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Scientific and Policy Analysis of Persistent, Bioaccumulative, and Toxic Chemicals: A Comparison of Practices in Asia, Europe, and North America The Report of a Consensus Panel November 2013

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Executive Summary

The basic purpose for identifying persistent, bioaccumulative, and toxic chemicals (PBTs) is to assist government and industry in taking rational protective steps for public health, safety, and the environment. This report, prepared by an international team of scholars and practitioners, evaluates how PBTs are currently identified and managed in Asia, Europe, and North America and provides recommendations for improving those processes.

The concepts of persistence, bioaccumulation, and toxicity are commonly used in the scientific literature, as is the internationally used concept of a persistent organic pollutant. PBT, as a term of art, appears to have originated in policies of the Japanese government in the 1970s, even though the term did not appear in the peer-reviewed scientific literature until the 1990s. The growing use of the term by policy makers, coupled with concerns about its inconsistent and changing meaning, motivated this in-depth investigation.
(p. 5)

… **A. Purposes and Scope of Report**

We are particularly interested in the extent of international variation in how PBT determinations are made and in how regulators make use of PBT determinations. In this report, therefore, we first examine how PBT determinations are made by public agencies, over time and in different jurisdictions, and then explain the various uses of PBT determinations by decision makers in the public and private sectors. Our interest is in the PBT practices and policies, not the outcomes for any specific substance. Based on this examination of practices and policies, we offer suggestions for both improvement and harmonization.
(p. 10)

Our focus is limited to PBTs, but we consider persistent organic pollutants (POPs) to be a subset of PBTs that are within the purview of our examination. We also present some findings and recommendations about "partial

PBTs"—chemicals that satisfy two of the three PBT properties. Throughout the report when we use the term PBT, we refer to all three properties, and thus the various types of partial PBTs are discussed separately. REACH applies the designation "very persistent, very bioaccumulative" (vPvB) to chemicals that are highly persistent and bioaccumulative but for which toxicity is unknown or poorly characterized. Chemicals that are vPvB could therefore be described as partial PBTs, but we view them as a subset of PBTs because toxicity is generally implied for these chemicals.

We concentrate primarily on industrial chemicals, recognizing that agricultural chemicals, biocides, and pharmaceuticals raise some different scientific and policy issues. Our primary focus is on PBT practices and policies in Asia, Europe, and North America, but we also address some other international activities. Although some PBT policies have arisen in the consideration of new chemicals, our focus is how PBT practices and policies should be integrated into the accelerated review of existing chemicals.
(pp. 10-11)

…**C. Survey of Current PBT Programs**

This section surveys selected PBT policies around the world. Our focus is on how policy makers make use of the PBT determinations listed in Table 3-1 above. The catalogue begins with international programs and then discusses regional, national, sub-national, and private programs.

1. International

a. Strategic Approach to International Chemicals Management
(pp. 42-43)

… b. Stockholm Convention on Persistent Organic Pollutants
(p. 43)

… *2. Regional*

a. Great Lakes Binational Toxics Strategy
(p. 44)

… b. European Union: Registration, Evaluation, Authorization, and Restriction of Chemicals
(p. 45)

… c. Convention for the Protection of the Marine Environment of the North-East Atlantic
(p. 48)

… *3. National*

a. Japan: Chemical Substances Control Law

Japan's 1973 legislation on industrial chemicals, known as the Chemical Substances Control Law (CSCL), or Kashinho, was the first regulatory program in the world to employ the PBT concept.272 We described the origin of the CSCL above; here, we discuss the law's substantive use of the PBT concept.

The CSCL employs a mix of hazard-based and risk-based approaches to chemicals management. The original law that the Japanese Diet enacted in 1973 was entirely hazard-based, beginning with a ban on the manufacture, importation, and use of PCBs followed by other chemicals that exhibit PBT properties, including most of the dirty dozen.273 In 2003, in response to a review of its regulatory system, Japan modified the CSCL to include consideration of ecological effects, exposure information, persistence, bioaccumulation, and information requirements on industry.274 **In light of Europe's experience with REACH and Canada's experience with its Chemicals Management Plan, Japan updated its law in 2009 to reflect a more risk-based approach.275**
(pp. 48-49)

The CSCL classifies existing substances into five groups.276 Chemicals that are not potential PBTs are labeled "General Substances."277 All of the remaining categories rely on some type of PBT-related determination.

The CSCL designates PBTs as Class I substances and prohibits their manufacture, importation (alone or in products), and use.278 At present, there are thirty Class I substances.279 Companies may apply to the Ministry of Economy, Trade, and Industry (METI) for use-specific exemptions. The legislation specifies that METI may only approve an application if the company shows that the quantity to be manufactured or imported is both necessary and no greater than that needed to meet domestic demand for a particular use. Applicants must also demonstrate that their equipment and safety procedures meet specified standards and that they possess the fiscal and technical bases to adequately control risks. Finally, applicants must show that substitute chemicals are difficult to obtain for the desired use and that the use is not likely to present a risk to human health or the environment. Upon approval, Class I substances must be strictly handled and labeled, and together, METI, the Ministry of the Environment, and the Ministry of Health, Labour, and Welfare may recall any chemical or product if they determine that it poses a risk.

Perfluorooctane sulfonate (PFOS) is one example of a Class I substance for which METI has approved three use-specific exemptions;280 however, very few others have been granted, and many consider the Class I designation to be a de facto ban.281The design of REACH authorization is similar to Japan's Class I designation, which adheres to the principle of precaution.

"Monitoring Substances" are those for which persistence and bioaccumulation have been established, but toxicity remains uncertain.282 In other words, Monitoring Substances are PBs—an example of what we designate "partial PBTs." These thirty-eight substances are considered candidates for the Class I designation; however, the CSCL applies risk management to Monitoring Substances as well. Manufacturers and importers must notify METI of the quantity of the listed substance that they produced or imported in the preceding fiscal year and must also inform companies down the supply chain of the chemical's status as a Monitoring Substance. Additionally, the government may compel manufacturers and importers to conduct hazard assessments of the substance if it suspects that it may be harmful to human health or the environment. The ministries may then use this information to determine whether or not to classify the substance as Class I.

Class II substances under the pre-2009 law were those which are persistent and toxic, but not bioaccumulative—another example of partial PBT designation. Under the new legislation, however, Class II substances are those which are hazardous to humans, plants, or animals "due to a considerable amount of the chemical substance remaining in the environment over a substantially extensive area or because it is reasonably likely that such a situation will arise in the near future in view of its properties and manufacture, import, use, etc."283 **This category, therefore, still includes PT substances, but it also seems to include substances that are subject to continuous release (and therefore have a use-based, persistence-like presence in the environment) as well as endocrine disruptors.284** The current twenty-three Class II substances were all listed prior to this change, so the scope of the amended Class II designation remains uncertain. Once designated as

Class II, substances are subject to quantity notification requirements not only for the prior year, but also planned quantities for the forthcoming fiscal year, which act as caps for the manufacture and importation of the substance. The CSCL also compels the ministries to develop and apply technical guidelines for production, handling, and labeling of Class II substances.
(p. 49)

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272 Government of Japan, Act No. 117 of 1973, http://www.meti.go.jp/policy/chemical_management/english/files/Act%20on%20CSCL_provisional.pdf; Ministry of Economy, Trade, and Industry (METI), Chemical Substances Control Act, History of the Law, http://www.meti.go.jp/english/information/data/chemical_substances01.html; Eisaku Toda, *The Management of Industrial Chemicals in Japan*, *in* Risk Assessment of Chemicals: An Introduction 575 (C.J. van Leeuwen & T.G. Vermeire eds., 2007); **Lawrence A. Kogan, *REACH Revisited: A Framework for Evaluating whether a Non-Tariff Measure has Matured into an Actionable Non-Tariff Barrier to Trade*, 28 Am. U. Int'l L. Rev. 489, 649 (2013).**
273 *See* Toda, supra note 272, at 577.
274 Thomas C. Berger & Martha E. Marrapese, Notification of New Chemicals Substances in Japan, Keller and Heckman Alert, March 4, 2004, http://www.khlaw.com/1117; Toda, supra note 272.
275 *See* Kogan, *supra* note 272, at 653–54 (indicating that Japan considered REACH and the Canadian CMP in its decision making processes prior to the adoption of its 2009 amendments).

280 Tadahiro Ikemoto, Ministry of Environment, Japan's Efforts on Management of PFOS, OECD Webinar, April 18, 2011, http://www.oecd.org/env/ehs/risk-management/47643243.pdf.
281 Toda, supra note 272, at 578.
282 CSCL, art. 2(4). For relevant regulations on Monitoring substances, see CSCL, art. 13–16.
283 CSCL, art. 2(3). For relevant regulations on Class II substances, see CSCL, art. 35–37.
284 Yoshiko Naiki, *Assessing Policy Reach: Japan's Chemical Policy Reform in Response to the EU's REACH Regulation*, 22 Journal Environmental Law 171 (2010); **Kogan, *supra* note 272, at 652**.

(p 87)