http://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1852&context=law_journal_law_policy

Better Safe Than Sorry: A Precautionary Toxic Substances Control Act Reform Proposal

By Andrew Liebler

46 Washington University Journal of Law & Policy 333 (2015)

… **This Note argues that (1) that the current US chemical regulatory system should be replaced with a regulatory scheme founded on the strong precautionary principle, which places the burden on chemical manufacturers to affirmatively prove the safety of their chemicals;8** (2) that such a scheme will lower the demand for chemical safety information needed for regulation while incentivizing data production;9 (3) that this information must be transparent and publicly available for peer-review;10 (4) that there must be an administrative appeals process for challenging chemical safety decisions; and (5) that the entire scheme must acknowledge both the realities of data shortage and the significant demands that these requirements place on the chemical manufacturing industry.
(pp. 334-335)

… ***A. Embracing the "Strong Precautionary Principle"***

The precautionary principle is a cornerstone element of many international regulatory regimes, including REACH. As applied, the principle generally holds that the regulation of anticipated risks from a chemical should be allowed to proceed even in the face of scientific uncertainty. There are two interpretations of the principle—the "weak" and "strong" precautionary principles.49 The "weak" version was most famously defined in the United Nations 1992 Rio Declaration, which held that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost- effective measures to prevent environmental degradation."50 This version is considered "weak" because it is permissive and doesn't require that any precautionary actions actually be taken by the government. Because of this, critics of the "weak" principle often describe it as a mere truism.51 On the other hand, **the "strong precautionary principle" holds that some regulation should automatically be undertaken in the face of serious risks, despite scientific uncertainty.52 In conjunction, the "strong" principle places a burden on the proponent of the risky activity to prove that the risks are reasonable and justified**.53
(pp. 344-345)

The drug approval process of the Federal Drug Administration (FDA), which is detailed later in this Note, is an example of the "strong precautionary principle" in action.54
(pp. 345-346)

The "strong precautionary principle" does not prescribe any particular regulatory response in the face of serious risk.55Instead, the principle simply establishes a norm for regulatory decision-making.56 There may, of course, be considerable variance in a government's definition of "serious risk" and the default regulations imposed under a strong precautionary scheme.57 Regardless, a strong precautionary scheme positions government as a preventative "gatekeeper" that forces the risk creator to justify the risk created.58 The "strong" version of the precautionary principle has been significantly criticized.59 Some critics contend that strong precaution stifles technological growth and paralyzes regulators.60 **Critics also claim that the principle requires manufacturers to show "zero risk" from their activities—an unfeasible requirement.61 In fact, critics cast the strong version of the principle as prohibiting any amount of activity that carries risk.62 Instead of strong precaution, many critics call for cost- benefit or risk analysis by the government for each regulatory decision.63**

---

52. According to Sachs, "the Strong Precautionary Principle suggests that some precautionary regulation should be a default response to serious risks under conditions of scientific uncertainty." Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1295 (Jan. 2003)…
53. *See* Justin Wade, *Sunstein's Blunder; Or, The Perils of Reconstructing Precaution*, 20 GEO. INT'L ENVTL. L. REV. 473, 485 (2008) ("Whereas the weak Precautionary Principle operates temporally by allowing action before full certainty, the 'strong' Precautionary Principle can be thought of in burden-shifting terms: a plausibly risky technology, such as genetic engineering, is considered presumptively unsafe until the manufacturer can prove the extent of the risk the technology poses to human or environmental health.").
54. *See infra* note 95.
55. *See* Sachs, *supra* note 8, at 1293–94.
56. Id. at 1295.
57. Id. at 1298; *see also* REACH IN BRIEF, supra note 32, at 4–6 (describing different default regulatory responses for "very high concern" chemicals versus others not classified as such).
58. *See* Sachs, *supra* note 8, at 1298.
59. *Id.* at 1299; *see also* Sunstein, *supra* note 51, at 1018–20; Cross, *infra* note 60.
60. *See* Sunstein, s*upra* note 51, at 1020; *see also* Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851 (1996) (generally criticizing the precautionary principle as stifling technological development and regulatory action).
61. *See* Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European "Fashion" Export The United States Can Do Without*, 17 TEMP. POL. & CIV. RTS. L. REV. 491, 517 (2008).
62. *See id.*
63. *See* Sunstein, *supra* note 51, at 1056–57…

(pp. 346-347)