity, but that is not in fact what occurred. Instead, the broader toxicity screen was but the first step. It allowed the agency to make the above-described division of the chemicals into three parts. Only as to the chemicals found insufficient for listing did the agency stop with the toxicity screen. Granted, the agency's original misleading nomenclature may have made it seem that it had found the evidence as to the other categories of chemicals to be "sufficient" or that the evidence "may be sufficient," but that was merely nomenclature.

Indeed, as noted above, the EPA in the preamble to the proposed rule announced the renaming of the screening categories to the more descriptive terms "high, medium, and low priority." As to those chemicals which survived the first screening, whether classified as of "high or medium priority," or according to the earlier, misleading nomenclature, the EPA went on to conduct further proceedings designed to achieve compliance with the more rigorous demands of the statute. This further process is summarized in documents included in the administrative record. *See* 59 Fed. Reg. 1788, 1789-90. Although the exact applications of step-two analysis varied with the nature of the data available on specific chemicals, typically the EPA's contractor reviewed the data as to those chemicals surviving the first screen, and senior scientists of the EPA reviewed the contractor's report and the existing data in what was called a "HERD" review (for Health and Environment Review Division of EPA's Office of Pollution Prevention and Toxics). Only where a case-by-case review of each chemical in one of the two categories revealed

that "there was sufficient evidence to establish that the candidate chemical met the statutory criteria for addition to EPCRA § 313," *id.* at 1790, did the Administrator add the chemical to the TRI.

The *AFL-CIO v. OSHA* decision upon which appellants rely does not suggest a contrary result. As always, of course, the question of sufficiency of an agency's stated reasons under the arbitrary and capricious review of the APA is fact-specific and record-specific. That OSHA had not given sufficient reasons under a different statute applying a different (substantial evidence) standard of review on a different factual record would not compel a similar result on our part even if that case were a binding precedential decision from our own circuit, which, of course, it is not. More specifically, from the Eleventh Circuit's decision, it appears that OSHA's failure to give reasons in that case was systemic and purposeful. Here, as we have already noted, the EPA undertook an on-the-record review of the data as to each candidate chemical. While we might describe the record of some of the chemical-by-chemical reviews as "brief" or "sketchy," that would not necessarily be pejorative. That a standard, such as the statutory standard in this case, is strict, does not require that the evidence to meet it be voluminous, and especially does not require that it be voluminously recorded. CMA's generic challenge to the sufficiency of the listing process fails. Insofar as appellants contend that the record is insufficient with respect to specific chemicals, we will address those contentions in our chemical-by-chemical analysis *infra*.

2. *"Human exposure" objections.*

Appellants, led by NPG, object to the refusal of the EPA to assess the likelihood of exposure of humans to each candidate chemical before listing it on the TRI as a chemical that "is known to cause or can reasonably be anticipated to cause" the undesirable consequences listed in 42 U.S.C. § 11023(d)(2)(B) & (C). Appellants argue first that the EPA's failure to consider exposure is a violation of the statute, and, alternatively, that the EPA's adoption of the policy of nonconsidera-

tion amounts to an unlawfully adopted legislative rule. Neither argument is meritorious.

a. The statutory argument.

NPG, in an argument adopted by the other appellants as to other chemicals, contends that the EPA failed to comply with the governing statute in adding NMP (N-Methyl-2-Pyrrolidone) to the TRI. NMP is a general purpose solvent used in paint stripping, lube oil extraction, and several industrial and agricultural applications. According to appellants, and undisputed by the EPA, NMP is chemically and heat stable, and has a low vapor pressure (that is, does not readily change from liquid to gas forms), making inadvertent atmospheric release unlikely. NMP is expensive and easily recycled, so that facilities have both the economic incentive and technical capability to minimize release into the environment. If released into water, NMP, being readily biodegradable, quickly breaks down into harmless and naturally occurring substances. Therefore, appellants contend, human exposure to a release of the chemical in a sufficiently large quantity to result in an adverse effect is highly unlikely. Appellants assert that in the face of that unlikelihood, the EPA violated the statutory standard by listing NMP as a TRI chemical that "can reasonably be anticipated to cause" adverse reproductive and developmental effects under subsection (B).

Appellants' argument is that no matter how toxic NMP might be, Congress could not have contemplated that such a chemical would be listed under the TRI as no substance "can reasonably be anticipated to cause" adverse health effects in humans unless it is likely to come into contact with humans (e.g., escape) in sufficiently large quantities to produce such adverse effects. Indeed, NPG contends that the EPA's contrainterpretation fails at the first step of the *Chevron* analysis: that is, that it runs contrary to the unambiguously expressed intent of Congress. In the view of NPG, by using the quoted language of reasonable anticipation, Congress must have intended the EPA to consider likelihood of exposure in making listing decisions. We disagree.

It is not the case that the congressional language mandating listing of a chemical that "is known to cause or can reasonably be anticipated to cause in humans" the enumerated adverse effects unambiguously incorporates the likelihood of contact between humans and the chemical. A simple analogy quickly refutes NPG's argument that the language is unambiguous. Consider a herpetologist and a student contemplating a reptile imprisoned in a glass cage. The student asks, "Can that snake's bite reasonably be anticipated to cause death in humans?" The scientist replies, "Yes." The scientist is not commenting on the likelihood of the serpent's escape, only the toxicity of its venom. Concededly, his answer could be taken to mean, "Yes, it is likely that this creature will escape, bite someone, and kill them." But that is certainly not the unambiguous purport of his words. Even so is the statutory language of Congress. It is conceivable that Congress may have contemplated release in its phrasing of the standard, but that is certainly not unambiguously the case. Therefore, under *Chevron,* as the wording of the statute is at most ambiguous, the most that can be required of the administering agency is that its interpretation be reasonable and consistent with the statutory purpose. *Chevron,* 467 U.S. at 843. The EPA's interpretation of the statutory phrase is not only reasonable, but indeed well justified.

Although we might simply say that the agency's interpretation of the words of Congress is reasonable on its face, in the same way that the student might reasonably understand the scientist to be describing the venomous characteristics of the snake, the EPA offers us stronger and more specific support for its interpretations. Section 313(d)(2) of EPCRA has three subheadings. Subheading (A) provides for listing based on causation of "significant adverse acute human health effect at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases." 42 U.S.C. § 11023(d)(2)(A). Subheading (B), the one implicated in the NMP controversy, provides for listings based on causation in humans of cancer, teratogenic effects, or "serious or irreversible" listed adverse effects including the provision implicated here: "other chronic

health effects." 42 U.S.C. § 11023(d)(2)(B). Subheading (C) provides for listing based on causation, as a result of toxicity, environmental persistence, or bioaccumulation, of "a significant adverse effect on the environment...." 42 U.S.C. § 11023(d)(2)(C).

Neither (B) nor (C) contains the language found in (A) requiring that causation be under the described circumstances of "concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases." If that language were present in the other two subsections, NPG's argument that Congress intended the EPA to consider the likelihood of accidental escape or other contact with humans would be much stronger—perhaps irrefutable. Indeed, if that language were in the statute, the EPA might well have interpreted the statute as appellants desire. But the language is not in the relevant subsections of the statute. The EPA reminds us that "where Congress includes particular language in one section of the statute but omits it in another, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Keene Corp. v. United States,* 508 U.S. 200, 208 (1993) (internal punctuation and citation omitted). Thus, it is, to say the least, not unreasonable for the EPA to have concluded that Congress meant to include consideration of the likelihood of human exposure to chemicals governed by (A) but not those governed by (B) or (C). We therefore reject appellants' statute-based argument.

b. The administrative argument.

Correctly anticipating that we might hold the EPA's interpretation of (B) and (C) not inconsistent with the statute on the question of exposure, appellants put forth a fallback position. They argue that even if the interpretation was not substantively erroneous, its adoption was procedurally flawed.

The EPA expressed its policy regarding consideration of exposure in the preamble to its final rule. 59 Fed. Reg. 61,432, 61,440-42. In that preamble, the agency notes that it has received many comments concerning the issue of whether

the statutory criteria "include an implicit exposure and thus risk component." *Id.* at 61,441. The agency then states that it has "reviewed its positions in [that] area," and expresses its "agree[ment] with many of the commentators that there are limited circumstances under which it is appropriate ... to consider exposure factors for listing decisions under § 313(d)(2)." It lists the circumstances under which "exposure considerations are appropriate" as including only determinations under subsection (A), under subsection (B) for chemicals of "low to moderately low" toxicity, and those under subsection (C) "that are low or moderately ecotoxic" without certain described serious adverse effects.

NPG mounts a two-front assault on the statements regarding exposure analysis in the preamble. First, it contends that the EPA's position amounts to a change in policy without a reasoned justification. Second, it argues that the preamble is a legislative rule that had not been properly promulgated. On review, we uphold the district court's determination that the EPA's policy expressed in the preamble survives both challenges.

First, NPG argues that the EPA's exposure policy pronouncement in its preamble constituted a change in agency policy. Appellants remind us that an agency is obligated "not to depart without reasoned explanation from its prior conclusions." *National Ass'n for Better Broadcasting v. FCC,* 849 F.2d 665, 669 (D.C. Cir. 1988) (internal punctuation omitted). This is undeniably correct. As the Supreme Court stated in an analogous context, "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first place." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42 (1983). Were the EPA to abandon a long-held exposure policy and take a new direction we would, as urged, require a thorough explanation of its reasons for doing so. Yet, the EPA's pronouncement in its preamble of its exposure policy is not a change in course. With one exception, the EPA has consistently stated, as it does in this rulemaking, that it will consider exposure under subsection (B) only when the chemi-

cal was of "low to moderately low" toxicity. The EPA concedes that in one case the agency denied a petition to add inorganic fluorides to the list based in part on the insignificance of industrial releases of the chemicals. The agency stated, "EPA has concluded that potential exposure must be a consideration in making decisions to add chemicals to the list." 52 Fed. Reg. 20,142, 20,145 (May 29, 1987). While some inorganic fluorides cause serious chronic health effects at high doses, the EPA determined that the exposure required for such effects to occur was not likely to result.

Whatever the reasons for the EPA's determination in that case, the agency has long maintained that it would consider exposure under subheading (B) only for low toxicity chemicals. The inorganic fluorides petition was denied over ten years ago. Since that time, the agency has made several dozen listing and delisting decisions under EPCRA. The inorganic fluorides case was the only instance in which the agency articulated a policy contrary to the one explicated in this rulemaking. Under these circumstances we cannot say that the agency has departed from prior practice in a way that requires more explanation than was provided. If anything, the inorganic fluorides case constituted such a departure, but that is not before us.

We also reject NPG's argument that the exposure policy amounts to a legislative rule that should have been issued for notice and comment rulemaking under 5 U.S.C. § 553. The APA excludes "general statements of policy" from the requirements of section 553. The precise distinction between a general statement of policy and a legislative rule is often elusive, but in seeking it we have found useful a two-part inquiry put forth in *American Bus Ass'n v. United States,* 627 F.2d 525 (D.C. Cir. 1980). There we said that, first, a general statement is one that "does not impose any rights and obligations" and, second, that a policy statement generally leaves the agency and its decisionmakers free to exercise discretion. *Id.* at 529. *See also Community Nutrition Inst. v. Young,* 818 F.2d 943, 946 (D.C. Cir. 1987). A legislative rule, in contrast, is one that: (1) "supplements" a statute; (2) "effect[s] a change in existing law or policy"; or (3) "grant[s]

rights, impose[s] obligations, or produce[s] other significant effects on private interests." *National Family Planning & Reprod. Health Ass'n v. Sullivan,* 979 F.2d 227, 237-38 (D.C. Cir. 1992). *See also Batterton v. Marshall,* 648 F.2d 694, 701-02 (D.C. Cir. 1980); *Chamber of Commerce v. OSHA,* 636 F.2d 464, 469 (D.C. Cir. 1980). We will also consider an agency's characterization of its own actions, although that characterization is not dispositive. *See Telecommunications Research and Action Center v. FCC,* 800 F.2d 1181, 1186 (D.C. Cir. 1986). Applying these principles we conclude that the EPA's exposure policy was exempt from the notice and comment requirements of section 553. The EPA's exposure policy merely informed the public that the agency would exercise its discretion by considering exposure only for low toxicity chemicals. The EPA did not thereby curtail this discretion; it did nothing more than clarify its own position. The policy does not impose rights or obligations or bind the agency to a particular result. Chemicals of low toxicity may be added despite the policy, just as chemicals of moderate or high toxicity are not necessarily added because of it.

Having disposed of appellants' general objections to the rulemaking, we will address the chemical-specific objections in turn.

B. *The Chemical-Specific Objections*

1. *Diisocyanates category*

Isophorone diisocyanate ("IPDI"), 2,2,4 trimethylhexamethylene diisocyanate ("2,2,4 TMDI") and 2,4,4 trimethylhexamethylene diisocyanate ("2,4,4 TMDI") were listed on the TRI as part of a category of chemicals known as the diisocyanates category. The EPA listed the category, which contains twenty chemicals, under subheading (B) based on chronic pulmonary toxicity observed in studies of six of the chemicals. CMA argues that the statute does not permit the EPA to list chemical categories without demonstrating separately that each individual chemical meets the statutory criteria.

In order to prevail, CMA must show that the challenged agency decision is "arbitrary, capricious, an abuse of discre-

tion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The final rule will be upheld so long as the agency has "acted within its delegated statutory authority, considered all of the relevant factors, and demonstrated a reasonable connection between the facts on the record and its decision." *Ethyl Corp. v. EPA,* 51 F.3d 1053, 1064 (D.C. Cir. 1995). In matters of statutory interpretation, the court first asks "whether Congress has directly spoken to the precise question at issue." *Chevron,* 467 U.S. at 842. If so, the matter is settled, "for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute," *id.*, meaning one that is "reasonable and consistent with the statute's purpose." *Nuclear Information Resource Service v. NRC,* 969 F.2d 1169, 1173 (D.C. Cir. 1992). At that point, the court need only conclude that the agency's understanding of the statute is "a sufficiently rational one to preclude a court from substituting its judgment" for that of the agency. *Chemical Mfrs. Ass'n v. NRDC,* 470 U.S. 116, 125 (1985).

As discussed above, EPCRA provides that "[a] chemical may be added if ... there is sufficient evidence" that the chemical "is known to cause or can reasonably be anticipated to cause" one of three effects. 42 U.S.C. § 11023(d)(2). In the absence of a statutory definition, the EPA defined "chemical" to mean "an individual chemical" *or* "a category of chemicals." Based on this interpretation, the EPA determined that a category of chemicals may be added based on sufficient evidence that characteristics common to the category give rise to the effects.

It is not the case that the term "chemical" unambiguously excludes "chemical categories." In fact, Congress itself used the word "chemical" to include "categories of chemicals" when it stated that the original TRI included "those chemicals on the list in Committee Print Number 99-169 of the Senate Committee on Environment and Public Works." 42 U.S.C. § 11023(c). The list in Committee Print Number 99-169

included both individual chemicals *and* twenty chemical categories, including chlorophenols, glycol ethers, and thallium compounds. In light of the surrounding text, therefore, CMA cannot successfully challenge the EPA's interpretation under step one of *Chevron*. Moreover, we have no reason, considering the surrounding text, to require the agency to adopt CMA's interpretation of "chemical" at *Chevron* step two. To the extent that there is any ambiguity in the term, the EPA has put forth an eminently reasonable interpretation. We hold that the EPA may add chemical categories to the TRI without demonstrating separately that each individual chemical meets the statutory criteria.

CMA also challenges the listing decision on the grounds that there was insufficient evidence with regard to IPDI, 2,2,4-TMDI, and 2,4,4-TMDI because the EPA failed to take account of differences between diisocyanates. A diisocyanate compound is a molecule composed of two isocyanate groups, each consisting of a carbon atom double-bonded to both an oxygen atom and a nitrogen atom. Diisocyanates vary in their physical and chemical characteristics. A diisocyanate may be aromatic, meaning that each of the isocyanate structures is bonded to a benzene ring, or aliphatic, meaning that it has no benzene ring. Diisocyanates may be in liquid or solid form and exhibit a range of molecular weights and vapor pressures. Moreover, some diisocyanates have an isocyanate group "para," meaning opposite, from the methyl group in a 6-carbon benzene ring that is thought to be highly reactive. The EPA believes that diisocyanates are appropriately added as a category because "members of this category are structurally similar (i.e., each contains the diisocyanate functionality), they induce a similar toxic effect (chronic pulmonary irritation), and their toxicity is due to the diisocyanate portion of the molecule common to all members." 59 Fed. Reg. 61,432, 61,442.

The EPA's conclusion that toxicity is caused by the diisocyanate portion of the molecule, and so could reasonably be expected in IPDI, 2,2,4-TMDI, and 2,4,4-TMDI, is supported by the fact that the six studied chemicals exhibit the full range of the category's widely varying physical and chemical

properties and each exhibits toxicity. Four of the observed chemicals are aromatic; the remaining two are aliphatic. The two aliphatic diisocyanates, by definition, do not have the highly reactive isocyanate group in the "para" position. Two of the six chemicals are solids; four are liquids. The chemicals also vary with respect to molecular weight and vapor pressure. In light of the chemicals' varied physical and chemical properties, it was reasonable for the EPA to attribute the pulmonary irritation to a common characteristic: the diisocyanate portion of the molecule. This determination is precisely the type of technical, scientific judgment this court will not second-guess. *See Environmental Defense Fund v. EPA,* 598 F.2d 62, 83-84 (D.C. Cir. 1978) ("EPA, not the court, has the technical expertise to decide what inferences may be drawn from the characteristics of related substances").

CMA also argues that the EPA ignored relevant evidence by declining to consider a four-week study that exposed male rats to IPDI in which the researchers did not find signs of pulmonary irritation. We disagree. The agency declined to credit the four-week study because it was short-term. Agency guidelines require that generally a study is not considered valid unless it is conducted for 90 days or longer. Guidelines at 29. In addition, the study did not clearly address pulmonary irritation. The EPA was not required to consider a study that did not clearly address the matter at issue. *Portland Cement Ass'n v. Ruckelshaus,* 486 F.2d 375, 394 (D.C. Cir. 1973), *cert. denied,* 417 U.S. 921 (1974) ("[C]omments must be significant enough to step over a threshold requirement of materiality before any lack of agency response or consideration becomes of concern."). This is not a case in which the EPA has disregarded direct evidence for more speculative assumptions. *See, e.g., Leather Indus. of America, Inc. v. EPA,* 40 F.3d 392, 403 (D.C. Cir. 1994) (EPA's reliance on assumptions arbitrary where record contained contradictory information). Instead, the agency reasonably determined that the study was inapposite. We, therefore, conclude that the EPA's decision to list IPDI, 2,2,4-TMDI, and 2,4,4-TMDI was consistent with the statute and supported by sufficient evidence.

CMA also challenges the agency's listing decision because, it claims, the agency failed to justify its determination that pulmonary irritation as observed in the diisocyanate studies is "serious or irreversible" as required by EPCRA. The EPA did not include statements in its rulemaking to the effect that "pulmonary irritation is a serious health effect because breathing is an essential life activity." Such a statement was not required because the seriousness of the effects is self-evident. Appellants have raised similar challenges to the listing of four of the remaining chemicals. We find these challenges equally meritless. With regard to each chemical, the agency cited effects such as lesions in the liver, kidneys, and spleen 2,6—Dimethylphenol ("DMP"); severe gastrointestinal irritation 2-Bromo-2-nitropropane-1,3-diol ("Bronopol"); increased liver-to-body weight ratios and non-neoplastic pathological changes in the stomach 3-iodo-2-propynyl butyl carbamate ("IPBC"); and reductions in male fertility index and female fecundity index N-Methyl-2-pyrrolidone ("NMP"). The agency was not required to discuss in detail the seriousness of these effects.

2. Polychlorinated alkanes

The EPA listed a category of chemicals called "polychlorinated alkanes." A polychlorinated alkane consists of chains of hydrogen, carbon and chlorine atoms and is obtained through the partial chlorination of paraffin, olefin, or acetylene feedstock. The EPA restricted the category to short-chain polychlorinated alkanes, meaning those with carbon chain lengths of 10 to 13 carbon atoms ("C_{10}," "C_{11}," "C_{12}," and "C_{13}"). The EPA also restricted the category based on the number of chlorine atoms and the average chlorine content. Within these parameters, the EPA included polychlorinated alkanes manufactured from each of the different feedstock, although the EPA's listing decision relied exclusively on studies of polychlorinated alkanes manufactured from paraffins. Based on these studies, the EPA determined that polychlorinated alkanes can be anticipated to cause serious chronic health effects and significant adverse effects on the environment. *See* 42 U.S.C. § 11023(d)(2)(B), (C).

CMA challenges the rule on the ground that the data relating to chlorinated paraffins cannot support the listing of

"alpha-olefins," that is, alkanes derived from olefin feedstock. When a polychlorinated alkane is manufactured from the chlorination of a paraffin it contains compounds with varying carbon chain lengths; the chains may have 10 carbon atoms ("C_{10}"), eleven carbon atoms ("C_{11}"), etc. Chlorinated alpha-olefins, by contrast, are composed almost entirely of chains with twelve carbon atoms ("C_{12}"). CMA complains that the EPA improperly relied on studies of chlorinated paraffins without independently testing the C_{12} fraction of the chlorinated paraffin mixture, and that there is no evidence that the C_{12} components are responsible for the observed toxicity.

The EPA maintains that "the chlorination of paraffins and [alpha-olefins] results in products that do not differ significantly structurally, physically, or toxicologically." 59 Fed. Reg. 61,432, 61,461. In support, the EPA compares the structure of a polychlorinated alkane derived from an olefin to the structure of a polychlorinated alkane derived from a paraffin. The distinguishing feature between an alkane and an olefin is the double bond between the first two carbon atoms in an olefin. When the olefin is chlorinated, the chlorine atoms attach at the double bond and change the double bond to a single bond, thereby changing the olefin to an alkane and making it indistinguishable from the polychlorinated alkane derived from the paraffin. As a result,

> an [alpha-olefin] and a paraffin, both with the same chain length and both with the same degree of chlorination, are essentially identical structurally (especially if the degree of chlorination is high); the same isomers can be predicted for the chlorination of an [alpha-olefin] and a paraffin of the same chain length. The physical properties of chlorinated [alpha-olefins] and the corresponding chlorinated paraffins are therefore expected to be very similar.

Id. at 61,463.

As we have stated, the EPA was entitled to list a category of chemicals based on its reasonable determination that a member of the category caused a relevant ill effect and that other members of the category could be expected to exhibit the same characteristics. In the case of polychlorinated

alkanes, the EPA has adequately defended its conclusion that alpha-olefins can be expected to exhibit the same toxic characteristics as chlorinated paraffins. These judgments cannot be challenged except with substantial and weighty evidence to the contrary. In the absence of such evidence, we give considerable deference to the EPA's technical judgment. *Huls America Inc. v. Browner,* 83 F.3d 445, 453 (D.C. Cir. 1996). We hold that the EPA has presented sufficient evidence for its decision to list polychlorinated alkanes.

3. *Bronopol*

Bronopol is an antimicrobial agent registered with the EPA as a pesticide. The EPA listed Bronopol under subheading (B) as a chronic toxicant based on studies indicating that oral doses of the chemical produce severe gastrointestinal irritation in rats, mice and dogs. CMA challenges the listing decision on the ground that Bronopol produces acute, but not chronic, effects.

The categorization of the gastrointestinal irritation as chronic, rather than acute, is significant. Under subheading (A), an acute toxicant can be listed only if the chemical would produce the effects "at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases." 42 U.S.C. § 11023(d)(2)(A). As we discussed in part A.2, *supra,* this "exposure" requirement does not apply to subheading (B) listings. CMA argues that Bronopol is at worst an acute toxicant, is unlikely to be released with any frequency, and so could not have been added to the list under subheading (A).

The statute does not provide definitions for either "chronic health effects" or "acute health effects," but the agency has defined "chronic health effects" to be "any serious or irreversible adverse effects other than those specifically listed in section 313 ... that result from long-term exposure to a chemical." Guidelines at 29. "Acute health effects" are defined, apparently, as effects resulting from short-term exposure to a chemical. *See* 59 Fed. Reg. 61,432, 61,450. In other words, according to the EPA the type of effect is defined by the duration of exposure to the chemical rather

than the duration and progress of the irritation. In this case, the EPA determined that Bronopol presents both acute and chronic hazards because dogs given a single high dose of Bronopol exhibited irritation, identified by the EPA as acute toxicity, while rats given low doses over a two-year period also exhibited irritation, identified as chronic toxicity.

Under *Chevron,* the agency is entitled to deference in its reasonable interpretation of an ambiguous statute. We note, however, that the agency's approach to distinguishing chronic health effects from acute health effects is at least questionable. The common meaning of chronic is: "marked by long duration, by frequent recurrence over a long time, and often by slowly progressing seriousness: not acute." WEBSTER'S THIRD NEW INT'L DICTIONARY 402 (3rd ed. 1961). Acute, conversely, is defined as: "having a sudden onset, sharp rise, and short course ... opposed to chronic." *Id.* at 23. One would think that a chronic health effect would be a health effect of a lengthy duration, marked by frequent recurrence over a long time and often slowly progressing. An acute health effect would be one that went away quickly. One might read the statute to provide that when a chemical causes recurring and persistent health problems it may be added to the TRI regardless of the likely human exposure. When the chemical causes sudden, short-term health effects it would be added to the TRI only if the effects were likely to arise as a result of frequently recurring releases.

Of course, we will not reverse an agency's interpretation of a statute merely because it is not the most obvious one, particularly where the litigants have not clearly raised an issue of statutory interpretation. We address the issue only as it is relevant to our consideration of a challenge CMA has raised, namely the apparent inconsistency between the treatment of Bronopol and the EPA's 1994 decision to stay the reporting requirements for hydrogen sulfide. In that decision, the agency was considering the results of a 90-day inhalation study. Commenters had noted that some of the respiratory effects were acute, rather than chronic, because they would have undergone repair as soon as exposures ceased. The reversibility of the effects was in dispute be-

cause the scientists inexplicably "sacrificed" (killed) the animals before reversibility could be established. In response to the comments, the agency stated that "some of the respiratory effects cited in the proposal (inflammation, edema, cellular necrosis, hyperplasia, and exfoliation) were better characterized as acute effects than as chronic effects." 59 Fed. Reg. 43,048, 43,049. Even though each effect had been the result of 90-day exposure, some of the effects were sudden and short-term, that is "acute," while others were long-lasting and persistent, that is "chronic." The crucial question was whether the effect "would have undergone biological repair as soon as exposures ceased." 58 Fed. Reg. 63,500, 63,509. In other words, in that decision the agency did not consider the length of exposure to be critical; the distinction depended on the length of the effect. As a result, a particular effect could be either chronic or acute, not both as suggested by the agency in this case.

Absent further explanation of its different approaches in the two cases, the agency has acted arbitrarily and capriciously in listing Bronopol as a chronic toxicant. We, therefore, remand for further proceedings on this issue.

4. *IPBC*

IPBC is a white, crystalline solid used in products to prevent the growth of mildew and fungi. The EPA listed IPBC as a chronic toxicant based on two animal studies. A 90-day study observed increased liver-to-body-weight ratios in rats following exposure to IPBC. A two-year study revealed "non-neoplastic pathological changes" in the rats' stomachs. Troy argues that the EPA failed to review the studies seriously or to indicate why stomach irritation in rats would suggest a potential hazard to humans given differences in the species' anatomies. Troy also argues that the EPA violated its own Guidelines which, Troy argues, require the EPA to present evidence of chronic toxicity in two or more species of animals.

Although the agency's presentation of the evidence might have been more detailed, the EPA has described its methodology and the results of the studies and has adequately

justified the basis for its scientific conclusions. Nor can we credit appellants' argument that differences in the anatomies of rats and humans invalidate these conclusions. Although it is true that humans do not have an organ equivalent to the rat's forestomach, the EPA has explained that the rat's forestomach contains a tissue known as squamous epithelium and this tissue is also found in the human esophagus, pharynx, larynx, oral cavity, and ano-rectal junction. We hold that the EPA has presented sufficient evidence to list IPBC.

Moreover, the EPA has done all that the Guidelines required of it with regard to IPBC. The Guidelines state that

> chemicals with adequate evidence of chronic toxicity in humans and/or two species of animals are considered "sufficient for listing" and may be added to the section 313 list following study validation, whereas chemicals with suggestive evidence of toxicity in humans or animals may be sufficient for listing and are evaluated on a case-by-case basis for addition to the list.

Guidelines at 29. Although the categories "sufficient for listing" and "may be sufficient for listing" appear to conflate the toxicity screen with the final listing decision, as we noted above, this categorization served only to exclude chemicals found to be "insufficient for listing." The Guidelines require, and EPA conducted, further proceedings with regard to any chemicals not excluded at this first step. This further review satisfied the "case-by-case" evaluation required for chemicals, such as IPBC, with only suggestive evidence of toxicity based on one species of animal. We, therefore, conclude that the agency did not act contrary to its Guidelines in listing IPBC.

5. *NMP*

The EPA listed NMP, a general purpose solvent, under subheading (B) based on evidence of developmental and reproductive toxicity. NPG argues that the agency improperly relied on criteria less stringent than those imposed by EPCRA. In listing the chemical, the EPA relied on a document called the Lifecycle Analysis which was completed in 1993 as part of the EPA's review of the chemical under the Toxic Substances Control Act, 15 U.S.C. §§ 2601-92. Rather

than starting from scratch with a separate EPCRA assessment, the EPA piggy-backed the EPCRA listing on the TSCA analysis, which took over nine years, considered numerous studies on the hazards of NMP, and concluded that NMP presents a "significant risk of reproductive and developmental harm in humans." The EPA then reviewed the Lifecycle Analysis and, for purposes of EPCRA, made the finding that there was sufficient evidence of the requisite hazard. We hold that the EPA's reliance on the Lifecycle Analysis was not improper. For purposes of the present rule, the EPA reviewed the Lifecycle Analysis and concluded that there was sufficient evidence of toxicity to meet the listing criteria. In particular, the EPA noted reductions in the male fertility index and in the female fecundity index, increased incidence of dams with decreased corpora lutea, reduced litter size, reduced postnatal survival, and reduced pup weight. 59 Fed. Reg. 1788, 1823. This independent analysis of the available evidence satisfied the agency's requirements under EPCRA.

6. *DMP*

DMP is an organic compound used in the manufacture of a number of products. The EPA proposed to list DMP under subheading (B) based on chronic effects indicated in two studies, both conducted by the same researcher in the Soviet Union in the 1960s. In both studies, rats which were orally administered DMP produced histologic lesions in the liver and kidneys. As indicated in the contractor's report, but not in the EPA's proposed rule, the Interagency Testing Committee ("ITC") assigned low confidence to the studies because details of the experiments were not reported. In particular, the studies do not indicate (1) the strain of animals used; (2) the number of animals tested at each dose level; (3) the number of animals in the control group (one experiment only); or (4) the purity of the test article. EPCRA requires the agency to rely only on "generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies." 42 U.S.C. § 11023(d)(2). EPA Guidelines require it to base listing decisions on laboratory tests that "follow an acceptable standard protocol." Guidelines at 29. Any one of the flaws

indicated in the Soviet studies would render the study invalid under EPA regulations, *see* 40 CFR § 792.185 (1994), which require reports of studies to disclose, *inter alia,* the number of animals or other test organisms used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification, a description of the dosage, dosage regimen, route of administration, and duration, a description of all circumstances that may have affected the quality or integrity of the data, and the locations where all specimens, raw data, and the final report are to be stored.

The EPA concedes that the ITC had low confidence in the studies, but argues that additional data considered along with the Soviet studies presents sufficient weight of the evidence for listing DMP. 59 Fed. Reg. 61,432, 61,455. The EPA asserts that it also relied on a third study in which mice were exposed to DMP. The proposed rule does not refer to the mouse study. The contractor's report did not cite the mouse study, nor did the Integrated Risk Information System, an EPA data base containing consensus positions on the toxicity of chemicals. Rather, the HERD profile on DMP cites the Hazardous Substances Data Bank entry for DMP which, in turn, cites the mouse study. If the agency in fact relied on the mouse study its reliance is well hidden in the record. We hold that the EPA's reliance on tests that were largely undocumented violates the agency's Guidelines and evidences arbitrary and capricious agency action. We, therefore, remand for further proceedings.

III. Conclusion

We hold, therefore, that the agency has acted arbitrarily and capriciously in listing Bronopol without further explanation of its departure from agency precedent. We also hold that the agency has acted arbitrarily and capriciously in listing DMP based on studies that do not satisfy agency regulations. On both issues we remand to the district court with instructions to remand the case to the agency for further proceedings consistent with this opinion. As to all other issues we affirm the judgment of the district court.

So ordered.