IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE TRUMPETER SWAN SOCIETY et al.,	)	
Plaintiffs	)	
v.	)	Civ. Action No. 12-929 (EGS)
LISA P. JACKSON, in her official capacity as Administrator, United States Environmental Protection Agency,	)	
and	)	
ENVIRONMENTAL PROTECTION AGENCY,	)	
Defendants.	)	

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION UNDER RULE 12(B)(1) AND FOR FAILURE TO STATE A CLAIM UNDER RULE 12(B)(6)

I. INTRODUCTION

Plaintiffs argue for two results in this case that are not compatible with the language of the Toxic Substances Control Act ("TSCA" or "Act"). First, they assert that Defendant the U.S. Environmental Protection Agency ("EPA" or "Agency") must consider their submission of March 13, 2012 ("Second Submission") to be a petition under TSCA section 21, 15 U.S.C. § 2620, even though the Second Submission effectively requests the same action by EPA – regulation of lead shot and bullets – on the same grounds as a petition submitted by Plaintiff the Center for Biological Diversity ("CBD") on August 3, 2010 ("First Petition"), without presenting any significant, non-cumulative new information. The result of adopting Plaintiffs' position would be to enable CBD to escape the effect of section 21's jurisdictional, 60-day limitations period for judicial review, which this Court relied on in dismissing CBD's claim regarding the

First Petition as untimely. Second, Plaintiffs insist that EPA has statutory authority to regulate lead shot and bullets under TSCA despite TSCA section 3(2)(B)(v)'s exemption of shells and cartridges – of which shot and bullets are, by definition, integral components – from such regulation. *See* 15 U.S.C. § 2602(2)(B)(v). This interpretation would allow indirect regulation of shells and cartridges exempted from TSCA's scope under section 3(2)(B)(v), frustrating Congress's intent of barring EPA from regulating ammunition. In neither case do Plaintiffs address how their preferred interpretation of TSCA can be reconciled with the Act's plain language, and therefore EPA's Motion to Dismiss should be granted.

II. ARGUMENT

A. TSCA Section 21 Does Not Preclude EPA from Treating a Duplicative Second Submission As a Motion to Reconsider Rather than As a Section 21 Petition.

Contrary to Plaintiffs' arguments, TSCA does not provide any particular standard that EPA must apply in determining whether a submission fits within the scope of the ambiguous term "petition" in TSCA section 21. The course of action that EPA did take – examining whether the Second Submission presented any significant new, non-cumulative information or was instead simply a recapitulation of the First Petition – was well within the bounds of its statutory discretion. Most importantly, EPA's chosen approach, which has been endorsed by the only federal court to examine this issue, ensures that TSCA section 21's jurisdictional, 60-day time limit on obtaining judicial review of a petition denial cannot be undermined through the use of duplicative, successive submissions purporting to be new petitions under section 21.

1. EPA Acted Consistently with TSCA's Plain Language.

EPA's treatment of the Second Submission as a motion for reconsideration rather than as a TSCA section 21 petition was entirely consistent with the language of the Act. Plaintiffs'

argument that TSCA's text requires EPA to either grant or deny a petition, Pls.' Opp. at 6-8, misses the mark. It fails to address the substance of EPA's decision here: that the Second Submission was not a "petition" within the meaning of section 21 in the first place. Accordingly, Plaintiffs' view of EPA's obligations in handling such a "petition" is irrelevant. Rather, the Court's must focus on whether EPA permissibly treated the Second Submission as a motion to reconsider its denial of the First Petition.[1]

Plaintiffs seem to believe that EPA must consider any submission as a section 21 petition as long as it purports to be such a petition, is properly filed with EPA, and sets forth factual support, without the Agency exercising any judgment as to whether the submission properly fits within the scope of section 21. *See* Pls.' Opp. at 7, 11. However, as this Court recognized in CBD's suit regarding its First Petition, the term "petition" is ambiguous. *CBD v. Jackson*, 815 F. Supp. 2d 85, 92-93 (D.D.C. 2011). Just as in that prior case, nothing in the language of section 21 addresses the situation here or bars EPA from construing this ambiguous term to exclude a duplicative, successive submission following the Agency's denial of a section 21 petition, instead considering that second submission as a motion to reconsider the initial denial. Given section 21's silence on this issue, EPA's treatment of the Second Submission was well within the traditional discretion of agencies to "control the disposition of their caseload." *Nader v. FCC*, 520 F.2d 182, 195 (D.C. Cir. 1975); *see also GTE Serv. Corp. v. FCC*, 782 F.2d 263, 274 n.12

[1] Plaintiffs cite *GTE Service Corp. v. FCC*, 782 F.2d 263 (D.C. Cir. 1986), for the proposition that "[a]n agency abuses [its] discretion when its manner of proceeding significantly prejudices a party or unreasonably delays a resolution," Pls.' Opp. at 5-6, implying that that statement is relevant to this Court's review. However, *GTE Service Corp.* was referring to circumstances where agencies had failed to reach *any* decision on matters before them over the course of five to ten years. *Id.* at 274 & n.13 (citing, for example, *Nader v. FCC*, 520 F.2d 182, 206 (D.C. Cir. 1975)). Here, EPA made a decision on Plaintiffs' Second Submission; it is simply one with which they disagree.

(D.C. Cir. 1986) ("A number of cases . . ., both of the Supreme Court and this court, have emphasized the inherent powers of an agency to control its own docket.").

Moreover, Plaintiffs never explain how their proposed approach would prevent parties from "circumvent[ing] the limitations period" in section 21, the concern that led the Southern District of Texas to endorse the interpretation that the Agency adopted here in a similar 1990 case, *Walker v. EPA*. EPA Mot. to Dismiss, Ex. 5, October 15, 1990 *Walker* Opinion at 3. The best they do is to suggest that EPA should instead have treated the Second Submission as a new section 21 petition and denied it on the ground "that it was identical to a previous petition." Pls.' Opp. at 7. Plaintiffs assert that when this denial was then challenged in court, "the question of whether the petition was a new petition or a mere resubmittal would still be relevant in the court's review of the petition." *Id.* However, this proposed approach – unlike EPA's – is inconsistent with the language of section 21. Section 21 relevantly states that, in a civil action challenging the denial of a citizen petition,

> [i]f the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that . . . . there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment . . . the court shall order the Administrator [of EPA] to initiate the action requested by the petition.

15 U.S.C. § 2620(b)(4)(B). This description of the scope of a civil action under section 21, encompassing only the question of the "unreasonable risk" posed by an alleged toxic substance, does not provide a basis for EPA to argue that a court should not undertake the relevant inquiry into the merits of a rulemaking request because that request duplicates a prior petition. Undoubtedly Plaintiffs would oppose any attempt by EPA to present such an argument in the hypothetical they describe; the fact that Plaintiffs suggest here that EPA *could* raise this sort of issue in a section 21 suit simply reveals that they realize that otherwise their proposed approach

would eviscerate the 60-day time limit on section 21 actions by allowing a petitioner to restart the clock for such a suit through filing of a duplicative second petition. Contrary to Plaintiffs' representation, that would indeed be an "untenable result[]." Pls.' Opp. at 8.

Plaintiffs also do not accurately describe the ostensible negative consequences of EPA's approach. EPA will not be able to "choose who its litigation opponent shall be," Pls.' Opp. at 7 n.1. In the scenario Plaintiffs discuss, with 98 petitions filed successively, the initial petition filed will likely be the one that EPA responds to first, a "first-to-file" result that is a familiar feature of litigation in the United States. *See, e.g.*, *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001) (recognizing that the False Claims Act bars successive plaintiffs from bringing repetitive claims once a suit alleging a particular FCA violation has been filed). Moreover, regardless of who is first able to file a section 21 suit, any party interested in the outcome such a suit is free to file a motion to intervene as a plaintiff in that action pursuant to Federal Rule of Civil Procedure 24.

Even more importantly, EPA's approach does not "unreasonably and unfairly restrict[] the public's access to the rulemaking process," Pls.' Opp. at 8, or constitute an attempt "to evade TSCA's *de novo* review." *Id.* at 8 n.2. Instead, it simply ensures that if petitioners wish to bring suit under section 21 to pursue TSCA regulation, they must abide by the jurisdictional time limits that Congress placed on such actions. Here, the filers of the First Petition, including CBD, were "provided an opportunity to have [their] petition considered by the court in a de novo proceeding." 15 U.S.C. § 2620(b)(4)(A). This Court has held that they failed to take advantage of that opportunity within the jurisdictional time limits of section 21, and CBD cannot evade the effect of that ruling merely by filing a second submission effectively duplicating its First Petition.

2. EPA's Treatment of Past Submissions Is Not Relevant Here.

Plaintiffs discuss a number of instances that they assert represent EPA decisions to "accept[] and address[] subsequent petitions on the same topic, containing similar requests." Pls.' Opp. at 8. Fundamentally, such examples are beside the point. Just as EPA has the discretion to consider a submission not to be a new section 21 petition where it duplicates a previously filed petition, so too may the Agency decide that a second submission should be addressed on its merits as an independent petition. The existence of cases where EPA has taken the latter approach therefore is not inherently inconsistent with its treatment of the Second Submission, given that the facts of each such situation may differ in pertinent respects and neither the parties nor the Court are aware of the full circumstances of each of the examples cited by Plaintiffs.

3. EPA's Handling of the Second Submission Reflects the Usual Treatment of Such Attempts to Evade a Jurisdictional Time Limit on Judicial Review.

EPA's course of action here accords with the D.C. Circuit's approach under other environmental statutes where a party seeks to avoid the effect of a jurisdictional time limit by seeking agency reconsideration. For example, in *American Road & Transportation Builders Ass'n ("ARTBA") v. EPA*, 588 F.3d 1109 (D.C. Cir. 2009), the D.C. Circuit dismissed a suit by ARTBA challenging EPA's denial of its petition for amendment of two Clean Air Act ("CAA") rules regarding the regulation of vehicle engines. *ARTBA* explained that section 307(b) of the CAA, 42 U.S.C. § 7607(b), "simultaneously authorizes and limits judicial review of EPA activity" by allowing parties to file a petition for review of a regulation promulgated under the CAA, but only "'within sixty days from the date notice of such promulgation'" or, if the petition "'is based solely on grounds arising after such sixtieth day, then . . . within sixty days after such

grounds arise.'" *ARTBA*, 588 F.3d at 112 (quoting 42 U.S.C. § 7607(b)(1)). The court held that – since the petitioner had neither filed suit within 60 days of promulgation of the challenged rules, nor identified any later-arising grounds for its suit, and EPA had not reopened the issue on its own – ARTBA could not restart the 60-day clock to petition for review of those rules under CAA section 307 simply by filing a petition for their amendment and then challenging EPA's denial of that petition. *Id.* at 1113; *see also National Mining Ass'n v. U.S. Dept. of Interior*, 70 F.3d 1345, 1350-52 (D.C. Cir. 1995) (similar decision with respect to Surface Mining Control and Reclamation Act). Thus, the D.C. Circuit affirmed EPA's position that, where Congress has established a jurisdictional time limit for challenges to EPA action, that time bar precludes a party from getting a second bite at the apple by seeking agency reconsideration, regardless of whether the party has previously been able to litigate the relevant issue. Plaintiffs suggest no reason why they should nevertheless be able to restart the clock for judicial review under a similar provision in TSCA.

Similarly, in analyzing whether to treat the Second Submission as a new section 21 petition based on whether it presented "significant newly discovered, non-cumulative material," EPA acted in concordance with the longstanding precedent of both the D.C. Circuit and the Supreme Court that a party must present new evidence (or other changed circumstances) in order to obtain judicial review of the denial of a petition to reconsider. *ICC v. Bhd. of Locomotive Eng'rs*, 482 U.S. 270, 284 (1987); *see also Southwestern Bell Tel. Co. v. FCC*, 180 F.3d 307, 311 (D.C. Cir. 1999) ("[A] petition seeking review of an agency's decision not to reopen a proceeding is not reviewable unless the petition is based upon new evidence or changed circumstances."). In fact, in reaching that holding, the Supreme Court specifically sought to ensure that such reconsideration petitions do not operate as a means for "extending indefinitely

the time within which . . . agency orders can be judicially overturned." *Bhd. of Locomotive Eng'rs*, 482 U.S. at 279; *see also id.* at 281 (refusing to allow for the "perpetual availability of review" in the face of a statutory limitations period "by the mere device of filing a suggestion that the agency has made a mistake and should consider the matter again").

Meanwhile, TSCA provides no mooring for Plaintiffs' claim that the Act provides some other standard that EPA should have applied in determining whether to treat the Second Submission as a section 21 petition. They assert that "EPA applied a standard in excess of that established by TSCA," but never specify where such a standard might be found in the statute or what it might be. Pls.' Opp. at 13. In fact, it is *EPA's* approach that adheres to the plain text of section 21, by preventing a plaintiff from obtaining review outside of that provision's jurisdictional, 60-day window.

4. EPA's Treatment of the Second Submission Is Consistent with the Legislative History of TSCA Section 21.

EPA's treatment of the Second Submission likewise presents no conflict with TSCA's legislative history, which – to the extent it addresses the issue of duplicative petitions at all – favors EPA's approach. While Congress stated that it was enacting section 21 to "'help to protect against lax administration of'" TSCA, Pls.' Opp. at 12 (quoting Sen. Rep. No. 94-698, at 13 (1976)[2]), it at the same time placed an express, jurisdictional time limit on a petitioner's ability to file a civil action under section 21 in pursuit of that goal. Such general statements, cherry-picked by Plaintiffs from legislative documents, simply cannot override the actual text of

[2] Plaintiffs appear to have miscited two congressional reports regarding TSCA. To the best of EPA's knowledge, the citation to H.R. Rep. No. 79-313 at 711 (1976) (Committee print) at pages 11-12 of Plaintiffs' Opposition in fact refers to H.R. Conf. Rep. No. 94-1679, at 98 (1976), while the citation to "*Id.* at 169," Pls.' Opp. at 12, should refer to Sen. Rep. No. 94-698, at 13 (1976). The relevant pages from the two reports are attached as Exhibits 1 (conference report) and 2 (Senate report) to minimize confusion.

section 21, which clearly bars what Plaintiffs seek here: an opportunity to challenge EPA's denial of its section 21 petition more than 60 days after that denial occurred.

Furthermore, the Conference Report statement that section 21 is meant to prevent EPA from "avoid[ing] any judicial review," when read in full, provides no reason to second-guess EPA's treatment of the Second Submission. H.R. Conf. Rep. No. 94-1679, at 98 (1976) (quoted in Pls.' Opp. at 11). That statement clearly pertains only to the portion of section 21 authorizing a petitioner to file suit if EPA has not acted on a petition within 90 days:

> [T]he conferee's main interest is to make certain that any such petitioner receive timely consideration of such petition. By requiring the Administrator to act on any such petition within 90 days, the conferees will facilitate such a petitioner's right to seek judicial review should the Administrator deny the petition. Otherwise, the Administrator could avoid any judicial review simply by failing to take any action.

H.R. Conf. Rep. No. 94-1679, at 98 (1976). Here, EPA did provide timely consideration of the First Petition, but CBD itself failed to timely challenge the result of that consideration. Nothing in the legislative history of TSCA suggests that CBD should be able to try again at its convenience.

In fact, as explained in EPA's Motion to Dismiss, in the context of petitions to amend or repeal a rule, Congress did express concern about subjecting EPA "to constant petitions challenging rules or orders for which adequate judicial review is provided under section 19," and therefore allowed review of denials of such petitions only under the APA. H.R. Conf. Rep. No. 94-1679, at 99 (1976) (quoted in EPA Mot. to Dismiss at 13). Plaintiffs argue that the lack of a similar measure with respect to petitions for new rules indicates that Congress intended citizens to be able to submit such petitions without any constraint. However, that reading ignores the fact that Congress accomplished the same end by placing a time limit on the opportunity for judicial review under section 21. EPA does not seek to cut off judicial review of a petition for any

petitioner complying with that time limit, but section 21 does not provide any entitlement to *continue* seeking review of the same petition where the petitioner fails to file suit within the applicable 60-day window.[3]

Plaintiffs' citation to *Environmental Defense Fund v. Thomas*, 657 F. Supp. 302, 306 (D.D.C. 1987), is also unavailing. *See* Pls.' Opp. at 11. That decision declined to adopt EPA's proposed approach for calculating the expiration of the 60 days for filing an action under section 21 where it would "punish the intended beneficiaries of the statute's action-forcing mechanism," instead applying a different calculation method under which the plaintiff's suit was timely filed within the applicable 60-day window. *Id.* at 307. But this Court has already held that the action challenging EPA's denial of the First Petition was *not* timely filed, and as Defendant-Intervenors point out, Plaintiffs cannot relitigate its original suit. *See* NSSF Mem. in Support of Mot. to Dismiss at 12. *Thomas* recognized that where section 21's statutory time limit for review of agency action does apply, it is "'jurisdictional in nature.'" 657 F. Supp. at 306 (internal quotation marks and citation omitted). EPA's treatment of the Second Submission simply implements that jurisdictional provision as enacted by Congress, and is therefore compatible with *Thomas*.

Meanwhile, the D.C. Circuit decision reviewing *Thomas*, *Environmental Defense Fund v. Reilly*, 909 F.2d 1497 (D.C. Cir. 1990), is not on point here. At the time that case came before

[3] Plaintiffs' argument also glosses over the fact that Congress's rationale for providing that denial of *any* section 21 petition for amendment or repeal of a TSCA rule would be subject only to deferential APA review was that such a rule would already have been subject to judicial review under TSCA section 19, 15 U.S.C. § 2618. With respect to a petition for a new rulemaking, on the other hand, an initial section 21 action would in fact be the first chance for a court to review the subject matter of the petition, and in that situation Congress provided that less deferential *de novo* review would apply. It is consistent with this approach to think that Congress would accept that, once a petitioner has had a first bite at the apple in seeking review under section 21, subsequent attempts to pursue the same rulemaking request need not receive the same level of judicial scrutiny.

the D.C. Circuit, the parties had settled their substantive claims under TSCA section 21 through a consent decree that was entered by the district court. *Id.* at 1500. The main issue in *Reilly* was whether the plaintiffs could continue to pursue overlapping claims under the Administrative Procedure Act. *Id.* at 1501. The legislative history cited by *Reilly* and referred to by Plaintiffs on page 11 of their Opposition – the statement that section 21 was designed to "ensure that bureaucratic lethargy does not prevent the appropriate administration of this vital authority," *Reilly*, 909 F.2d at 1499 (quoting 122 Cong. Rec. 32,857 (1976) (statement of Sen. Tunney)) – was merely part of the court's background description of that provision. And *Reilly*'s discussion of section 21's application to petitions for rulemaking as opposed to petitions for amendment or repeal of an existing rule does not touch on how a *duplicative* rulemaking request should be treated. *See Reilly*, 909 F.2d at 1503 (cited in Pls.' Opp. at 11).

5. EPA's Reading of Section 21 Merits *Chevron* Deference.

Plaintiffs' arguments for why *Chevron* deference is not due to EPA's interpretation of the ambiguous term "petition" are cursory and unpersuasive. Plaintiffs mention that the Agency's interpretation was contained in a "single letter," was not arrived at through notice-and-comment rulemaking, and was not published in the Federal Register. *Id.* at 12-13. However, as noted in EPA's Motion to Dismiss, the D.C. Circuit has granted deference under *Chevron* to an agency interpretation contained in a letter, not arrived at through notice-and-comment rulemaking, and not published in the Federal Register.[4] *Cal. Valley Miwok Tribe v. United States*, 515 F.3d 1262, 1266 (D.C. Cir. 2008) (cited in EPA Mot. to Dismiss at 17); *see also NationBank of North Carolina, N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 254-55, 257 (1995) (deferring

[4] EPA did post the letter responding to the Second Submission online. *See* EPA, Section 21 Petitions Filed With EPA Since September 2012, http://www.epa.gov/oppt/chemtest/pubs/petitions.html#petition12 (last visited Sept. 19, 2012).

under *Chevron* to statutory interpretation contained in letter issued by Comptroller of the Currency in granting individual bank's application to sell annuities); *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1280 (D.C. Cir. 2004) (similar as to FDA letter decision). *California Valley*'s analysis was guided by the framework laid out by the Supreme court in *Barnhart v. Walton*, which held that an agency's statutory interpretation "is not automatically deprived of the judicial deference otherwise its due [under *Chevron*] because it was previously reached through means less formal than notice-and-comment rulemaking." 535 U.S. 212, 213 (2002) (cited in *Cal. Valley Miwok Tribe*, 515 F.3d at 1266). Instead of a narrow inquiry focusing on the use of particular rulemaking procedures, *Barnhart* identified "the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time" as relevant factors in determining "the appropriate legal lens through which to view the legality of the Agency interpretation . . . at issue." 535 U.S. at 222.

Most of these factors support the application of *Chevron* deference here. EPA was addressing an "interstitial" legal issue – the threshold question of what constitutes a "petition" for purposes of TSCA section 21, on which Congress was silent; the Agency has relevant expertise in administering section 21 over the course of the last 30 years; and this interpretation is central to the application of section 21 with respect to enforcement of the jurisdictional time bar on section 21 citizen suits. Finally, and perhaps most significantly, EPA previously relied on this same interpretation in the Walker matter as early as 1990, and that interpretation was upheld by a federal court. *See* EPA Mot. to Dismiss, Ex. 5, October 15, 1990 *Walker* Opinion. Furthermore, the Supreme Court's complementary analysis in *United States v. Mead Corp.*,

which focuses on the existence of indications that "Congress would expect the agency to be able to speak with the force of law," also supports deference to EPA's interpretation. Here, Congress delegated authority to EPA to resolve section 21 petitions, *see* EPA Mot. to Dismiss at 29-30, and in doing so gave no indication that it intended to disturb EPA's "inherent power[] to control its own docket." *GTE Serv.*, 782 F.2d at 274 n.12. Accordingly, EPA's reasonable interpretation of the statutory term "petition" should be given deference under *Chevron*.

B. EPA Did Not Act Arbitrarily in Determining that the Second Submission Should Not Be Treated as a Wholly New Section 21 Petition.

1. EPA Reasonably Focused on the Material Differences Between the Two Submissions.

EPA's ultimate decision that the Second Submission should be treated as a motion to reconsider was reasonable, given that it presented no significant, non-cumulative new information. Plaintiffs question EPA's conclusion that the Second Submission was "substantially the same" as the First Petition, asserting that EPA failed to focus on "what is contained in the petition." Pls.' Opp. at 15. However, Plaintiffs are incorrect: the Second Submission Denial Letter does discuss the contents of both the First Petition and Second Submission. *See* EPA Mot. to Dismiss, Ex. 4 at 1-2. EPA simply centered its analysis on whether there were any "*substantive*" differences between the two submissions, both as to the relief sought and the information presented by each. *Id.* at 1 (emphasis added).

The Agency's focus on the existence of actual relevant, material differences between the two submissions was reasonable; otherwise, a petitioner could create what Plaintiffs would apparently consider to be a new petition by making superficial alterations to the original petition, or by adding irrelevant but new evidence, even if the underlying substance were still essentially the same. Likewise, EPA was within its discretion to consider as truly "new" evidence only

those citations that actually post-dated the First Petition, since allowing a petitioner to present pre-existing studies as new evidence warranting reconsideration would provide an easy way for the petitioner to avoid any time limit on seeking judicial review: leave out one or two available studies from the first petition in case, so that if the window for judicial review expires one can simply add those in and present that petition as a "new" submission to restart the clock. *See Bhd. of Locomotive Eng'rs*, 482 U.S. at 279 (providing for judicial review of an agency denial of a petition for reconsideration based on alleged new evidence only so that the petitioner will have the opportunity to present "facts which, *through no fault of his own*, the original proceeding did not contain" (emphasis added)). The fact is, it may not be difficult for a petitioner who has failed to comply with a jurisdictional time limit on judicial review to come up with irrelevant or cumulative information to add as purported "new evidence" in order to create a "new" petition to an agency. EPA's consideration of whether the Second Submission contained "significant newly discovered, non-cumulative material" was a therefore a reasonable approach to forestalling such efforts. EPA Mot. to Dismiss, Ex. 4 at 2.

The four-factor analysis set forth in *Walker* is also relevant in highlighting the reasonableness of EPA's determination because it similarly addresses the problem of preventing repetitive submissions. While, as Plaintiffs note, that decision rested on "the content of each" submission being compared, the court did not occupy itself with identifying minor variations between the two submissions at hand, but rather zeroed in on the fact that the second submission was "a repetitive request for identical action on an identical issue long after the time period has expired," and thus its consideration as a new petition would allow the petitioner to evade the jurisdictional time limit of section 21. EPA Mot. to Dismiss, Ex. 5, October 15, 1990 *Walker* Opinion at 3. In doing so, the Southern District of Texas looked beyond the particular studies or

arguments contained in the submission to also examine who was filing it and when. While Plaintiffs express uncertainty as to "why the identity of the requesting parties should be a factor in determining if a petition is a resubmittal of a previous petition," Pls.' Opp. at 18, it seems fairly straightforward to think that where parties participate in the filing of a second rulemaking request not long after failing to timely contest the denial of a previous similar request, their purpose may be to evade the effect of section 21's jurisdictional time limit.

2. The Differences Between the Content of the Two Submissions Were Not Material.

Since the risks posed by lead shot and bullets are irrelevant if EPA lacks statutory authority to regulate them, the key substance of the First Petition and the Second Submission is their discussion of the statutory exclusion in TSCA § 3(2)(B)(v), 15 U.S.C. § 2602(2)(B)(v). EPA therefore reasonably concluded that the differences between the two submissions were not substantive because they did not present any new information on this point. EPA Mot. to Dismiss, Ex. 4, at 1. In other words, EPA did not find any basis to consider the Second Submission to be a new petition warranting a fresh look precisely *because* the essential substance of the two submissions – a request for EPA to regulate substances outside its statutory authority – was the same. *See* 75 Fed. Reg. 58,377, 58,378 (Sept. 24, 2010) ("[B]ecause of the absence of legal authority under TSCA to grant the petitioners' first request [for regulation of lead shot and bullets], this request was resolved without reaching the factual argument set forth by the petitioners."). That EPA would respond in the same way to each submission, *see* Pls.' Opp. at 15, is simply the product of that fundamental overlap.

Given EPA's focus on the fact that both the First Petition and Second Submission asked the Agency to regulate lead shot and bullets, Plaintiffs' citation of allegedly new details about the particular effects of lead ammunition and the effectiveness of existing regulations is irrelevant.

Plaintiffs refer to seven new sources relating to "population level effects on two species of wildlife (condors and eiders) from chronic lead poisoning," "the effectiveness of California regulations banning lead ammunition in the condor range on reducing blood lead levels in California condors, golden eagles and turkey vultures," and "additional evidence that spent lead ammunition is the primary route of lead exposure for California condors, bald eagles, golden eagles and turkey vultures." Pls.' Opp. at 21-22.[5] This purportedly new information, as EPA judged, fundamentally does not alter the identity between the core substance of the two submissions: a request for regulation lying outside EPA's statutory authority. Meanwhile, although Plaintiffs criticize EPA's statement that the Second Submission replicates large portions of the First Petition nearly verbatim, *see* Pls.' Opp. at 22, even a brief review of the two documents shows that whole paragraphs, pages, and even sections remain unchanged from one to the other, with only occasional insertions describing purportedly new information (along with

[5] Should the Court decide that these sources are relevant, it is worth noting that they include: a non-published, non-peer reviewed conference presentation (Finkelstein et al. 2011), EPA Mot. to Dismiss, Ex. 3, Second Submission at 80; and what appears to be a two-page policy paper that does not include any original research and relies on sources dating to 2009 at the latest (Raptor Research Foundation 2011), Second Submission at 98; *see also* Raptor Research Foundation White Paper (2011), http://www.raptorresearchfoundation.org/wp-content/uploads/2010/12/2011_lead_poisoning.pdf (last visited Sept. 19, 2012). It is not clear what the 2011 "Spectacled Eider Recovery" document attributed to the U.S. Fish and Wildlife Service is, since no citation is provided, Second Submission at 105, but an Internet search based on that title and date leads to a two-page pamphlet that also does not include any original research. *See* http://alaska.fws.gov/fisheries/fieldoffice/fairbanks/pdf/Specs.pdf (last visited Sept. 19, 2012). Plaintiffs' characterization of these documents as "new studies" may at best be called a charitable one. Pls.' Opp. at 21-22. The other studies mentioned – California Department of Fish and Game 2009, 2010; Kelly and Johnson 2011; and Kelly et al. 2011 – relate to the effects of lead on California condors, golden eagles, and turkey vultures, which were already the subject of 11 pages of discussion in the First Petition, largely duplicated in the Second Submission. *Compare* EPA Mot. to Dismiss, Ex. 1, First Petition at 20-31 *with* EPA Mot. to Dismiss, Ex. 3, Second Submission at 29-41; *see also* Pls.' Opp. at 22 (describing these studies as providing "additional evidence" regarding arguments presented in First Petition).

deletions of those portions of the First Petition relating to CBD's request for regulation of lead fishing gear). *Compare, e.g.*, EPA Mot. to Dismiss, Ex. 1, First Petition at 2-3, 14-31 *with* EPA Mot. to Dismiss, Ex. 3, Second Submission at 2-4, 23-41.

Also unavailing is Plaintiffs' argument that the Second Submission newly brought legislative history relating to TSCA section 3(2)(B)(v) to EPA's attention, and therefore the Agency should have considered it a wholly new petition. Pls.' Opp. at 20. As discussed *supra* at 14, to allow a party to submit 30-year-old information as "new" evidence would open the door for easy evasion of section 21's 60-day limitations period. It would also put the burden on *EPA* to investigate and expressly discuss any potentially relevant existing evidence in response to a petition in order to forestall the filing of future duplicative petitions, when TSCA section 21 states that it is the *petitioner* that must present "the facts which it is claimed establish" the need for regulation under TSCA. 15 U.S.C. § 2620(b)(1). Finally, Plaintiffs' argument assumes that when EPA denied the First Petition it was ignorant of the legislative history of the Act it administers, including the legislative history relating to the specific statutory provision that the Agency was construing. That EPA did not discuss that legislative history in the Federal Register notice explaining the basis for denying the First Petition is understandable given that the Agency considered the meaning of TSCA section 3(2)(B)(v) to be plain based on its text alone. *See* 75 Fed. Reg. at 58,378.

That the Second Submission narrowed the relief requested in the First Petition also did not make any material difference regarding the underlying goals and arguments contained in both submissions. Regardless of what caused "concern with the public" or was "raised in the press," Pls.' Opp. at 17, EPA did not rely on the broad scope of the relief requested in the First Petition as a basis for its denial. Plaintiffs' suggestion that "the scope of the relief requested was

a consideration of EPA in its decisionmaking process" on the First Petition, based solely on the statement in the letter denying that Petition that "EPA has determined that TSCA does not provide the Agency with authority to address lead shot and bullets as requested in your petition, due to the exclusion found in TSCA § 3(2)(B)(v)," *see* Pls.' Opp. at 17, strains credulity given EPA's explanation in the accompanying Federal Register notice that its denial was based on "a lack of authority to regulate lead in bullets and shot under TSCA" – with no mention of the particular relief requested by CBD. 75 Fed. Reg. at 58,378. In its essentials, the Second Submission was the same as the First Petition.

3. The Identity of the Parties Filing the Two Submissions, and Their Timing, Also Support EPA's Treatment of the Second Submission As a Motion to Reconsider.

Plaintiffs emphasize that 98 other parties have joined CBD in this second attempt to seek EPA regulation of lead shot and bullets under TSCA. *See* Pls.' Opp. at 18. However, Plaintiffs' focus is on the wrong end of the issue – which parties are *different*, as opposed to which are the *same*. As explained above, *supra* at 15, the *Walker* analysis appears to be concerned with the latter, as a way to detect whether there is some party seeking a second chance to obtain judicial review under section 21 after failing to abide by that provision's 60-day time limit with respect to its original petition. Here, that indeed seems to be the case, given CBD's central role in both submissions. *See* NSSF Mem. in Support of Mot. to Dismiss at 10. While it may be that CBD could "just as easily find another person or organization to re-file a petition on their own," Pls.' Opp. at 18 (emphasis omitted), the fact remains that it did not do so, and is now back again for a second time. Furthermore, the number of parties that CBD recruited to join it in this suit is irrelevant, especially given that their only evident level of participation is being listed on the petition and – as to six of them – on the Complaint.

Similarly, the timing of events leading up to this litigation suggests that it is a vehicle for CBD to re-file the suit that it was unsuccessful in bringing with respect to the First Petition. Plaintiffs incorrectly focus on whether some absolute amount of time elapsed between the two submissions. Pls.' Opp. at 19. However, as explained in EPA's Motion to Dismiss at 19, it is just as much the sequence of events – with the Second Submission filed just six months after CBD's claim regarding the First Petition was dismissed as untimely – that suggests this Court should view the Second Submission and this suit as an attempt to escape the effect of that initial dismissal.

C. TSCA Section 3(2)(B)(v) Exempts Lead Shot and Bullets from EPA Regulation Under TSCA.

1. In Order to Be Effective, the Plain Language of TSCA Section 3(2)(B)(v) Must Encompass the Constituent Components of the Exempted Items.

EPA's Motion to Dismiss explains that the exemption in TSCA section 3(2)(B)(v), 15 U.S.C. § 2602(2)(B)(v), for "any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code," must apply to shot and bullets because they are intrinsic components of shells and cartridges, two items that are subject to taxation under 26 U.S.C. § 4181. EPA Mot. to Dismiss at 22-23. Plaintiffs' cramped reading of these two provisions would render the TSCA exemption for firearms and ammunition without effect by allowing indirect regulation of shells and cartridges through regulation of their components, a problem that they never squarely confront.

Plaintiffs insist that the cross-reference to 26 U.S.C. § 4181 was merely meant to incorporate only the list of articles in that provision, and therefore TSCA section 3(2)(B)(v) does not bar the regulation of any individual constituent components of those articles . Pls.' Opp. at 25. However, Congress expressly did not prohibit the regulation under TSCA of "any article

listed" in section 4181. Instead, Congress exempted "any article *the sale of which is subject to the tax imposed by section 4181*." 15 U.S.C. § 2602(2)(B)(v). That language goes beyond a mere cross-reference to a list and implicates the question of what is actually being "subject to" taxation when 26 U.S.C. § 4181 is applied; therefore, contrary to Plaintiffs' contention, it *does* matter "whether the component parts are effectively taxed or not when a cartridge or shell is taxed under section 4181." Pls.' Opp. at 25. Shot and bullets, which are constituent components of shells and cartridges, are effectively subject to that tax.

EPA is not arguing that a bullet is the same as a cartridge, or a shot is the same as a shell, Pls.' Opp. at 24, but rather that TSCA's regulatory exemption for shells and cartridges must include their constituent components – shot and bullets. Otherwise everything from gun magazines to gun barrels would be fair game for EPA regulation under TSCA, leading to *de facto* regulation of guns and ammunition. Plaintiffs present no solution to this problem other than to argue it is not their intent to seek gun control. *See* Pls.' Opp. at 29 (suggesting that TSCA section 3(2)(B)(v) was meant only to prevent the use of "TSCA . . . as a back-door mechanism for gun control because it can harm people when fired from a gun"). But the plain language of 15 U.S.C. § 2602(2)(B)(v) offers no loophole for those with a particular intent; instead, it completely removes shells and cartridges from EPA's regulatory jurisdiction, and with them their constituent components of shot and bullets.

2. Even if TSCA Section 3(2)(B)(v) Is Ambiguous, EPA's Interpretation of the Provision Should Be Upheld.

Plaintiffs rely entirely on one piece of legislative history to establish the reasonableness of their interpretation of TSCA section 3(2)(B)(v): a House Report stating that the exemption for pistols, revolvers, firearms, shells, and cartridges "does not exclude from regulation under the bill chemical components of ammunition which could be hazardous because of their chemical

properties." H.R. Rep. No. 94-1341, at 10 (1976) (quoted in Pls.' Opp. at 27). However, that passage itself contains the rebuttal to Plaintiffs' arguments. They recognize that "Congress was clearly concerned that TSCA not be used as a mechanism for gun control," Pls.' Opp. at 28, yet their construction of TSCA section 3(2)(B)(v) would allow just that forbidden result by permitting EPA to regulate shells and cartridges under TSCA.

EPA's reading, on the other hand, provides a clear line between exempted and non-exempted chemical substances, while still allowing for regulation of "chemical components of ammunition" – *i.e.*, lead – when used in other contexts. Such regulation might indirectly affect shot and bullets if EPA were to impose a *general* restriction on the use of chemical substances such as lead, as in Plaintiffs' hypothetical regarding a ban on any sale of lead at all, Pls.' Opp. at 29, but that type of incidental effect is *not* the same as *specifically* regulating *integral constituent components* of shells and cartridges as such.[6] In the former case, the object of EPA's regulation would be a chemical substance as used in multiple contexts beyond ammunition; in the latter instance, EPA would be specifically targeting shot and bullets alone for regulation, effectively achieving a result prohibited by TSCA section 3(2)(B)(v) – the regulation of shells and cartridges. Thus, EPA's interpretation of TSCA section 3(2)(B)(v) merits deference as a "reasonable accommodation" of both Congress's express bar on regulating shells and cartridges under TSCA and the Act's general authorization for the Agency to regulate chemical substances and mixtures. *See Chevron*, 467 U.S. at 845 (internal quotation marks and citation omitted).

[6] Given that no such regulation banning all sales of lead has been proposed, it is not clear that Plaintiffs are correct in their assumption that EPA *would* have statutory authority to impose such a direct ban on the sale of lead specifically destined for use in ammunition. However, a ban on the sale of lead for other purposes could affect the overall supply of lead in a way that would indirectly impinge on the market for lead ammunition.

EPA's interpretation is not rendered unreasonable by the fact that the equivalent provision in the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2052(5)(E), expressly bars regulation by the Consumer Products Safety Commission of components of articles taxed under 26 U.S.C. § 4181. Indeed, Plaintiffs have it backwards. While the available legislative history does not indicate why, four years after enacting the CPSA in 1972, Congress chose to include somewhat different language in TSCA, its intent in both cases was clearly the same. *See* EPA Mot. to Dismiss at 26. Therefore, these two provisions should be read to have the same scope even if they do not use the exact same language. *Cf. FAIC Securities, Inc. v. United States*, 768 F.2d 352, 363 (D.C. Cir. 1985) (holding that statutes with "common purpose" should not "be construed to reach different results" even though their provisions regarding the same regulatory topic had different language); *McGlotten v. Connelly*, 338 F. Supp. 448, 453 (D.D.C. 1972) (interpreting two statutory provisions to have same coverage despite their differing language because Congress intended them to operate "in the same fashion") (cited in *Investment Annuity, Inc. v. Blumenthal*, 609 F.2d 1, 4 n.13 (D.C. Cir. 1979)). Otherwise, there would be regulation of items under TSCA that would be barred under the CPSA, and Plaintiffs offer no explanation of why Congress would desire such a result given that it expressed the exact same purpose in enacting both 15 U.S.C. § 2052(5)(E) and 15 U.S.C. § 2062(2)(B)(v).

3. EPA's Reading of TSCA Section 3(2)(B)(v) Merits *Chevron* Deference.

EPA's construction of the definition of "chemical substance," a key term in a statute that the Agency administers, merits *Chevron* deference. TSCA section 3(2)(B)(v)'s cross-reference to the Internal Revenue Code does not deprive EPA of its role as the delegated authority for implementing TSCA, including the definition of the term "chemical substance," as Plaintiffs argue. Pls.' Opp. at 31. It is clear from the parties' briefing that – if this Court determines that

the language of TSCA section 3(2)(B)(v) is ambiguous – the dispute in this case centers on Congress's intent in enacting section 3(2)(B)(v) itself; there is no question regarding the purpose of 26 U.S.C. § 4181. *See* EPA Mot. to Dismiss at 27-32 (explaining that EPA's reading of TSCA section 3(2)(B)(v) is reasonable given the text of that provision, its legislative history, and EPA's past practice in applying the provision); Pls.' Opp. at 27-30 (arguing that EPA's interpretation of TSCA section 3(2)(B)(v) is not consistent with Congress's intent based on the legislative history of that provision, without any discussion of the legislative intent behind 26 U.S.C. § 4181). While EPA disputes Plaintiffs' construction of the plain meaning of 26 U.S.C. § 4181, we seek *Chevron* deference only with respect to EPA's interpretation that the exemption in TSCA section 3(2)(B)(v) must encompass the constituent components of shells and cartridges as well as those items themselves, if the Court decides that shot and bullets are not subject to taxation under 26 U.S.C. § 4181.

Plaintiffs' only other argument on this front is that *Chevron* deference is not warranted where an agency is determining the scope of its own authority.[7] Pls.' Opp. at 30. However, they are simply incorrect that it is an open question in this Circuit whether *Chevron* deference applies in such a circumstance. The cases they cite for this proposition date back to 1988 and 1990, and have since been superseded. *See* Pls.' Opp. at 30 n.8. As the D.C. Circuit stated in *Transmission*

[7] The suggestion that the *de novo* review standard in section 21 has any role to play here, *see* Pls.' Opp. at 31-32, is not consistent with the applicable *Chevron* framework. The *de novo* standard applies to judicial review under *TSCA section 21* in determining if a rulemaking proceeding is warranted under TSCA because a petitioner has presented *factual* evidence as to whether, in this case, a chemical substance presents an "unreasonable risk to health or to the environment." 15 U.S.C. § 2620(b)(4)(B). It has no relevance to the question of whether EPA administers TSCA section 3(2)(B)(v), which is the threshold issue in deciding if the Agency's interpretation of that provision merits *Chevron* deference. *See* EPA Mot. to Dismiss at 9. In case there is any dispute, EPA does administer TSCA. *See* 15 U.S.C. § 2601(c) ("It is the intent of Congress that the Administrator shall carry out this chapter . . . .").

Access Policy Study Group v. FERC, "it is the law of this circuit that the deferential standard of *Chevron* . . . applies to an agency's interpretation of its own jurisdiction." 225 F.3d 667, 694 (D.C. Cir. 2000) (citing *Oklahoma Natural Gas Co. v. FERC*, 28 F.3d 1281, 1283-84 (D.C. Cir. 1994)).

Congress entrusted EPA with the task of administering TSCA, including application of the definition of "chemical substance" and its statutory exemptions. EPA arrived at a reasonable reading of TSCA section 3(2)(B)(v) in the course of fulfilling that duty, and if the Court determines that section 3(2)(B)(v) is ambiguous, that interpretation merits deference under *Chevron*.

III. CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiffs' complaint.

Respectfully submitted,

Dated: September 24, 2012

IGNACIA S. MORENO
Assistant Attorney General

/s/ Madeline Fleisher
MADELINE FLEISHER, MA Bar #670262
Environmental Defense Section
United States Department of Justice
P.O. Box 7611
Washington, D.C. 20044
Telephone: (202) 514-0242
Fax: (202) 514-8865
madeline.fleisher@usdoj.gov

OF COUNSEL:

ERIN S. KOCH
U.S. Environmental Protection Agency
Office of General Counsel
1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2012, I served the foregoing Reply with the corresponding Notice of Electronic Filing via CM/ECF system, which sent notification of such filing to all attorneys of record.

/s/ Madeline Fleisher__
MADELINE FLEISHER

Exhibit 1

94TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 94-1679

TOXIC SUBSTANCES CONTROL ACT

SEPTEMBER 23, 1976.—Ordered to be printed

Mr. STAGGERS, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 3149]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

* * * * * * *

JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The House amendment struck out all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment which is a substitute for the Senate bill and the House amendment. The differences between the Senate bill, the House amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clarifying changes.

FINDINGS, POLICY, AND INTENT

Senate bill (section 2)

Section 2(a) outlines Congressional policy underlying the Toxic Substances Control Act. Congress finds that: human beings and the environment are exposed to numerous chemical substances and mixtures; some of these may cause or contribute to an unreasonable risk of injury to health or the environment; and the effective regulation of such substances and mixtures in interstate commerce necessitates regulation of intrastate commerce as well.

Subsection (b) sets forth that it is the policy of the United States that adequate data on the health and environmental effects of such chemical substances and mixtures should be developed. Such data development should be the responsibility of those who manufacture and process such chemical substances and mixtures. Adequate authority should exist to regulate chemical substances and mixtures, but the exercise of such authority should not unduly impede technological innovation.

Subsection (c) contains a declaration of Congressional intent as to how the Administrator shall fulfill the responsibilities under this Act. The Administrator shall carry out this Act in a reasonable and prudent manner and consider the environmental, economic, and social impact of any action taken or proposed under this Act.

House amendment (section 2)

The House amendment is nearly identical to the Senate bill. However, the House amendment confines its data development man-

designed to protect against the risk to health or the environment, unless the rule (A) is identical to that issue under this Act, (B) is adopted under the authority of another Federal law, or (C) prohibits the use of such substance or mixture other than in its use in the manufacture or processing of other chemical substances or mixtures.

In addition to the specific exemptions from the preemption provision, the conference substitute provides a means whereby a State or political subdivision may seek an exemption from the preemptive effects of a Federal requirement in order to provide a higher degree of protection for their citizens than that provided by a requirement under this Act. The Administrator may, by rule, grant an exemption if compliance with the State or local requirement will not cause a violation of the applicable requirement under this Act, if the State or local requirement will provide a significantly higher degree of protection from the risk, and if the State or local requirement will not unduly burden interstate commerce.

JUDICIAL REVIEW

Senate bill (section 19)

The Senate's provision authorized pre-enforcement judicial review of any rule under the Act or an order issued under section 5(c). Any rule promulgated under section 3(b), 5 or 6 shall not be affirmed unless supported by substantial evidence on the record taken as a whole.

House amendment (section 19)

The House provision authorizes pre-enforcement judicial review of rules issued under section 4, 5 or 6(a). Such rules shall not be affirmed unless supported by substantial evidence based on the record taken as a whole.

Conference substitute (section 19)

Section 19 of the conference substitute provides for judicial review in the courts of appeals of the United States for certain rules promulgated under the Act. The jurisdiction for preenforcement review and review of determinations of the Administrator relating to cross-examination is exclusively vested in such courts. Not later than 60 days after the date of promulgation of a rule under section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(c), or 8 any person may file a petition for judicial review of the rule in the appropriate U.S. court of appeals.

The section specifically defines the rulemaking record to include the rule being reviewed (which would include the statement of basis and purpose pursuant to section 553(c) of title 5, United States Code), any transcript required to be made of an oral presentation, any written submission of interested parties, and any other information which the Administrator considers to be relevant to the rule and with respect to which the Administrator published a notice in the Federal Register identifying the information on or before the date of the promulgation of such rule. In addition certain findings and statements required to be made with respect to specific rules must also be included in the rulemaking record. In the case of a rule under section 4(a), the finding required by that section must be included in the record. In the case of a rule under section 5(b)(4), the finding required to be made

by that section must be included in that record. In the case of a rule under section 6(a), the finding required by section 5(f) or section 6(a), as the case may be, and the statement required by section 6(c)(1) must be included in the rulemaking record.

The section includes authority for the submission of additional data and oral or written views and for the modification of the rule being reviewed.

Generally section 706 of title 5, United States Code, applies to review of a rule under this section. However, in the case of review of a rule under section 4(a), 5(b)(4), 6(a) or 6(e), the bill provides that the courts shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole. This provision is in lieu of paragraph 2(E) of section 706 of title 5. It is the intent of the conferees that the traditional presumption of validity of an agency rule is to remain in effect. The conferees recognize that in rulemaking proceedings such as those contained in this bill, which are essentially informal and which involve both determinable facts and policy judgments derived therefrom, the traditional standard for review is that of "arbitrary and capricious". However, the conferees have adopted the "substantial evidence" test because they intend that the reviewing court focus on the rulemaking record to see if the Administrator's action is supported by that record. Of course, the conferees do not intend that the court substitute its judgment for that of the Administrator.

Further, in the case of review of a rule under section 6(a), the court shall set the rule aside if it finds that action by the Administrator in excluding or limiting cross-examination or rebuttal submissions precluded disclosure of disputed issues of material fact necessary for a fair determination of the rulemaking proceeding taken as a whole. Also, in review of such rules, section 706(2)(D) will not apply with respect to review of the Administrators actions respecting limitations or exclusions of cross-examination or rebuttal submissions, and review of such actions can occur only during preenforcement judicial review.

Section 19 also provides that the court may not review the contents and adequacy of any statement required to be made pursuant to section 6(c)(1) or any statement of basis and purpose required by section 553(c) of title 5 of United States Code to be incorporated in the rule except as part of a review of a rulemaking record taken as a whole.

Section 19 provides that in a judicial review proceeding under this section the court may award the costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. In addition, in any review of such an action the Supreme Court may also award such costs of suit and reasonable fees.

The section also provides that the remedies provided in section 19 shall be in addition to, and not in lieu of, any other remedies provided by law. This provision should not be construed, however, to negate the provision in this section which specifically provides that the United States courts of appeals shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) if any district court of the United States would have had jurisdiction of such an action but for the provisions of this section.

97

CITIZEN'S CIVIL ACTIONS

Senate bill (section 20)

Subsection (a) authorizes any person to commence a civil action in specified district courts against (A) any person including the United States or any governmental agency or instrumentality alleged to be in violation of this Act or any rule or order prescribed under sections 4, 5, or 6(a). Such suits may also be brought to compel the Administrator to perform any nondiscretionary act or duty.

Subsections (b), (c), and (d) specify certain procedural provisions. No action may begin until the Administrator and the alleged violator have received proper notice of the alleged violation. If the Administrator has instituted a civil action against an alleged violator to compel compliance, then no action may be brought under this section. However, if the Administrator does not commence such action until after the person bringing the citizen's civil action has notified the alleged violator of intention to sue under this Act, then the person who gave such notification may intervene in the suit brought by the Administrator. The Administrator may intervene in any civil action under this section to which the Administrator is not a party. The court may award the costs of the suit and reasonable fees for attorneys and expert witnesses. The court may also consolidate two or more civil actions involving the same defendant, the same issues, or the same alleged violations when appropriate.

House amendment (section 20)

The House amendment contains the same provision as the Senate bill.

Conference substitute (section 20)

The conference substitute contains the provision included in both the Senate bill and the House amendment with a clarification that citizen's civil actions may also be brought for violations of an order under section 5 or 6.

CITIZENS' PETITIONS

Senate bill (section 21)

Section 21 of the Senate bill authorizes any person to petition the Administrator to issue a rule or order or to take other action for the purpose of protecting against an unreasonable risk of injury to health or the environment. If the petition is denied or not acted upon within 90 days, the petitioner may bring a civil action in a United States district court to compel the Administrator to initiate the requested action. If the petitioner demonstrates by a preponderance of the evidence in a *de novo* proceeding that the action requested in the petition conforms to the applicable requirements of the Act, the court shall order the Administrator to initiate the requested action.

House amendment (section 21)

The House amendment authorizes any person to petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 5(c), or 6(a). If the petition is denied, the petitioner may file a civil action to compel the Administrator

to initiate the rulemaking proceeding. If the petitioner requests the issuance of a rule under section 4, 5(c), or 6(a) (as opposed to the modification or repeal of such a rule) the petitioner has an opportunity for a *de novo* proceeding before the court. If the petitioner makes the requisite showings for the applicable provision, the court must order the Administrator to initiate the requested action unless the court finds that the failure of the Administrator to initiate the requested action was not unreasonable.

Conference substitute (section 21)

The conference substitute authorizes any person to petition the Administrator to initiate a proceeding for the issuance, amendment or repeal of an action under section 4, 5(e), 6, or 8 of the Act. It should be noted that a petition under this section may be used to initiate a proceeding under section 5(f) since a proceeding under that section is for the issuance of a rule under section 6(a). The Administrator must grant or deny any petition under this section within 90 days after it is filed.

The conference substitute thereafter provides for different judicial review of the Administrator's denial of a petition, depending upon whether such petition seeks the issuance of a rule or order or the amendment or repeal of an existing rule or order.

The substitute affords greater rights to a person petitioning for the issuance of a rule or order because in such a situation the Administrator will not previously have addressed the issue by rule or order. If the Administrator denies or fails to respond to a petition for the issuance of a rule or order, the petitioner may commence a civil action in a United States district court to compel the Administrator to take the action requested in the petition. In the court, the petitioner is entitled to a *de novo* proceeding. If the petitioner demonstrates to the court by a preponderance of the evidence that there is an adequate basis for the issuance of the rule or order requested, the court shall order the Administrator to initiate the requested action.

The court may defer requiring the Administrator to take the requested action if it finds that the extent of risk of injury to health or the environment alleged by the petitioner is less than those risks of injury which the Administrator is addressing under this Act and there are insufficient resources to do both. If a deferral is granted, the conferees anticipate that the Administrator may seek extensions as needed.

The conference substitute provides different treatment for review of petitions for amendment or repeal of rules or orders, because the Administrator already will have addressed the general subject matter in an existing rule or order and the Administrator's determination will have been subject to review under section 19 of this Act. Therefore, the conferee's main interest is to make certain that any such petitioner receive timely consideration of such petition. By requiring the Administrator to act on any such petition within 90 days, the conferees will facilitate such a petitioner's right to seek judicial review should the Administrator deny the petition. Otherwise, the Administrator could avoid any judicial review simply by failing to take any action.

The conferees believe that a petition for amendment or repeal of an existing rule or order should contain newly discovered, noncumulative

material which was not presented for the Administrator's consideration in promulgating the rule or order. Failure to include such information would be an adequate basis for denying the petition.

At the same time, the conferees do not intend that the Administrator be subjected to constant petitions challenging rules or orders for which adequate judicial review is provided under section 19. Therefore, if the Administrator denies a petition to amend or repeal an action under section 4, 5(e), 6, or 8, the conference substitute permits review of such denial only under the Administrative Procedure Act.

NATIONAL DEFENSE WAIVER

Senate bill (section 22)

The Senate bill directs the Administrator to waive compliance with any provision of this Act upon the request of the Secretary of Defense and a determination by the President that the interest of national defense requires such a waiver. The Administrator shall maintain a written record of the basis for the waiver. In addition, the Administrator shall publish notice of the waiver in the Federal Register, unless the Administrator determines, upon request from the Secretary of Defense, that such publication is contrary to national defense interests, in which case, the Administrator shall notify the Armed Services Committees of the Senate and the House of Representatives.

House amendment (section 22)

The House amendment is similar to the policies and procedures of the Senate bill except that only the President, not the Secretary of Defense, is authorized to request a national defense waiver from the Administrator and to request that publication of the waiver not be placed in the Federal Register for national defense reasons.

Conference substitute (section 22)

The conference substitute includes the provision of the House amendment.

EMPLOYEE PROTECTION

Senate bill (section 23)

Section 23 of the Senate bill provides protection for employees who cooperate with the Administrator in carrying out the Act. The provision prohibits any employer from discharging any employee or otherwise discriminating against the employee with respect to compensation, terms, conditions, or privileges of employment because the employee commenced, caused to be commenced, or is about to commence a proceeding under the Act. Protection is provided for employees who have testified or are about to testify in any proceeding under the Act or who have assisted or participated in a proceeding or any other action to carry out the purposes of the Act. The Secretary of Labor shall conduct investigations of alleged violations and issue orders to require any person who violates the prohibitions to take affirmative action to remedy any such violation. Any person adversely affected by an order of the Secretary may obtain judicial review of the order in the United States court of appeals for the circuit in which the violation allegedly occurred. The Secretary is authorized to enforce the orders in the dis-

Exhibit 2

Calendar No. 668

94TH CONGRESS
2d Session
SENATE
REPORT
No. 94-698

TOXIC SUBSTANCES CONTROL ACT

REPORT

OF THE

SENATE COMMITTEE ON COMMERCE

ON

S. 3149

together with

ADDITIONAL VIEWS

TO REGULATE COMMERCE AND PROTECT HUMAN HEALTH AND THE ENVIRONMENT BY REQUIRING TESTING AND NECESSARY USE RESTRICTIONS ON CERTAIN CHEMICAL SUBSTANCES, AND FOR OTHER PURPOSES

MARCH 16, 1976.—Ordered to be printed

U.S. GOVERNMENT PRINTING OFFICE
57-010 WASHINGTON : 1976

CONTENTS

	Page
Purpose and brief description	1
Background and needs	3
Description	6
Responses to arguments	10
Legislative background	13
Section-by-section analysis	14
Sec. 1. Short title and table of contents	14
Sec. 2. Findings, policy, and intent	14
Sec. 3. Definitions and exclusions	14
Sec. 4. Testing of chemical substances and mixtures	15
Sec. 5. Premarket notification of chemical substances	17
Sec. 6. Regulation of hazardous chemical substances and mixtures	20
Sec. 7. Imminent hazards	21
Sec. 8. Reporting and retention of information	21
Sec. 9. Relationship to other laws	23
Sec. 10. Research, collection, dissemination, and utilization of data	23
Sec. 11. Inspections and subpoenas	24
Sec. 12. Exports	24
Sec. 13. Entry into customs territory of the United States	25
Sec. 14. Disclosure of data	25
Sec. 15. Prohibited acts	25
Sec. 16. Penalties	26
Sec. 17. Specific enforcement and seizure	26
Sec. 18. Preemption	27
Sec. 19. Judicial review	27
Sec. 20. Citizen's civil action	28
Sec. 21. Citizen's petitions	29
Sec. 22. National defense waiver	29
Sec. 23. Employee protection	29
Sec. 24. Studies	30
Sec. 25. Administration of act	30
Sec. 26. Authorization for appropriations	31
Sec. 27. Annual report	31
Changes in existing law	32
Estimated costs	32
Record votes in Committee	32
Text of S. 3149 as reported	33
Agency comments	73
Additional views of Mr. Baker	89

Calendar No. 668

94TH CONGRESS 2d Session | SENATE | REPORT No. 94-698

TOXIC SUBSTANCES CONTROL ACT

MARCH 16, 1976.—Ordered to be printed

Mr. MAGNUSON, from the Committee on Commerce, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 3149]

The Committee on Commerce having considered the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, reports favorably thereon and recommends that the bill do pass.

PURPOSE AND BRIEF DESCRIPTION

The purpose of S. 3149 is to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances. The bill is designed to fill a number of regulatory gaps which currently exist. They are:

1. PREMARKET REVIEW

While certain environmental health statutes may be used to protect health and the environment from chemical substances, only pesticides, drugs, and food additives undergo premarket scrutiny prior to first manufacture. The Clean Air Act (77 Stat. 392), the Federal Water Pollution Control Act (66 Stat. 755), the Occupational Safety and Health Act (84 Stat. 1596), and the Consumer Product Safety Act (86 Stat. 1207), do not provide for this type of premarket scrutiny.

2. DIRECT REGULATION OF CHEMICALS

While air and water laws authorize limitations on discharges and emissions, the Occupational Safety and Health Act authorizes the establishment of ambient air standards for the workplace, and the Consumer Product Safety Act authorizes standards with respect to

(4) Citizens are authorized to bring suits to enjoin certain violations and to require the Administrator of EPA to perform his mandatory duties. A citizens' petition provision is also provided whereby citizens may receive judicial review of petitions to EPA which were denied or not acted upon.

BACKGROUND AND NEEDS

The last century has witnessed the ever-accelerating growth of the chemical industry. Sales now exceed $100 billion a year. This industry has developed a vast new array of chemicals. In fact, it is estimated that there are presently 2 million recognized chemical compounds in existence with nearly 250,000 new compounds produced each year. While most of these compounds will never be commercialized, the Environmental Protection Agency estimates that approximately 1,000 new chemicals each year will find their way into the marketplace and subsequently into the environment through use or disposal.

As the industry has grown, we have become literally surrounded by a man-made chemical environment. We utilize chemicals in a majority of our daily activities. We continually wear, wash with, inhale, and ingest a multitude of chemical substances. Many of these chemicals are essential to protect, prolong, and enhance our lives. Yet, too frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers.

In 1971, the Council on Environmental Quality in a report entitled "Toxic Substances" concluded that regulatory mechanisms to control toxic chemicals were "inadequate." This report was the impetus for the original Toxic Substances Control Act legislation.

After 15 days of hearings and extensive analysis over the last 5 years, the Toxic Substances Control Act has evolved into a comprehensive measure to protect the public and the environment from exposure to hazardous chemicals. The legislation would assure that chemicals receive careful premarket scrutiny before they are manufactured or distributed to the public. This provision would end the present situation where chemicals can be marketed without notification of any governmental body and without any requirement that they be tested for safety. Thus, this provision would no longer allow the public or the environment to be used as a testing ground for the safety of these products.

In a recent speech supporting toxic substances control legislation, Russell E. Train, the Administrator of the Environmental Protection Agency, pointed out that—

> Most Americans had no idea, until relatively recently, that they were living so dangerously. They had no idea that when they went to work in the morning, or when they ate their breakfast—that when they did the things they had to do to earn a living and keep themselves alive and well—that when they did things as ordinary, as innocent and as essential to life as eat, drink, breathe or touch, they could, in fact, be laying their lives on the line. They had no idea that, without their knowledge or consent, they were often engaging in a grim game of chemical roulette whose result they would not know until many years later.

Dr. Train's view is a reflection of the fact that in the last few years the list of commonly utilized and widely dispersed chemicals that

such a risk is presented. If the agency agrees that such a risk is presented, it must determine if the risk can be prevented or reduced to a sufficient extent by action taken under the law administered by it.

If the other Federal agency issues the order declaring that there is no unreasonable risk or initiates action under the other law, the Administrator may not take action under this authority to prevent the unreasonable risk.

With respect to other laws administered by the Administrator, the Administrator is directed to coordinate his actions with actions taken under those Federal laws and to use the authority contained in those laws unless this authority would be more appropriate.

In order to insure that information is gathered and premarket notification takes place, the restriction on the Administrator's authority would not apply to section 4 (testing), section 5 (premarket notification), or section 8 (reporting and information gathering).

6. CITIZENS PARTICIPATION

The bill contains a citizen's suit provision which authorizes suits against the Administrator where he has failed to perform a nondiscretionary duty and against others who are alleged to be in violation of sections 4 (testing), 5 (premarket notification), or 6(a) (restrictive rules). The provision is modeled after similar provisions in the Safe Drinking Water Act (88 Stat. 1660) Consumer Product Safety Act, Clean Air Act, Federal Water Pollution Control Act, and Noise Control Act.

In addition, citizens are authorized to petition the Administrator to take action the purpose of which is to protect against unreasonable risks of injury to health or the environment. If the Administrator fails to take action within 90 days on such a petition, or denies it, judicial review of the denial or failure is authorized. After gathering evidence in a *de novo* procedure, the courts would be authorized to require the initiation of the action requested if the petitioner has shown that the action requested is justified. The citizen's petition provision is similar to that contained in the Consumer Product Safety Act.

7. EMPLOYEE PROTECTION

Discrimination against any employee who participates in proceedings, testifies in a proceeding, or participates in any other action necessary to carry out the purposes of the legislation is prohibited.

A procedure is provided whereby the Secretary of Labor would conduct a proceeding and may order the reinstatement of the employee if violations are found.

In addition, the Administrator is required to continually evaluate the effects on employment which may result from the issuance of rules or orders under the bill. If requested by an employee whose employer has acted against him or her because of any rule or order issued under this bill, or when such actions are threatened, the Administrator is required to investigate the matter and to make findings of fact with respect to such allegations.

not synthesize large numbers of new chemicals. Synthesis of new chemicals takes place primarily within the major companies which have the financial capability to engage in this kind of research. Therefore, most small chemical companies should not be subject to the premarket notification requirements of section 5.

There are also provisions which will serve to limit the small companies' financial obligations when testing is required. A cost-sharing procedure, for example, is provided where a chemical company that wishes to produce a chemical discovered by someone else shares the cost of developing the test data. One of the explicitly stated bases for determining how these costs are to be apportioned is the market shares of the company which is required to provide reimbursement. A small company will usually have a smaller market share and therefore the reimbursement requirements will be minimized.

Also, in each case where restrictive rules are authorized, the Administrator is required to protect against "unreasonable risks." In determining what is an "unreasonable" risk a balancing of risks and benefits is required. The effect of a rule on small business, of course, is one of the things that the Administrator must weigh in balancing risks and benefits.

The legislation also allows the Administrator to exclude substances from any or all provisions of the Act, if such substance does not present an unreasonable risk. The products developed by small businesses may be excluded by the Administrator utilizing this provision if such risks are not presented.

Under the rulemaking procedures of this legislation, compensation is available to pay attorneys' fees and other costs of representing persons before EPA who could not otherwise afford it. Small businessmen could well be eligible for such help. Also an amendment accepted by the committee provides authority to require replacement or repurchase by manufacturers or processors of banned or restricted products. This provision will prevent small retailers and wholesalers from being saddled with large inventories of otherwise unusable products.

5. There is precedent for the de novo procedures contained in the citizens' petitions provisions and such procedures are necessary.

The citizens' petitions provision in the legislation is analogous to a provision contained in the Consumer Product Safety Act. This section will assure that the Environmental Protection Agency is forced to focus on the provisions of the bill directed at protecting health and the environment from the dangers of toxic chemicals. The citizens' petitions provision is limited to petitions "the purpose of which [are] to protect against an unreasonable risk of injury to health or the environment." If a citizen can show by a preponderance of the evidence that the action requested in a citizen's petition conforms to the applicable requirements, then EPA should be required to initiate an action. It should be noted that in reviewing a denial of the citizen's petition by the Environmental Protection Agency the court can only require EPA to initate an action. The court would not be allowed in this situation to determine the content of a rule or outcome of such a proceeding.

The court, if petitioned, shall conduct a *de novo* review of any denial or failure to act on a citizen's petition by the Environmental Protection Agency. In a judicial review of the Administrator's denial of a

citizen's petition or failure to act, there would be no record upon which the review could be based, and therefore a *de novo* procedure is essential to provide the opportunity to develop such a record.

The responsiveness of government is a critical concern and the citizens' petition provision will help to protect against lax administration of the bill.

6. The economic burdens that may be imposed as a result of this legislation are not substantial particularly when considered in the context of the economic, health, and other benefits.

There have been widely varying estimates from the chemical industry of the total cost to the industry of the legislation. The Dow Chemical Co., for example, has estimated that the legislation would cost the chemical industry $2 billion per year. The Manufacturing Chemists Association estimated that these costs would range from $340 million to $1.3 billion per year. The Environmental Protection Agency, however, estimates that the annual total cost to the chemical industry from the enactment of this legislation will be far lower and will range from $80 to $140 million per year.

In order to analyze the accuracy of these studies, the committee requested the General Accounting Office to examine these estimates. The General Accounting Office report to the committee seriously questioned the high estimates of the Dow and Manufacturing Chemists' Association studies, and stated that EPA's estimates were more reliable and realistic and that the legislation, if enacted, would cost the chemical industry between $100 to $200 million a year.

It is important to note that in the testing and key regulatory provisions of the legislation, it is specifically required that the Administrator evaluate the risks and the benefits of his actions before taking regulatory action. Thus, costs are not to be incurred unless they are offset by benefits of at least the same magnitude. In comparing risks, costs, and benefits, however, it is important to recognize that one is weighing noncommensurates, and it is not feasible to reach a decision just on the basis of quantitative comparisons. The burdens of human suffering and premature death are extraordinary and must be given full consideration in such decisions.

Legislative Background

S. 3149 had its genesis in the 92d Congress. On February 10, 1970, the Administrator of the Environmental Protection Agency transmitted by executive message a legislative proposal which was introduced by Senators Hart and Magnuson, by request, as S. 1478, the "Toxic Substances Control Act of 1971."

Eight days of hearings were held in the 92d Congress on S. 1478 and amendment No. 338 which proposed major changes in the legislation. The Senate passed the bill on May 30, 1972, following Committee action. The House of Representatives acted late in the session but there was insufficient time to reconcile the differences between the Senate and House bills.

In the 93d Congress, S. 426 was introduced on January 18, 1973 by Senators Magnuson, Tunney, and Hart. Three days of hearings were held on S. 426 and S. 888, the Administration's bill.

79-313 O - 77 - 12

Following Committee action, the Senate passed S. 426 on July 18, 1973. The House of Representatives passed S. 426 with amendments in lieu of H.R. 5356 on July 23, 1973. However, as in the 92d Congress, the conference was unable to resolve the differences between the House and Senate bills.

In the 94th Congress, S. 776 was introduced on February 20, 1975, by Senators Tunney, Hart, and Magnuson. Hearings were held on March 3, 5, 10, April 5, and October 24, 1975.

The Subcommittee on Consumer Protection and Finance of the Interstate and Foreign Commerce Committee of the House of Representatives reported H.R. 10318 on December 3, 1975. The Senate Committee on Commerce met in executive session on February 3, 4, and 17, 1976, to consider a substitute text offered by Senators Hartke, Tunney, and Hart which conforms quite closely to H.R. 10318. The Committee unanimously ordered the substitute text reported favorably with amendments as an original bill, S. 3149.

Section-by-Section Analysis

SECTION 1—SHORT TITLE AND TABLE OF CONTENTS

The short title of the proposed Act is the "Toxic Substances Control Act." A table of contents is provided.

SECTION 2—FINDINGS, POLICY, AND INTENT

Subsection (a) puts forth congressional findings that humans and the environment are exposed to a large number of chemical substances and mixtures and that some may cause an unreasonable risk of injury to health or the environment. The findings also state that the regulation of chemical substances and mixtures in intrastate commerce is necessary to the effective regulation of interstate commerce in such substances and mixtures.

Subsection (b) sets forth the policy of the United States that adequate data should be developed with respect to chemicals and mixtures and that manufacturers should have the responsibility of developing the data. The subsection further states that adequate authority should exist to appropriately regulate subsances and mixtures and that authority should not impede or unduly create unnecessary economic barriers to technological innovation.

Importantly, subsection (c) states that it is the intent of Congress that the Administrator "shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator proposes to take under this Act." While this section of the bill is not an operative section, the intent of Congress as stated in this subsection should guide each action the Administrator takes under other sections of the bill.

SECTION 3—DEFINITIONS AND EXCLUSIONS

Subsection (a) sets forth the definitions which are used in the bill.

Of particular importance is the definition of a "chemical substance." The term means any substance of a particular molecular identity including a combination of substances occurring as a result of a chemical reaction, or any element or uncombined radical.

The term does not include any mixture, which is a combination of chemical substances which do not react chemically with each other and the combination is not the result of a chemical reaction, or combination of chemicals occurring in nature. Mixtures may be addressed under the provisions of the Act, but is excluded from the definition of chemical substance so that automatic premarket notification does not take place under section 5. As the term "mixture" includes "articles containing chemical substances", the use of the latter term has been deleted throughout the bill.

In addition, the term does not include pesticides, tobacco, or tobacco products, nuclear material (as defined in the Atomic Energy Act), firearms and ammunition (to the extent subject to taxes imposed under section 4181 of the Internal Revenue Code), or food, drugs, cosmetics, or medical devices (as defined in the Federal Food, Drug, and Cosmetic Act). The term food also means food as defined in the Poultry Products Inspection Act, the Federal Meat Inspection Act, and the Egg Products Inspection Act. With respect to the explicit exclusion of nuclear materials, nothing in the bill should be construed as an *implicit* exclusion of such materials from related Acts which contain no *explicit* exclusion, such as the Federal Water Pollution Control Act.

Subsection (b) authorizes the Administrator to exclude from coverage under this Act or any provision of the Act, any substance or mixture if the Administrator determines, by rule, that an unreasonable risk of injury to health or the environment is not presented. The exclusion under this subsection would not apply to the imminent hazards authority of section 7 or the mandatory reporting of unreasonable risk information under section 8(e). Rules under this subsection are to be promulgated in accordance with the rulemaking provisions of section 6(c) which are similar to the rulemaking provisions of the Magnuson-Moss Warranty Federal Trade Commission Act (88 Stat. 2183).

Exclusions under this subsection must be carefully drawn so that unreasonable risks associated with the chemical substance or mixture which may occur subsequent to the time of the exclusion are avoided as well as risks known at the time of the exclusion. The situation must be avoided where new unpredictable uses, for example, of a chemical substance, may not be properly controlled under the provisions of this Act because of the existence of an exclusion under this subsection.

SECTION 4—TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

Subsection (a) sets forth the conditions under which the Administrator must require testing of a chemical substance or mixture.

First, if a chemical substance or mixture (a) may present an unreasonable risk of injury to health or the environment, (b) there are insufficient data or experience to reasonably determine or predict the effects, and (c) testing is necessary to develop data, then the Administrator must require testing.

Second, if a chemical substance or mixture may present a significant human or environmental exposure because of production in substantial quantities or for other reasons, and the substance or mixture may perhaps present an adverse effect on health and the environment, the Administrator must require testing if the two other criteria ((b) and (c) above) are also satisfied. If there is no reliable data or experience available to the Administrator, the finding required with respect

ical substances, mixtures, or any article containing such substances or mixtures. The limitations are (1) if the Administrator has required by rule the testing of a chemical substance or mixture under section 4, no State or political subdivision may subsequently require testing for purposes similar to those required under the rule, and (2) if the Administrator prescribes a requirement under section 5 or 6 of this act to protect against an unreasonable risk presented by a chemical substance, mixture, or article containing a chemical substance or mixture, no State or political subdivision may subsequently regulate such substance, mixture, or article unless the regulation is identical to that prescribed by the Administrator or unless the State or political subdivision bans the use or distribution of such substance, mixture, or article within the territorial jurisdiction of the State or political subdivision.

Subsection (b) specifies conditions under which the Administrator may by rule exempt a State or subdivision from the limitations imposed in subsection (a). A State or subdivision may be exempted if their requirements would not cause a violation of this act, a significantly higher degree of protection is afforded, and undue burdens on interstate commerce would not result.

SECTION 19—JUDICIAL REVIEW

Subsection (a) specifies that not later than 60 days after the promulgation of any rule under this Act or an order under section 5(e), any person may file a petition for judicial review of such rule. The Administrator shall transmit to the Attorney General, who shall file in the court, the record of the proceedings on which the Administrator based such rule or order as provided in section 2112 of title 28, United States Code. The term "record" means such rule or order, any transcript required of any oral presentation, any written submission of interested parties, and any other information the Administrator considers relevant and with respect to which the Administrator, on or before the date of promulgation of such rule or order, published a notice in the Federal Register identifying such information. Of course, the record need not contain written documentation of each and every widely accepted scientific principle or fact which may support the rule or order issued. In these cases, it should be presumed that agency expertise is definitive so that an extensive record need not be developed or judicial review result with respect to widely accepted scientific principle.

Subsection (b) authorizes petitioners to apply to the courts for leave to adduce additional data, views, or arguments. If the petitioner satisfies the court that such additional information would be material and that there are reasonable grounds for the petitioner's failure to adduce such information in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity for oral presentation and written submissions. Upon the basis of the additional information, the Administrator may modify the findings or determinations upon which the rule or order reviewed by the court was based. Modified or new findings together with the Administrator's recommendation, if any, for modifying or setting aside such rule or order shall be filed with the court.

Subsection (c) grants the courts jurisdiction, upon the filing of a petition under subsection (a), (1) to review the rule or order involved in accordance with chapter 7 of title 5, United States Code, and (2) to grant appropriate relief, including interim relief, as provided in such chapter. This subsection explicitly states that any rule promulgated by the Administrator under section 5 or 6 and reviewed under this section shall be affirmed unless the rule is not supported by the substantial evidence on the record taken as a whole. Review of all other actions taken (or inaction) shall be on an "arbitrary or capricious" basis in accordance with chapter 7 of title 5, United States Code.

Any considerations or findings required of the Administrator in the process of developing a rule or order under this Act shall not be reviewable apart from the review of the final rule or order.

Subsection (d) specifies that remedies provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

SECTION 20—CITIZEN'S CIVIL ACTION

The provisions of this section are intended to provide a remedy if the Administrator is lax in carrying out his duties under this Act. Subsection (a) authorizes any person to commence a civil action against persons alleged to be in violation of this act or any rule prescribed under section 4 (testing), section 5 (premarket notification), or section 6 (restrictive rules) to restrain such violation. In addition, actions are authorized against the Administrator to compel him to perform any duty which is not discretionary under this Act. Actions shall be brought in the appropriate district court.

Subsection (b) specifies certain limitations on the announcement of a civil action. No action may be commenced before the expiration of a specified time period after proper notice has been given of an alleged violation or failure of the Administrator to perform a duty under this act. Also, no action may be commenced if the Administrator, or Attorney General on his behalf, has commenced and is diligently prosecuting a civil action to require compliance with this Act.

Subsection (c) authorizes the Administrator to intervene in any civil action under this section to which the Administrator is not a party. The court is authorized to award costs of suit and reasonable fees for attorneys and expert witnesses, if appropriate.

Nothing in this section shall restrict the right of any person under any statute or common law to seek enforcement of this Act, or any rule under this Act, or to seek any other relief.

Subsection (d) authorizes a court, upon application of the defendant, to consolidate two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations when such actions are pending in two or more judicial districts.

SECTION 21—CITIZEN'S PETITIONS

This provision provides a means to initiate procedures for issuance of a rule or order under this act to protect against unreasonable risk of injury to health or the environment. Included, for example, would be a testing requirement under section 4(a), a restrictive rule under

section 6(a), or a modification of a section 3(b) rule which would have the effect of further protecting against unreasonable risks by reducing the extent to which a chemical substance or mixture is excluded from coverage under the Act. Subsection (a) authorizes any person to petition the Administrator to issue such a rule or order.

Subsection (b) requires the Administrator to either grant or deny a petition within 90 days after filing. If a petition is granted, the Administrator shall promptly commence an appropriate proceeding to comply with such petition. If a petition is denied, the Administrator shall publish in the Federal Register the reasons for such denial.

If the Administrator denies a petition (or fails to act within the 90-day period), the petitioner may commence a civil action within 60 days, in a U.S. district court to compel the Administrator to initiate the action requested. Because of the absence of an adequate record for the court to review in such a case, the opportunity is granted to the petitioner for a judicial review based on a preponderance of the evidence in a *de novo* proceeding. If the petitioner can satisfy the court by a preponderance of the evidence in such a proceeding that the action requested in the petition conforms to the applicable requirements of this act, the court shall order the Administrator to initiate the action requested by the petitioner.

SECTION 22—NATIONAL DEFENSE WAIVER

The Administrator is directed to waive compliance with any provision of this Act upon request of the Secretary of Defense and upon a determination by the President that the requested waiver is necessary in the interest of national defense.

SECTION 23—EMPLOYEE PROTECTION

Subsection (a) prohibits an employer from discharging or otherwise discriminating against any employee because the employee, or any person acting pursuant to a request of the employee, participates or intends to participate in any way in any proceeding or action for the purposes of carrying out the intent of this Act.

Any employee who believes that he or she has been discharged or otherwise discriminated against is authorized by subsection (b) to file a complaint with the Secretary of Labor within 30 days of the alleged violation. The Secretary is to investigate such an alleged violation and shall, within 90 days, issue an order either providing relief or denying the complaint, unless the Secretary and the person alleged to have committed such violation agree to a settlement. The forms of relief which the Secretary can provide are prescribed in this subsection.

Subsection (c) authorizes judicial review of an order issued under subsection (b) upon petition by any person adversely affected or aggrieved by such order.

Whenever a person has failed to comply with an order issued under subsection (b), subsection (d) directs the Secretary of Labor to file a civil action in the appropriate district court to enforce such action. In such civil actions the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages.