

ABA SEER TSCA Standard for Taking Regulatory Action Under TSCA (“Safety Standard”) Briefing Paper

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EXECUTIVE SUMMARY²

In reviewing the statute, regulations, guidance and case law utilized in implementing the Toxic Substances Control Act (TSCA), the ABA SEER Pesticide, Chemical Regulation and Right-to-Know Committee,³ with the support of the Section's Special Committee on Congressional Relations, developed this paper outlining the regulatory standard in TSCA to provide a frame of reference for underlying issues of policy.

Section 6 of TSCA (15 U.S.C. § 2605) authorizes the Environmental Protection Agency (EPA or the Agency) to initiate a rulemaking whenever the Agency finds that there is a "reasonable basis to conclude" that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture "presents, or will present an unreasonable risk of injury to health or the environment." In such circumstances, the Agency "shall" by rule apply one or more requirements to such a substance or mixture "to the extent necessary to protect adequately against such risk using the least burdensome requirements."⁴

In contrast, if S. 1009, the Chemical Safety Improvement Act (CSIA or S.1009) is enacted, when a chemical substance comes under EPA review, the continued production and use of the substance would be permitted only if the Agency has determined the substance meets or is likely to meet the "safety standard." The proposed safety standard provides that "no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance" under the intended conditions of use for the chemical substance.

² The ABA is a diverse, non-partisan nongovernmental organization that includes legal practitioners from private sector, public sector, non-profit world, and academia, reflecting a wide diversity of political and policy views. As such, the Section has not taken a formal position endorsing or opposing non-ABA policy proposals or legislation.

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⁴ Section 6 is generally interpreted to be applicable to "existing" chemical substances. EPA can take action under section 5 of TSCA to limit the manufacturing, processing, distribution and use of "new" chemical substances (those that have not yet been listed on the Inventory of chemical substances pursuant to section 8 of TSCA (15 U.S.C. § 2607(b)) when EPA determines the substance "may present" an unreasonable risk to human health or the environment. The so-called "may present" standard reflects a lower threshold for action in recognition of the fact that the Agency may lack the data on a "new" chemical substance necessary to make the more certain "will present" finding required for regulating existing substances pursuant to section 6 of TSCA. The "new" chemicals provisions of TSCA section 5 are dealt with in a separate briefing paper.

I. CURRENT PROVISIONS OF TSCA ADDRESSING THE “STANDARD FOR REGULATION”

The scope of the Agency’s authority to initiate regulatory action under TSCA is established by variations of the “unreasonable risk” standard, as reflected in Table 1.

Table 1. TSCA standards for Agency regulatory actions

Section of TSCA	Required Agency Finding
Section 4 (rulemaking to require testing)	There is insufficient data and experience to evaluate a chemical substance, testing is necessary to develop data to allow evaluation, and the chemical substance either (A) “ <i>may present</i> an unreasonable risk of injury to health or the environment,” or (B) “is or will be produced in substantial quantities, and ... enters or may reasonably be anticipated to enter the environment in substantial quantities or ... there is or may be significant or substantial human exposure to such substance or mixture.”
Section 5(e) (order to limit or prohibit use of a new chemical substance pending the development of additional information)	Insufficient information “to permit a reasoned evaluation of the health and environmental effects” and either the substance “ <i>may present</i> an unreasonable risk of injury to health or the environment” or it “is or will be produced in substantial quantities, and ... enters or may reasonably be anticipated to enter the environment in substantial quantities or ... there is or may be significant or substantial human exposure to such substance or mixture.”
Section 5(f) (order and proposed rule pending a Section 6 rulemaking limiting manufacture of a new chemical or new uses)	A new chemical substance or new uses of an existing chemical substance that “present[] or will present an unreasonable risk of injury to health or the environment.”
Section 5(b)(4) (rulemaking to list chemicals of concern)	The chemical substance “presents or may present an unreasonable risk of injury to health or the environment.”
Section 6 (rulemaking for regulation of chemical substance)	A reasonable basis to conclude that a chemical substance “presents or will present an unreasonable risk of injury to health or the environment.”

The variations in the standard for taking different regulatory actions reflect Congress's intent that a lower threshold for action should apply when EPA is merely taking action to collect data or information concerning an existing substance (*e.g.*, section 4 Test Rules) or limiting the entry of a new substance into commerce, compared to the standard that must be met when restricting substances already in commerce (in which greater commercial investments have been made and restrictive actions are likely to be more disruptive to commerce). Thus, in the case of a new chemical which is subject to the premanufacture notification (PMN) requirement, the Agency has a lesser burden to meet (the "may present an unreasonable risk" standard) when taking an action to restrict activities involving the new chemical substance because the Agency's action is being taken as a precautionary measure *pending the development of additional information necessary to make a more reasoned evaluation* concerning whether the substance will present an unreasonable risk.

In the case of existing chemicals in commerce, the Agency must make a more definitive finding ("presents or will present and unreasonable risk"). In enacting TSCA, the House of Representatives contrasted the "unreasonable risk" determination under section 6 with that under sections 4 and 5, stating:

[A section 6] requirement may remove a substance from the market or impose lesser restrictions on its availability and such a requirement is not of limited duration. Thus, the effect on society may be far reaching. As a result regulatory effect will be of greater significance in a determination of unreasonable risk for purposes of section 6 than for a determination for purposes of section 4 or 5(g). Conversely, with respect to section 4 or 5(g), because the regulatory effect of action taken under either of those sections is less than that of action taken under section 6, the requirements for a determination of unreasonable risk for purposes of section 4 or 5(g) are less demanding.⁵

Likewise, when the Agency is seeking merely to compile and keep current a list of chemicals of concern pursuant to section 5(b) (15 U.S.C. § 2604(b)), EPA may include substances that meet either the "presents" finding or the "may present" finding.

The perception that the standard that EPA must meet in order to take regulatory actions on existing chemical substances that restrict or ban their use and the rulemaking mechanisms through which EPA must maneuver to do so set too high a bar for regulatory action has been a significant factor in mobilizing certain advocates for TSCA "reform."

Section 6 of TSCA (15 U.S.C. § 2605) specifies EPA's authority to issue regulations or related requirements addressing hazardous chemical substances and mixtures. Section 6(a) authorizes EPA to issue a rule regulating the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture when the Administrator can reasonably conclude that one or more of these activities presents or will present an unreasonable risk of

⁵ H.R. Rep. No. 94-1341, at 17 (1976); H.R. Conf. Rep. No. 94-1679, at 14-15 (1976) (emphasis added) ("House Report"). Section 5(g) to which the House Report refers to corresponds to the existing TSCA section 5(e).

injury to health or the environment. The regulation must reflect the least burdensome requirements that adequately protect against the unreasonable risk. The regulation may:

- Prevent the substance or mixture from being manufactured, processed or distributed in commerce, or limit how much is manufactured, processed or distributed in commerce (this can be done for all uses of the substance or mixture, or just one use);⁶
- Prohibit or otherwise regulate the substance's or mixture's commercial use, or the disposal by those who use or dispose of it for commercial purposes;⁷ and/or
- Set labeling, recordkeeping or notification requirements.⁸

In promulgating a regulation under section 6(a), the Administrator must issue a statement describing the health and environmental impacts of the chemical substance or mixture, the benefits of the substance or mixture and substitutes for it, and the economic consequences of the rule, after considering the effect on the national economy, small business, technological innovation, the environment and public health.⁹

Under section 6(b), if the Administrator can reasonably conclude that a particular manufacturer's or processor's activities are unintentionally causing or will cause the substance or mixture to present an unreasonable risk of injury to health or the environment, the Administrator may issue an order requiring the manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture. Moreover, the Administrator can require such procedures to be revised if determined inadequate to prevent the risk of injury. If the Administrator determines the current quality control procedures have already allowed distribution in commerce of a substance or mixture presenting an unreasonable risk of injury to health or the environment, the Administrator may issue orders requiring notification or the replacement or repurchasing of the substance or mixture.¹⁰

II. LEGAL TREATMENT INCLUDING CASE LAW ON THE TSCA UNREASONABLE RISK STANDARD FOR REGULATION

The term "unreasonable risk" is not defined in TSCA. The legislative history indicates that Congress intended for the Agency to apply a balancing test when considering taking regulatory action and weighing the reasonableness of any risk:

⁶ 15 U.S.C. § 2605(a)(1), (2).

⁷ 15 U.S.C. § 2605(a)(5), (6).

⁸ 15 U.S.C. § 2605(a)(3), (4), (7).

⁹ 15 U.S.C. § 2605(c)(1).

¹⁰ 15 U.S.C. § 2605(b).

In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society.¹¹

Courts have interpreted section 6 of TSCA to require the Agency to undertake a careful analysis that balances the risks presented by the regulated substance against both the burden and economic impacts of the regulation as well as the comparative risks and benefits of alternatives to the targeted substance.

In a landmark case that struck down EPA's rule phasing out and ultimately banning asbestos, the Court of Appeals for the Fifth Circuit considered both the meaning of the term "unreasonable risk" and the evidence required for EPA to justify regulation of a chemical under TSCA section 6. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). The court held that the determination of whether a risk posed by a substance is "unreasonable" involves a balancing test in which "[t]he regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers." *Id.* at 1222. EPA must consider both alternatives to a ban and the costs of any proposed actions in determining whether the risk posed by the substance is "unreasonable." *Id.* at 1215. When regulation of a substance would be exorbitantly costly and burdensome because no feasible substitutes exist, the risk presented by the targeted substance might not be considered unreasonable. Accordingly, in *Corrosion Proof Fittings*, the court cited the high costs of alternatives to asbestos in concluding that EPA had failed to show that the risks posed by asbestos were unreasonable. For example, the court noted that EPA's "ban of asbestos shingles will cost \$23-34 million to save 0.32 statistical lives (\$72-106 million per life saved)" which "reveals that its economic review of its regulations, as required by TSCA, was meaningless." *Id.* at 1222-23. Citing a report that ingested toothpicks cause roughly one death per year, the court noted that the government generally, and EPA specifically, "regularly rejects, as unjustified, regulations that would save more lives at less cost." *Id.* at 1223 n.23.

In addition, section 19 of TSCA requires that Agency rules issued pursuant to section 6(a) TSCA be reviewed applying the "substantial evidence standard" taking into consideration the rulemaking record as a whole—a standard less deferential than the arbitrary and capricious standard generally brought to bear in challenges under section 706 of the Administrative Procedure Act. *Corrosion Proof Fittings*, 947 F.2d at 1213-14. The combination of a "will present" finding, the need to implement the least burdensome alternative, and the substantial evidence standard constrain EPA's current authority to restrict existing chemicals in commerce.

¹¹ H.R. Conf. Rep. No. 94-1679, at 14 (1976) (emphasis added).

In contrast, a section 4 testing requirement may be imposed if a chemical substance may present an “unreasonable risk” to human health and the environment. The D.C. Circuit upheld EPA’s interpretation of TSCA “as empowering the Agency to issue a test rule on health grounds where it found a more-than-theoretical basis for suspecting that the chemical substance in question presents an ‘unreasonable risk of injury to health.’” *Chem. Mfrs. Ass’n v. EPA*, 859 F.2d 977, 979 (1988). The court rejected the assertion that TSCA requires a “more-probable-than-not” finding of unreasonable risk when seeking new test data. The D.C. Circuit found support for EPA’s “more-than-theoretical” interpretation in the legislative history, which indicated that the word “may” in section 4 was intended to focus the Agency’s attention on chemical substances about which there is merely “a basis for concern.” *Id.* at 985 (citing H.R. Rep. No. 94-1341, at 17, H.R. Conf. Rep. No. 94-1679, at 61). Otherwise, EPA would be required “to gather ‘adequate’ information to make a reasonable prediction or determination of risk before issuing a test rule. To say the least, this is not mandated by the statutory history.” *Id.*

III. “UNREASONABLE RISK” AS APPLIED IN OTHER FEDERAL STATUTES

There are other federal statutes, some administered by EPA and others not, that employ regulatory standards similar to TSCA’s. Among them are the Consumer Product Safety Act (CPSA), 15 U.S.C. §§ 2051 to 2089; the Federal Hazardous Substances Act (FHSA), 15 U.S.C. §§ 1261-1278a; and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y. These statutes are discussed, in pertinent part, below, as is the Restatement (Second) of Torts.

A. Consumer Product Safety Act

The Consumer Product Safety Act (15 U.S.C. §§ 2051-2089) establishes a regulatory framework “to protect the public against unreasonable risks of injury associated with consumer products,”¹² “assist consumers in evaluating the comparative safety of products,” “develop uniform safety standards for consumer products and ... minimize conflicting State and local regulations,” and “promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.” 15 U.S.C. § 2051(b) (emphasis added).

The CPSA established the Consumer Product Safety Commission (Commission), which has the authority, among other things, to promulgate safety standards and to ban hazardous products. 15 U.S.C. §§ 2053, 2054, 2056, 2057. The Commission may promulgate consumer product safety standards, which may consist either of performance requirements or requirements for warnings and instructions, as long as the standards are “reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product.” 15 U.S.C. § 2056(a) (emphasis added); *see also* 15 U.S.C. §§ 2056a, 2058. The term “risk of injury” means “a risk of death, personal injury, or serious or frequent illness.” 15 U.S.C. § 2052(14). The CPSA does not define “unreasonable risk.”

¹² A “consumer product” is “any article, or component part thereof, produced or distributed for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or for the personal use, consumption, or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.” 15 U.S.C. 2052(a)(1).

The unreasonable risk of injury standard was reviewed in *Southland Mower Co. v. Consumer Product Safety Commission*, 619 F.2d 499 (5th Cir. 1980). In that case, the Fifth Circuit stated that the determination of whether an unreasonable risk of injury exists involves a balancing test like that in tort law. *Id.* at 508. In particular, a regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation imposes upon manufacturers and consumers. *Id.* at 508-09. Under this balancing test, even a “very remote possibility that a product would inflict an extremely severe injury could pose an ‘unreasonable risk of injury’ if the proposed safety standard promised to reduce the risk effectively without unduly increasing the product’s price or decreasing its availability or usefulness.” *Id.* at 509 (citing *Aqua Slide ‘N’ Dive Corp. v. Consumer Product Safety Commission*, 569 F.2d 831, 839-40 (5th Cir. 1978)). Conversely, if the potential injury is less severe, its occurrence must be proven more likely to render the risk unreasonable and the product safety standard warranted.

In *Southland Mower*, the regulatory action taken by CPSA was intended to reduce the risk of injuries such as amputation of toes, fractures of bones in the feet or toes, and deep lacerations and contusions. The court held, “[w]hile the seriousness of these injuries cannot be gainsaid, it does not rise to the level of gravity that would render almost any risk, however remote, unreasonable if the risk could be reduced effectively by the proposed regulation. Substantial evidence that such injury is significantly likely to occur is therefore necessary to sustain this portion of the lawn mower safety standard.” The court went on to observe that, “[t]he statutory term ‘unreasonable risk’ presupposes that a real, and not a speculative, risk be found to exist and that the Commission bear the burden of demonstrating the existence of such a risk before proceeding to regulate.” *Id.* at 510. The court determined that Congress intended for injuries resulting from foreseeable misuse of a product to be counted in assessing risk.

The Commission has the burden of establishing the nature of the hazard and the likelihood that its proposed rule would reduce the hazard at a reasonable cost. *D. D. Bean & Sons Co. v. Consumer Product Safety Commission*, 574 F.2d 643 (1st Cir. 1978). While the Commission does not have to conduct an elaborate cost-benefit analysis in reaching its determination, it does have to shoulder the burden of examining relevant factors and producing substantial evidence to support its conclusion that they weigh in favor of promulgation of the standard. *Aqua Slide ‘N’ Dive Corp.*, 569 F.2d at 831-34.

The CPSA requires manufacturers of products subject to safety standards or regulations under the CPSA or another act enforced by the Commission to certify that the product conforms to all applicable standards, based on a test of each product or upon a reasonable testing program. 15 U.S.C. § 2063. Children’s products, generally, are also subject to third-party testing requirements. *Id.* Manufacturers, distributors and retailers are also required to report to the Commission any information they obtain which reasonably supports the conclusion that a product fails to comply with a safety rule, voluntary safety standard or regulation, or contains a defect which could create a substantial product hazard, as well as information which supports the conclusion that a product creates an unreasonable risk of serious injury or death. 15 U.S.C. § 2064(b). The duty to report is a continuing one, which is not extinguished by the expiration of the time within which the applicable regulation requires a report to be made. *See U.S. v. Advance Mach. Co.*, 547 F. Supp. 1085 (D. Minn. 1982).

In *Gulf South Insulation v. Consumer Product Safety Commission*, 701 F.2d 1137 (5th Cir. 1983), the court determined that complaints of acute irritant effects from use of urea-formaldehyde foam insulation identified a real problem, but that regulation could not issue unless the severity of injury that might result from the product, factored by the likelihood of injury, offset harm which the regulation imposed upon manufacturers and consumers. The court ruled that the agency's failure to demonstrate how likely it was that acute symptoms would occur required setting aside the agency's proposed ban on the use of this material. Similarly, in *ASG Industries, Inc. v. Consumer Product Safety Commission*, 593 F.2d 1323 (D.C. Cir. 1979), the Commission's authority to predicate a finding of unreasonable risk on a projection of technological advances occurring in the future required that the Commission have some reasonable basis in the record for the projection, as contrasted with mere speculative desire.

B. Federal Hazardous Substances Act

The Federal Hazardous Substances Act (15 U.S.C. §§ 1261-1278a) prohibits the introduction or delivery into interstate commerce of "hazardous substance(s)" (15 U.S.C. § 1263), and provides for criminal penalties (15 U.S.C. § 1264) and seizures of banned products (15 U.S.C. § 1265). Like the CPSA, the FHSA allows the Commission to regulate hazards that present an "unreasonable risk" of consumer injury. See 15 U.S.C. § 1261; *Forester v. Consumer Prod. Safety Comm'n of U.S.*, 559 F.2d 774, 789 (D.C. Cir. 1977). Courts have stated that this means that the Commission "must determine (1) that the risk posed by the hazard is an unreasonable one, and (2) that there is a sufficient nexus between the regulation and the hazard it is designed to prevent. The requirement that the risk be 'unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers." *Id.* at 789.

C. Federal Insecticide, Fungicide and Rodenticide Act

The Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. §§ 136-136y, mandates that EPA regulate the use and sale of pesticides¹³ to protect human health and preserve the environment. Unlike chemical substances under TSCA, pursuant to FIFRA pesticide products cannot be distributed for commercial use without a specific authorization (registration) from EPA for an intended use. In particular, FIFRA provides that "no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the EPA Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit ... or an emergency exemption." 7 U.S.C. § 136a(a). "Unreasonable adverse effects on the environment" is defined to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb) (emphasis added).

¹³ FIFRA defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer." 7 U.S.C. § 136(u).

In contrast to TSCA, which places the burden of proof on EPA, under FIFRA, manufacturers have the initial burden of proof. In particular, FIFRA requires a manufacturer seeking to register a pesticide to submit a proposed label to EPA as well as certain supporting data that demonstrate, *inter alia*, that its pesticide will not cause “unreasonable adverse effects on the environment.” 7 U.S.C. §§ 136a(c). The specific data that must be submitted depend on the nature of the pesticide and its intended use. Generally, however, registrants must either (1) submit their own test data or (2) cite to data in the public literature or previously submitted to the Administrator. *See* 7 U.S.C. § 136a(c)(1)(F); 40 C.F.R. §§ 158.100-158.740. *See also Cheminova A/S v. Griffin L.L.C.*, 182 F. Supp. 2d 68 (D.D.C. 2002). FIFRA places a continuing burden on the registrant of pesticides to notify EPA if the registrant learns any additional facts regarding unreasonable adverse effects of the pesticide. *See* 7 U.S.C. § 136d(a)(2).

EPA will generally approve a registration if it determines that the proposed labeling satisfies FIFRA’s requirements and that the pesticide “when used in accordance with widespread and commonly recognized practice ... will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5) (emphasis added); *see also* 40 C.F.R. § 152.112(f). The registration can be either unconditional or conditional. 7 U.S.C. § 136a(c); *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174, 180-181 (D.D.C. 2012). EPA has argued, and courts have agreed, that “crafting registration conditions rather than simply denying an application gives the Agency the flexibility it needs to balance risks and benefits of a product, thus maximizing the availability of pesticides to the public while being consistent with FIFRA’s prohibition on unreasonable adverse effects.” *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174, 180-181 (D.D.C. 2012).

Once registered, pesticides are still subject to continuing scrutiny by EPA. *See generally* 7 U.S.C. § 136d. If at any time it appears that a registered pesticide no longer conforms to FIFRA’s standards or if questions arise as to the safety of the registered pesticide, EPA may initiate proceedings to impose use restrictions on, or cancel the registration of, a pesticide. *Id.* § 136d(b); 40 C.F.R. § 164.80(b). To justify cancelling a registration, EPA must show that a pesticide “when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment.” 7 U.S.C. § 136d(b). An EPA order “shall be sustained if it is supported by substantial evidence when considered on the record as a whole.” 7 U.S.C. § 136n(b). Substantial evidence means “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Gulf Oil Corp. v. E.P.A.*, 548 F.2d 1228, 1230 (5th Cir. 1977).

The risk-benefit prong of the “unreasonable adverse effects” standard was reviewed in *Ciba-Geigy Corp. v. U.S. E.P.A.*, 874 F.2d 277 (5th Cir. 1989). There, a manufacturer challenged EPA’s decision to cancel the registration of a pesticide used on golf courses and sod farms due to a risk of harm to birds on the grounds that EPA had misapplied FIFRA’s standard for cancellation by ignoring the word “generally” in the phrase “generally causes unreasonable adverse effects on the environment.” *Id.* at 278. The Fifth Circuit agreed, holding that the proper standard includes a determination that a pesticide not only causes unreasonable risks, but that it does so “with considerable frequency.” *Id.* at 280. The court further held that because FIFRA defines “adverse effects” as “unreasonable risks,” EPA need not find that a pesticide

causes actual adverse consequences, but only that it creates a significant probability that adverse consequences could occur. *Id.* at 279. In this regard, the D.C. Circuit held that EPA need only show that a product creates a significant probability of harm occurring and does not have to have proof of actual harm. *See Nat'l Grain Sorghum Producers Ass'n v. EPA*, 1996 U.S. App. LEXIS 10867 (D.C. Cir. Apr. 22, 1996).

D. Restatement of the Law—Torts

While not controlling authority, the Restatements of the Law are treatises that set forth general legal principles that American courts usually follow. The Restatement (Second) of Torts § 291, in examining how unreasonableness is determined, provides:

1. Where an act is one which a reasonable man would recognize as involving a risk of harm to another, the risk is unreasonable and the act is negligent if the risk is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.
2. In terms of magnitude of risk, § 293 identifies the following factors for consideration: (a) the social value which the law attaches to the interests which are imperiled; (b) the extent of the chance that the actor's conduct will cause an invasion of any interest of the other or of one of a class of which the other is a member; (c) the extent of the harm likely to be caused to the interests imperiled; (d) the number of persons whose interests are likely to be invaded if the risk takes effect in harm.

IV. THE STANDARD AS MODIFIED BY CSIA (I.E. “NO UNREASONABLE RISK OF HARM TO HUMAN HEALTH OR THE ENVIRONMENT WILL RESULT FROM EXPOSURE”)¹⁴

Introduced in 2013, S. 1009, the Chemical Safety Improvement Act, proposes to reverse the burden that is currently embedded in the standard for taking regulatory action under TSCA. Under the proposed law, when EPA reviews a chemical substance, the substance could continue to be produced and used only if the Agency affirmatively determines that “no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance” when used for its intended purpose.¹⁵

Under the CSIA, this safety standard would guide EPA as it conducts a risk-based safety assessment of new chemical substances under the amended section 5 as well as under section 6 when reviewing each “high priority substance” on the “active Inventory” of existing chemical

¹⁴ As this Briefing Paper was going to print, lawmakers in the House of Representatives released a bill in “Discussion Draft” form, entitled the Chemicals in Commerce Act. *See* U.S. House of Representatives, *Press Release: Shimkus Unveils Discussion Draft of Chemicals in Commerce Act* (February 27, 2014), available at <https://energycommerce.house.gov/press-release/shimkus-unveils-discussion-draft-chemicals-commerce-act>. This Briefing Paper does not attempt to analyze this new bill.

¹⁵ CSIA, § 3(16).

substances.¹⁶ CSIA would provide EPA with the authority to proceed through rulemaking and to issue administrative orders when additional data are needed to develop either a safety assessment or safety determination under section 6 or to “meet the testing needs of the implementing authority under another Federal statute.”¹⁷

For purposes of new chemical substances, the CSIA—like the current TSCA—would establish lower thresholds for the Agency to act with respect to those substances for which premanufacture or new use notifications are required. Thus, a substance requiring notification which is determined to be “*likely* to meet the safety standard under the intended conditions of use” will be permitted to enter commerce unrestricted by Agency action. As with the current law, if the Agency determines under the CSIA that additional information must be developed before a safety determination can be made for a new chemical substance, the Agency may immediately (by a consent agreement or unilateral order) regulate a new substance until such information is available. Finally, the Agency may by order ban or otherwise limit the manufacture, processing, distribution, use or disposal of a substance that is determined to be *unlikely* to meet the safety standard.

The CSIA states that the safety assessment is to be based “*solely* on considerations of risk to human health and the environment.”¹⁸ EPA would be authorized to promulgate regulations setting forth procedures for, *inter alia*, conducting these safety assessments, including the order in which safety assessments would be performed, the information that EPA would collect, the timeline for each assessment, and the methodology by which each assessment would be conducted.¹⁹

The CSIA would require each safety assessment to “evaluate existing hazard, use, and exposure information for the chemical substance under the intended conditions of use of the chemical substance, including information submitted by interested persons,” as well as use the “best available science.”²⁰ The CSIA would empower EPA to issue a rule or an administrative order requiring regulated entities to develop and/or submit additional data if additional data are needed in order to perform the assessment for high priority substances.²¹ Notably, the safety assessment would not be considered a final agency action subject to judicial review, which would eliminate one potential litigation obstacle for regulatory action.²²

¹⁶ *Id.* § 6(b)(1). An existing substance on the “active” Inventory would be designated by EPA as “high priority” pursuant to the prioritization process established under section 4 of the CSIA.

¹⁸ *Id.* § 6(b)(1). The same limitation is not specifically addressed for purposes of new chemicals reviews conducted under section 5 in the CSIA.

¹⁹ *Id.* § 6(b)(2), (4).

²⁰ *Id.* § 6(b)(4)(D)(i), (E).

²¹ *Id.* § 6(b)(5).

²² *Id.* § 6(b)(6).

Once the safety assessment is completed, EPA would be directed to conduct a “safety determination” to determine whether the chemical substance meets or does not meet the safety standard under its intended conditions of use, or if additional data and information is needed.²³ As with safety assessments, the CSIA would permit EPA to issue a rule or an administrative order requiring regulated entities to develop and/or submit additional data if additional data are needed in order to perform the safety determination for high priority substances.²⁴ This safety determination would be considered a final agency action subject to judicial review.²⁵ In making its safety determination, EPA would take into account the intended uses of the substance, the ranges of exposure under those conditions of use, the weight of the evidence of risk and the magnitude of that risk.²⁶ Based on the outcome of the safety determination, EPA would be authorized to take a number of regulatory actions, including a ban on or phase-out of the chemical substance, use restrictions, limits on quantities manufactured, and/or warning or labeling requirements.²⁷ If the chemical substance does not meet the safety standard, EPA would publish a statement on the availability, risks and economic feasibility of alternative substances as well as the economic and social benefits of alternative regulatory restrictions.²⁸ The CSIA, as it is currently drafted, lacks specific deadlines for the safety assessment and safety determination processes.

V. CONCLUSION

Although critics and supporters alike have described the CSIA’s safety standard as indistinguishable from TSCA’s current “unreasonable risk” standard,²⁹ such criticisms ignore certain distinctions, including the CSIA’s use of unreasonable risk of “harm” rather than “injury” and the requirement that when applying the CSIA safety standard in assessments and determinations, the Agency must focus *solely* on considerations of risk to human health and the environment, at least for purposes of section 6. Thus, the importance of these differences and how they might be applied when interpreted in the differing contexts of sections 5 and 6 of the CSIA are likely to be observable only if and when EPA begins applying the revised standard to specific substances and determination, in both new and high priority chemical evaluations, and even then perhaps only if the courts are requested to review such determinations and interpret the revised regulatory standard.

²³ *Id.* § 6(c)(2).

²⁴ *Id.* § 6(c)(8).

²⁵ *Id.* § 6(c)(11).

²⁶ *Id.* § 6(c)(3).

²⁷ *Id.* § 6(c)(9)(A-C).

²⁸ *Id.* § 6(c)(9)(D).

²⁹ *See, e.g.*, Testimony of Daniel Rosenberg, Natural Resources Defense Council, Senate Committee on Environment and Public Works, July 31, 2013 at 5; Testimony of Thomas O. McGarity, University of Texas School of Law, Senate Committee on Environment and Public Works, July 31, 2013 at 10; Testimony of Linda J. Fisher, DuPont, Senate Committee on Environment and Public Works, July 31, 2013 at 3.