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ENVIRONMENTAL DEFENSE FUND MEMORANDUM

Date: **June 21, 2011**

Re: **TSCA Section 5(b)(4)**

This memorandum provides an analysis of the authority of the Environmental Protection Agency (EPA) to list chemicals under Section 5(b)(4) of the Toxic Substances Control Act (TSCA or the Act) and addresses several related legal questions. It concludes that EPA has clear authority to list chemicals of concern under Section 5(b)(4) and that the legal threshold for such action is the same as that in Section 4(a) of the Act. It further concludes that even if the legal standard in Section 5(b)(4) is not interpreted to be identical to that in Section 4(a), it must be read as requiring much less certainty than Section 6 of the Act. Finally, it concludes that EPA has significant discretion in deciding what factors to consider in deciding whether or not to list a chemical, including the potential economic impact of such listing.

I. Relevant Legal Provisions in TSCA

The Toxic Substances Control Act authorizes EPA to regulate chemicals and mixtures that pose "an unreasonable risk of injury to health or the environment."[1] In exercising this authority with respect to unreasonable risks, the Agency must apply one of several different legal standards. In some cases the Administrator is authorized to act where she determines that a chemical "presents or will present" an unreasonable risk of injury. In other cases, she is authorized to act where she determines that a chemical "may present" such a risk. In still another case, she is authorized to act more quickly where a chemical is "likely to result in an unreasonable risk of serious or widespread injury." These different legal thresholds may be at issue in the Office of Management and Budget's ongoing and somewhat prolonged consideration of EPA's proposal to list chemicals pursuant to Section 5(b)(4) of the Act.

The relevant statutory provisions are summarized immediately below.

[1] *See* 15 U.S.C. §§2603-2606.

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Legal thresholds in TSCA related to findings of unreasonable risk (emphases added):

Section	EPA Authority	Legal threshold
4(a)(1)	Required testing of chemicals	"*may present* an unreasonable risk of injury to health or the environment"
5(b)(4)	Listing of chemicals	"*presents or may present* an unreasonable risk of injury to health or the environment"
5(e)	Restriction of chemical manufacture, use, distribution or disposal pending development of further information	"*may present* an unreasonable risk of injury to health or the environment"
5(f)	Restriction of chemical manufacture, use, distribution or disposal to address risk before a rule under Section 6 can protect against such risk	"*presents or will present* an unreasonable risk of injury to health or environment"
6(a)	Restriction on chemical manufacture, use, distribution or disposal of chemical	"*presents or will present* an unreasonable risk of injury to health or the environment"
6(d)	Imposition of an immediate effective date for restriction on chemical manufacture, use, distribution or disposal under a proposed rule	**"***likely to result in* an unreasonable risk of *serious or widespread* injury to health or the environment"
7	Civil action to obtain seizure or other relief with respect to an imminently hazardous chemical or mixture or article containing such chemical or mixture	"*presents* an *imminent* and unreasonable risk of *serious or widespread* injury to health or the environment"

Section 5(b)(4) states in full:

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including –

(I) the effects of the chemical substance on health and the magnitude of human

exposure to such substance; and
(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.
(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2) of this section, would constitute a significant new use of such substance.
(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).[2]

II. Legal Issues Related to Section 5(b)(4)

A. EPA has clear authority to list chemicals under Section 5(b)(4).

The plain language of this provision establishes with certainty that EPA is authorized to act by rule to establish and keep current a list of chemicals that may present an unreasonable risk to human health or the environment. There is no plausible interpretation of this language to conclude that EPA lacks authority to take such action, as long as EPA adheres to the procedural requirements laid out in the provision.

B. The statute does not require EPA to articulate or take public comment on the criteria used to select chemicals for listing.

Section 5(b)(4) provides specific terms for EPA's listing of chemicals. These terms include a requirement that EPA "consider all relevant factors" before establishing the list, including the health and environmental effects of and magnitude of exposure to chemical substances.[3] It also requires that EPA "make and publish with the rule" its finding that a listed chemical "presents or may present an unreasonable risk of injury to health or the environment."[4] The provision does not, however, make any mention of the substantive criteria by which EPA shall establish or update such a list. In fact, the provision does not require even that EPA articulate criteria to the public. Given the inclusion of specific terms within this provision and the omission of any requirement for articulation of criteria, the plain meaning of the provision is that it does not require EPA to articulate criteria for listing chemicals, either before or after a proposed rulemaking that identifies specific chemicals.

This reading is further supported by the language of Section 5(b)(4)(C), in two respects. First, that language provides for extensive public comment requirements, directing the Administrator to offer an opportunity for oral presentations from the public, as well as written

[2] 15 U.S.C. §2604.
[3] 15 U.S.C. §2604(b)(4)(A)(ii).
[4] 15 U.S.C. §2604(b)(4)(C).

comments, and requiring that the Administrator maintain a transcript of any oral presentation.[5] These obligations go beyond those of a standard rulemaking and ensure ample opportunity for comment after publication of a proposed rule. They support the conclusion that Congress intended for EPA to issue a proposed rule listing specific chemicals and allowing for extensive public input after the proposal, not for EPA to delay listing until after the public has commented on a generic set of criteria for listing.

Second, Section 5(b)(4)(C)(iii) expressly requires EPA to "make and publish with the rule" its finding that a chemical substance or mixture "presents or may present an unreasonable risk of injury to health or the environment."[6] This mandate simply would not make sense if the section were to be interpreted to require EPA to issue a rule laying out general criteria before proposing to add specific chemicals to the list. Under this language, if EPA were to propose a rule to establish criteria for listing chemicals, the Agency would be statutorily required to "make and publish" with that rule a finding that certain chemicals "present or may present an unreasonable risk." Yet such a finding would be impossible to reach unless specific chemicals were named. As a result, the only plausible reading of this provision is that EPA may—and arguably must, if it is going to act under this section at all—issue a proposed rule to list specific chemicals, but it is neither authorized nor required to propose a rule establishing the criteria by which it will list such chemicals.

One could argue that although the section does not require the articulation of criteria by rule, it nonetheless allows for the articulation of criteria through other agency action, in advance of a proposed listing of chemicals by rule. It is true that the statute does not foreclose this approach by the Agency. However, given the absence of such a requirement in the statute and the inclusion of unusual and extensive public comment opportunities as discussed above, it is clear that Congress intended for the Agency to move directly to listing without being delayed by the development and publication of generic criteria, by rule or otherwise.

C. EPA has authority to list groups of chemicals, in addition to individual chemicals.

Section 5(b)(4) authorizes EPA to establish "a list of chemical substances." Some stakeholders may suggest that this language authorizes EPA only to list chemicals individually and not to list a group or category of chemical substances. In the context of the entire statute and its interpretation by EPA, however, this reading is not persuasive. In at least one other provision—Section 5(h)(4), related to exemptions from new chemical requirements—EPA has interpreted the term "chemical substance" to include categories of chemical substances.[7] In light of this established interpretation, EPA clearly is acting within its authority to interpret the phrase "chemical substance" in Section 5(b)(4) to include categories of chemical substances and to establish a list that includes such categories, as well as individual chemicals.

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[5] 15 U.S.C. §2604(b)(4)(C).
[6] 15 U.S.C. §2604(b)(4)(C)(iii).
[7] See EPA, *Polymer Exemption Overview* (online at http://www.epa.gov/oppt/newchems/pubs/polyexem.htm).

D. The Section 5(b)(4) required finding that a chemical "may present" an unreasonable risk is the same as that in Section 4(a) and EPA should require the same level of evidence that it has required under Section 4(a).

Section 5(b)(4) requires EPA to find that a chemical substance "presents or may present an unreasonable risk of injury to health or the environment." This language is substantively identical to that in Section 4(a).[8] On its face, therefore, this section provides for the same legal standard that EPA has faced in the Section 4 context. It is a standard canon of statutory interpretation that the same language within a single statute shall be presumed to have a single meaning.[9] This principle of interpretation applies even where the practical impact of language may be different.[10] Thus, even if some suggest that the listing of a chemical under Section 5(b)(4) will have a greater impact on manufacturers and processors than the issuance of a testing requirement under Section 4(a), the parallel language in the two provisions dictates that the legal standard be the same.

That interpretation is further supported by the fact that different language was included elsewhere in the statute, both in other parts of Section 5 and in Section 6. Where a statute includes different language in its provisions, such differences are presumed to be intentional.[11] In this case, varying language in Sections 4, 5 and 6 (see chart above) makes clear that Congress intended different standards to apply with respect to the testing of chemicals, the listing of chemicals, and the imposition of requirements on the manufacture, use, distribution and disposal of chemicals.

E. Based on prior Administrative and judicial interpretations of Section 4(a), Section 5(b)(4) should be interpreted as requiring only preliminary evidence that establishes a "more than theoretical" basis for concluding that a substance "may present" an unreasonable risk.

Agency and judicial interpretation of Section 4 provides precedent for interpretation of the "may present" standard in the Section 5(b)(4) context. For example, in *Chemical Manufacturers Association vs. EPA*, the court upheld EPA's interpretation of Section 4(a) to find that the "may present" threshold was met "where EPA's basis for suspecting the existence of an "unreasonable risk of injury to health" is substantial—i.e., when there is a more-than-theoretical basis for suspecting that some amount of exposure takes place and that the substance is sufficiently toxic that such level of exposure could present an "unreasonable risk of injury to

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[8] There is one difference between the text of these two sections, but it is not material to the questions considered in this memorandum: Where Section 5(b)(4) authorizes the Administrator to act with respect to any chemical that "presents or may present" a risk, Section 4(a) pertains only to a chemical or mixture that "may present" such a risk. This distinction likely reflects the differing circumstances of the two provisions—in the context of Section 4, the statute presumes that EPA lacks sufficient data to determine that a chemical currently and definitively presents an unreasonable risk. In the context of Section 5(b)(4), however, no such inadequacy of data is presumed and thus the inclusion of the phrase "presents or" is necessary.

[9] [Case law.]

[10] [Case law.]

[11] [Case law.]

health."[12] This means that in the context of Section 5(b)(4), EPA need only demonstrate a "substantial (i.e., more than theoretical) probability" of an unreasonable risk of injury.[13]

Though they provide an overall framework for interpretation of the "may present standard," Agency and judicial interpretation of Section 4(a) offer little guidance on what specific evidence will suffice to demonstrate a "substantial probability" of an unreasonable risk in cases where the finding is risk-based, as opposed to exposure-based. A risk-based finding is distinct from an exposure-based finding, in that it rests on evidence of hazard, as well as exposure.[14] With respect to an exposure-based finding, EPA has established criteria that form the basis for a finding to support a test rule.[15] These criteria may be relevant to a risk-based finding insofar as they speak to the requirement for evidence of exposure.[16] No such criteria have been articulated with respect to the hazard aspect of a risk-based finding, beyond the core principle that the Agency must find a "substantial (i.e., more than theoretical) probability" of an unreasonable risk.[17]

F. Even if the "may present" standard in Section 5(b)(4) is not interpreted to be the same as that in Section 4(a), it must be interpreted as significantly less restrictive than the "presents or will present" standard in Section 6.

A simple comparison of the text of Sections 4(a) and 5(b)(4) to the text of Section 6 makes plain that the "presents or may present" standard requires a lesser degree of evidence than the "presents or will present" standard.

By definition, the phrase "may present" conveys far less certainty than the phrase "will present."[18] Given the statute's inclusion of these two different phrases and their plain meaning, the only logical conclusion is that Congress intended to require a lesser degree of evidence for a finding that a chemical "may present" a risk than it required for a finding that a chemical "will present" a risk. This reading also makes sense within the context of the statute, given that the listing of a chemical pursuant to Section 5(b)(4) is inherently less burdensome to chemical manufacturers and processors than the imposition of restrictions on activities involving that chemical pursuant to Section 6.

G. The statute does not require consideration of economic impact in the determination of whether or not to list a chemical.

Chemical industry stakeholders have argued that the listing of specific chemicals or categories of chemicals under 5(b)(4) would have a catastrophic economic impact, suggesting that EPA should refrain from listing chemicals based on the potential economic impacts.[19] In the

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[12] *Chemical Manufacturers Ass'n v. EPA*, 859 F.2d 977 (D.C. Cir., 1988).
[13] *Id.*
[14] *See* EPA, *TSCA Section 4 Test Rules* (online at http://www.epa.gov/opptintr/chemtest/pubs/sct4rule.html).
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *See Chemical Manufacturers Ass'n v. EPA*, 859 F.2d 977 (D.C. Cir., 1988).
[19] *See, e.g.,* SPI: The Plastics Industry Trade Association, *EPA Proposal to List 8 Phthalates As*

face of this objection, it is important to note that consideration of such effects is not required by the statute.

Section 5(b)(4) requires the Administrator to consider "all relevant factors" in making a finding that a chemical "may present" an unreasonable risk. The provision enumerates only two specific factors that must be included within this consideration: 1) the health effects of the chemical and magnitude of human exposure, and 2) the environmental effects of the chemical and magnitude of environmental exposure.[20] The section makes no mention of economic impact.

This section stands in contrast to others in the statute that expressly require consideration of economic impact. For example, Section 6(a) requires the Administrator to consider the same two factors enumerated in Section 5(b)(4) but also *further* requires consideration of the benefits of a chemical substance for various uses and the availability of substitutes, as well as consideration of "the reasonably ascertainable economic consequences of the rule."[21] That section also restricts the Administrator's authority to actions that are "necessary to protect adequately against" an unreasonable risk, and then only where the actions use "the least burdensome requirements."[22] Section 5(b)(4) contains no such restrictions. Given that Congress expressed a clear ability and willingness to require consideration of economic impact elsewhere in the statute, the absence of such a requirement in Section 5(b)(4) makes clear that EPA may act without considering economic impact and need not demonstrate that the listing of a chemical under this section is "necessary to protect adequately" against an unreasonable risk.[23]

H. The listing of a chemical in a proposed rule triggers export notification requirements.

Section 12(b)(2) unambiguously imposes export notification responsibilities on those who export a listed chemical upon publication of a proposed rule under Section 5(b)(4). The export notification duty is stated as follows:

> If any person exports or intends to export to a foreign country a chemical substance or mixture for which … a rule has been proposed or promulgated under Section 5 … such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule ….[24]

This section makes clear that the notification duty applies once a rule has been "proposed or promulgated."

Chemicals of Concern Under TSCA Section 5(b)(4) ("We believe if you list phthalates there will be a significant decrease in our business if not a complete elimination of the majority of the markets we currently sell.") (online at http://www.whitehouse.gov/omb/2070_meeting_01072011).

[20] 15 U.S.C. §2604(A)(ii)(I)-(II).

[21] 15 U.S.C. §2605(c)(1)(C)-(D).

[22] 15 U.S.C. §2605(a).

[23] 15 U.S.C. §2605(a).

[24] 15 U.S.C. §2611(b)(2).

At least one set of observers has suggested that the statute may not require export notification until a final rule is promulgated.[25] The plain language of the section does not support that interpretation. Section 12(b)(2) states with absolute clarity that export notification is required for a chemical for which "a rule has been *proposed* or promulgated under Section 5."[26] The only plausible interpretation of this language is that when a rule is proposed under Section 5(b)(4) to list a specific chemical, exporters of that chemical must comply with the notification requirements of Section 12, even before a final rule is issued.

The same observers also have argued that export notification requirements do not apply until EPA issues a final rule to require data under Section 5(b)(4), notwithstanding the plain text of Section 12.[27] This argument rests on an examination of the legislative history of the statute and specifically relies on evidence that early versions of the legislation did not apply the notification requirements to chemicals listed under Section 5(b)(4) unless and until EPA issued a final rule requiring the submission of data.[28]

Regardless of whether or not this understanding of the legislative history is accurate, this argument fails because it violates a cardinal principle of statutory interpretation—that is, that the plain meaning of statutory text trumps any interpretation of legislative history.[29] In this case, Section 12(b)(2) contains an unambiguous requirement for export notification in the case of a proposed rule under Section 5. The provision places no qualification on that requirement and contains no suggestion that "Section 5" means something other than *all* of Section 5. In fact, to interpret "Section 5" in this context to refer only to Section 5(b)(1)-(3) and not to Section 5(b)(4) amounts to a claim that Congress did not mean what it said. Such a conclusion is not consistent with the core principles of statutory interpretation.[30]

This conclusion is further supported by the fact Section 12(b)(1) explicitly references the imposition of data requirements, stating:

> If any person exports or intends to export to a foreign country a chemical substance or mixture *for which the submission of data is required* under section 2603 or 2604 (b) of this title, such person shall notify the Administrator…."[31]

The inclusion of a reference to data requirements in Section12(b)(1) and the omission of such a reference in Section 12(b)(2) indicates that Congress did not intend to impose such a requirement in all cases.

Finally, a conclusion that export notification is not required for a chemical listed pursuant to Section 5(b)(4) runs directly counter to the clear intent of Section 12. By requiring prompt notification of the upcoming export of chemicals that are subject to regulatory action, this section

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[25] *See* C. Auer et al., *TSCA Section 5(b)(4) 'Chemicals of Concern' List: Questions, Issues, Concerns*, BNA Daily Environment Report, No. 98 at B-3 (May 24, 2010).
[26] 15 U.S.C. §2611(b)(2) (emphasis added).
[27] *See* C. Auer et al., *supra* note 28.
[28] *Id*. at B-4.
[29] *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* 467 U.S. 837 (1984).
[30] *Id.*
[31] 15 U.S.C. §2611(b)(1) (emphasis added).

ensures that other countries are alerted in a timely manner to chemical concerns that are known to or suspected by the United States. Notification is not limited to cases where the Agency has found conclusive evidence of unreasonable risk, as demonstrated by the inclusion of Section 4 test rules as a trigger for notification—a test rule is not necessary where risk has already been proven.[32] Because the clear intent of Section 12 is to share information with countries affected by U.S. exports of chemicals that may pose a risk to the citizens of those countries, it is not plausible to conclude that Congress intended to exclude chemicals listed under Section 5(b)(4) from notification. These "chemicals of concern" are precisely those that Section 12 must be understood to capture, and their exclusion from Section 12 would undermine the most core purpose of that section.[33]

I. Listing of a chemical in a proposed rule does not automatically require EPA to issue a SNUR with respect to that chemical, but in many cases a SNUR will be required.

Section 5(b)(4) provides that the Administrator shall, in listing any chemical under this section, "identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance."[34] This language does not require the issuance of such a significant new use rule (SNUR) in all cases, as indicated by the phrase "if any" and the reference to Section 5(a)(2), which contains the standard criteria for EPA determination that a proposed use is a significant new use. This language cannot be read to require EPA automatically to issue a SNUR for each listed chemical or for all new uses of a listed chemical.

The provision does, however, require EPA to consider which new uses of a chemical will be significant, and it is likely that for many listed chemicals, at least some new uses will be deemed significant. This is because the listing of a chemical indicates some level of concern about the chemical, a concern that can be used to justify issuance of a SNUR. EPA can issue a SNUR to require notification before a new or existing chemical can be used in "new ways that might create concerns."[35] Given the level of concern that necessarily underlies the listing of a chemical under Section 5(b)(4), it is likely that any new use of a listed chemical that will significantly alter the chemical's use with respect to the factors named in the statute—volume of manufacture and processing; the type or form of human or environmental exposure; the magnitude and duration of human or environmental exposure; and the manner and methods of manufacturing, processing, distribution and disposal—may result in issuance of a SNUR.[36]

Some may argue that issuance of a SNUR with respect to listed chemicals will amount to a ban on the identified significant new uses, since a SNUR will require those seeking approval for a significant new use to provide data showing that the new use "will not present an

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[32] 15 U.S.C. §2611(b)(1).
[33] *See* EPA, *TSCA Section 5(b)(4) Concern List* (online at http://www.epa.gov/oppt/existingchemicals/pubs/sect5b4.html).
[34] 15 U.S.C. §2604(b)(4)(B).
[35] See EPA, *Managing Chemical Risk* (online at http://www.epa.gov/oppt/existingchemicals/pubs/managechemrisk.html#relevant).
[36] 15 U.S.C. §2605(a)(2).

unreasonable risk of injury."[37] Because the listing under 5(b)(4) is based on an EPA finding that the chemical "may present an unreasonable risk of injury," some may fear that no manufacturer or processor will ever be able to show that a new use "will not present an unreasonable risk of injury."

This concern should not be permitted to weaken EPA's authority to list chemicals under Section 5(b)(4) for two reasons. First, the plain language of Section 5(b)(4) authorizes EPA to list chemicals based on concern about unreasonable risk, without regard to the impact of such a listing on new uses of such chemicals. Theoretical concerns about the impact of such listing on new uses cannot be relied on to diminish the clear statutory authority granted to EPA. Second, it clearly remains possible that a manufacturer or processor could demonstrate that a new use "will not present an unreasonable risk," even where EPA has issued a finding that the chemical "may present" such a risk. As discussed above, a "may present" finding under Section 5(b)(4) involves a lesser degree of certainty than a finding under Section 6 that a chemical "presents or will present" an unreasonable risk. As a result, Section 5(b)(4) listing allows for demonstration by a manufacturer or processor that a new use does not, in fact, present such a risk.

Whatever the concerns about the implications of listing chemicals under Section 5(b)(4), it is clear that EPA must issue a SNUR with respect to any new use of chemical listed that is "significant" as EPA has interpreted that term under Section 5(a).

III. Summary of Conclusions

EPA has clear authority under Section 5(b)(4) to list chemicals of concern and is not required to establish criteria in advance of the issuance of a proposed rule listing specific chemicals. EPA's authority also extends to the listing of categories of chemicals. The legal threshold for action under Section 5(b)(4) should be interpreted as identical to that in Section 4(a), which requires only a "more than theoretical" basis for concluding that a chemical "may present" an unreasonable risk. Even if Section 5(b)(4) is interpreted to mean something different from that in Section 4(a), it should be interpreted to be far less restrictive than the standard in Section 6. In addition, Section 5(b)(4) does not require consideration of economic impact in the decision to list a chemical. Finally, the statute is clear that listing of a chemical in a proposed rule under Section 5(b)(4) triggers export notification under Section 12, and may require the issuance of a SNUR with respect to significant new uses of the chemical.

[37] 15 U.S.C. §2604(b)(2)(B).