PBT Chemicals: Risk Management without the Rules

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B(a)P, PCDDs, PCDFs, PCBs, PBDEs, DEF and DDT—this alphabet soup of chemical acronyms represents but a slice of a category of chemicals that share a common feature: they are so-called PBT chemicals, where "P" stands for persistent, "B" for bioaccumulative, and "T" for toxic. Included in this category are chemicals that have important industrial or commercial uses. Others appear only as impurities, combustion products, or similar unwanted substances. But whatever their commercial importance, PBT chemicals are significant from a health and environmental perspective because they persist in the environment, bioaccumulate in and up through food chains and, depending on their particular toxicological properties, present risks to humans and other species.

This article focuses on chemicals that are related to commercial activities and therefore may be susceptible to risk-management measures taken by the business entities involved. Further, although I refer to these chemicals generically as PBT chemicals (or simply as PBTs), it might be more accurate to term them "possible PBT" chemicals, because one or more of the three characteristics have not been scientifically established for many such chemicals.

In recent years, health and environmental themes have recurred with respect to the scientific, business, and legal aspects of PBT chemicals. This article discusses certain key elements with respect to PBT risk assessment and risk management activities.

Chemical risk assessment typically is expressed as the function of a chemical's toxicity and its exposure profile. The significance of a chemical's risk depends upon the level of toxicity and the amount of exposure involved. Thus, a highly toxic chemical may be seen as presenting a high risk even though it is present only in moderate or low-exposure situations. Similarly, a chemical to which there are high levels of exposure may be considered to present a high risk even if the chemical is only moderately toxic.

A chemical's toxicity is an inherent property of the chemical. Toxicity is determined by the chemical's basic structure, and is characterized in terms of endpoints (e.g., cancer, teratogenicity, target organ effects, endocrine disruption). Another important concept is target organisms, or populations at risk. This includes both defined groups of humans (e.g., young children, types of workers, pregnant women, persons with specified infirmities), and various nonhuman species (e.g., consumable fish, domestic animals, arctic mammals, waterfowl). Information about a particular chemical's overall "tox profile" is rarely complete or static, and usually is derived from a combination of data sources (e.g., in vitro tests, animal tests, human epidemiological studies), "accepted" assumptions about safety and other factors, and critical scientific judgment (by drawing upon structure-activity relationships (SARs) between untested chemicals and those for which data already exist).

The exposure profile of a chemical likewise depends on a variety of factors. These include amounts of the chemical released to environmental media, the chemical's persistence or degradation in the environment (with attention to whether possible degradation products themselves present risks), bioaccumulation, and routes of bodily intake (inhalation, ingestion, dermal absorption). Other terms that refer to exposure factors include "environmental fate" and chemical "sources and pathways."

Once introduced into the environment, a highly persistent chemical can be expected to remain in ecosystems for long periods without substantial degradation, travel long distances, and move freely between land, water, and air. A chemical that scores high on a bioaccumulation index usually will accumulate and magnify in tissues, and thus build up through food chains (e.g., from fish to humans).

As with toxicity evaluations, it is rarely the case that a complete body of exposure information and data exist for a particular chemical. Rather, exposure assessors often must use existing "surrogate" information, such as production volume and types of uses, and work from basic decision rules to arrive at estimates of the types and levels of exposure of target populations to particular chemicals.

Chemical risk management encompasses the range of measures that may be taken to minimize and otherwise control possible chemical risks to particular human and/or environmental populations. Such measures may include design and technological features, institutional controls, and personal protective devices. They may be undertaken in response to a variety of incentives—on a voluntary basis, through legal mandate, or in response to business or other financial pressures. But whatever form they take,

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risk management actions have the common goal of controlling chemical exposures by reducing, minimizing or altogether eliminating the exposure of human and/or environmental populations to particular chemicals and products containing such chemicals.

In carrying out risk assessment and risk management activities for specific chemicals, it is useful to consider four categories of possible human exposure: (1) workers throughout the commercial chain; (2) persons living, or otherwise regularly present, in proximity to industrial facilities; (3) consumers who use products containing the chemicals—whether as intended components, or as trace impurities; and (4) the general population, who may be exposed following releases of the chemicals (or of precursors to the chemicals) to environmental media. Exposures in the fourth category may occur via inhalation and/or ingestion (with dermal uptake being less common), and are particularly apt to occur with chemicals that are both persistent and bioaccumulative.

Chemical exposures to environmental populations generally result from releases of chemicals to environmental media, and typically are considered important for two basic reasons: (1) the risks that might be presented to the species per se (e.g., diminished fish populations, effects on animals' reproductivity), and (2) the risks that might be presented to humans through their contact with the species (most notably, via human ingestion of the species). Some contend that the very presence of a man-made chemical in one or more nonhuman species demonstrates that the chemical is both persistent and bioaccumulative.

The Nature of PBT Risk Assessments

In light of the large number of man-made chemicals, and the challenges of performing risk assessments on individual substances (particularly the need to fill toxicity and exposure data gaps), both industry and government have developed schemes for sorting chemicals into priority groupings. This sorting generally precedes a more in-depth evaluation and, as appropriate, exposure control (i.e., risk management).

In the 1970s and early 1980s, the predominant point of departure in prioritizing "chemicals of concern" was by reference to certain toxicity endpoints. For example, particular chemicals were identified as suspect carcinogens or teratogens, based on existing test data, epidemiological studies, and/or SAR evaluations. Once identified, these chemicals would be further sorted based on exposure factors such as production volumes and uses. Environmental fate characteristics, including possible persistence and bioaccumulation, also might be considered in priority-setting to address the likely movement of chemicals through the environment and, possibly, up food chains.

Beginning in the late 1980s, a second point of departure for prioritizing chemicals of concern was adopted in the form of various exposure-based "high production volume" (HPV) programs. Primarily through the activities of the international Organization for Economic Cooperation and Development (OECD) and the United States Environmental Protection Agency (EPA) (as a key player in the OECD), extensive programs have been established seeking industry sponsorship of a range of toxicity tests for chemicals that exceed specified production volumes. For example, the Screening Information Data Set (SIDS), which is at the heart of the OECD's Voluntary Testing Program for International High Production Chemicals, sets out a range of toxicity and chemical-property data that are to be developed for HPV chemicals. There are approximately six hundred chemicals on the OECD SIDS working list, about half of which are the subject of active test programs.

The basic premise of these programs is that, at least for chemicals that are produced in large quantities, industry should develop and make public sufficient toxicity information and data so that basic risk assessments may be performed concerning key toxicological endpoints. The link to risk management actions is straightforward: once a chemical's potential risks are known and publicized, a range of considerations likely will drive industry to undertake risk management measures, including, in some cases, phase-out of the chemical, without formal government regulation.

With some notable exceptions, persistence, bioaccumulation, and other environmental fate characteristics have not, until recent years, been key factors in the prioritization of chemicals for more in-depth scientific scrutiny. Among the exceptions were: (1) the U.S. Congress' 1976 requirement in TSCA that PCBs be phased out of commerce, with only limited exceptions for existing, low-risk applications or for EPA-approved essential uses, and (2) Japan's long-standing use of fate characteristics as a decision point for making regulatory judgments concerning new chemicals.

Since the late 1990s, however, PBTs have increasingly been singled out for priority attention in the risk assessment arena. This in turn has spurred increased scrutiny of such chemicals from a risk management perspective.

In 1998, EPA published a draft *Multimedia Strategy for Priority Persistent, Bioaccumulative, and Toxic (PBT) Pollutants* that was intended to "further reduce risks to human health and the environment from existing and future exposure to priority [PBT] pollutants." www.epa.gov/oppt/pbt/pbtstrat.htm. This document listed certain Guiding Principles for implementing EPA's PBT Strategy, described a number of agency actions underway to address specific PBT chemicals, and articulated some Strategy Elements, including the implementation of non-regulatory National Action Plans for twelve Level 1 substances (e.g., dioxins, PCBs, mercury, and several already-banned pesticides). Thereafter, some EPA programs incorporated PBT "screens" into their own, statute-specific decision-making. For example, in 1999 EPA's TSCA pre-manufacture notification office adopted a policy placing heightened review standards on new chemicals that pos-

sess (or might possess) certain P, B and/or T characteristics. Similarly, EPA's pesticides office has been using PBT-related screening criteria in reviewing registration applications for new pesticides and re-registration applications for existing ones. However, EPA to date has not issued a final PBT Strategy and continues to focus its attention on developing the action plans for the same twelve chemicals listed in the 1998 strategy document.

Perhaps of more significance than the PBT Strategy's specific action items are two basic concepts that it embraces: (1) chemicals with demonstrated P, B and T properties merit tight restrictions, if not outright bans; and (2) chemicals with demonstrated P and B (but not T) properties should be carefully evaluated for a range of major human toxicity endpoints, and should be treated with caution until and unless they are demonstrated to be "clean" for each of those endpoints. In fact, industry and government often are asked to undertake risk management actions prior to receiving the results of both toxicity and risk assessments.

Some believe that a cautionary approach is especially warranted for P and B chemicals because of the potentially diffuse and ubiquitous nature of the exposures involved. Some argue that because PBT risks involve populations exposed to environmental releases, those populations are innocent in that they either are not associated with the industrial use(s) that result in the chemical releases, or their only association is as consumers of products that contain the chemicals. In either event, the argument goes, they are unknowingly and unwillingly exposed to chemicals that will not go away for a long period of time.

The same point is argued for environmental populations that are found to have elevated levels of chemicals (i.e., amounts above natural background levels): the chemicals should not be present in nonhuman species, whether aquatic or terrestrial. Moreover, to the extent such species are located long distances from industrial or otherwise populated areas, the very presence of the chemicals in local species indicates that the chemicals are both persistent and bioaccumulative (i.e., that the chemicals are stable, persist, move long distances through environmental media, and bioaccumulate in and up the food chain). Often pointed to are findings of chemicals in boreal or arctic fish and animals, some of which are symbols or mascots of environmental and conservation organizations.

A final note about exposure and risk assessments for PBT chemicals: it is neither technically difficult, nor particularly expensive, to screen for the presence of specific chemicals in humans and other species. Blood, tissue, breast milk and/or hair samples typically are used, and the laboratory tools are widely available. Moreover, such samples can be retained for years, thus facilitating the development of baseline data against which the results of future sampling can be compared to identify possible trends. This is not to say that this type of work is totally free of uncertainty and scientific disagreement. But on balance, identifying the presence of specific PBT chemicals in nonhumans and various other species can be a significant factor in both scientific and commercial judgments, including cautionary risk-management approaches.

Risk Management and Liability Considerations

U.S. environmental laws—most notably TSCA, FIFRA and EPCRA—give regulators a number of means to effect risk management actions for chemicals, including PBT chemicals that present risks to health or the environment. These laws authorize government officials to: (1) require industry to develop, provide, and make public information and data that are needed for both toxicity and exposure assessments; (2) perform risk assessments, as well as evaluations of possible design, engineering, and institutional controls; and (3) impose a range of risk management controls upon business activities throughout the commercial chain.

To date, most actions by EPA concerning PBT chemicals have focused upon: (1) the types of testing, priority-setting, and related assessment activities described above, and (2) heightened scrutiny by the new chemicals notification and pesticides registration programs to substances that evidence PBT characteristics. EPA has not used its traditional command-and-control authorities to impose risk management (i.e., exposure) controls on a substantial number of existing chemicals.

In addition to its leading role in OECD activities aimed at HPV chemicals, EPA has participated in some bilateral programs to address chemical contamination of environmental media (e.g., the Canada-U.S. Binational Toxics Strategy, and the Sound Management of Chemicals Program of the North American Commission for Environmental Cooperation) (CEC members are the United States, Canada, and Mexico). Further, EPA has taken steps to implement elements of the United Nations' Convention on Persistent Organic Pollutants (POPs Treaty). However, the United States has not ratified POPs (which came into force on May 17, 2004) and therefore is not officially a party to the treaty. Further, POPs at this time seeks to eliminate from the world only twelve compounds, ten of which already are the subject of EPA's PBT Strategy.

Reflecting their own health and environmental policies, businesses will seek to ensure that their products do not harm or otherwise present unreasonable risks to humans or environmental populations. Many companies thus undertake risk management activities, including product stewardship, if they produce or otherwise are responsible for PBT chemicals.

Further, the relative absence of conventional regulatory controls in this country does not mean, however, that risk management decisions have been left solely to the prerogative and goodwill of chemical producers and users, to be taken on a voluntary basis without substantial outside

input, suasion, or pressure. Rather, a number of external drivers typically influence corporate decisions concerning PBT chemicals.

First, potential tort liabilities can play an important role in corporate decision-making, and PBT chemicals are candidates for at least two types of tort claims: (1) claims by persons living in the vicinity of industrial plants that PBT chemicals have been released to the environment, are present in surrounding environmental media, and therefore present health risks; and (2) claims by persons in the general population that PBT chemicals are present in their bodies and can be linked to particular companies' products or other commercial activities. PBT-related tort claims are particularly significant because they can lead both to significant monetary judgments and to orders for injunctive relief. Moreover, to be successful, such claims need not prove actual harm. Rather, demonstrated prospects of future injury may be sufficient for a court to order a company to pay for medical monitoring, chemical testing, and similar forms of chemical and health evaluations that also might, at a future date, result in the awarding of damages for injuries to health.

Tort claimants typically seek class certification of all persons who are alleged to be similarly situated. If certified, class claims on behalf of all persons in the vicinity of a facility can encompass a large population seeking substantial monetary and injunctive relief. If class status is granted to persons in the general population, the resulting litigation costs alone—not to mention actual awards of damages and injunctive relief—may place a business in a bet-the-product, or even bet-the-company, situation.

Second, largely for the same reasons, companies commercially downstream from the principal producer or processor of a PBT chemical may engage in "product deselection"— a decision to discontinue use of that particular chemical in favor of a non-PBT substitute. Any such substitute(s) presumably must provide technical, performance, and economic characteristics comparable to the PBT chemical that is being replaced. But, depending upon the urgency of the user-company's need to move to a substitute, that company may be willing to engage a substitute that involves a compromise in one or more of these characteristics. In this manner, the market can dictate risk management actions including, in some instances, the ultimate step of chemical phase-out.

Third, corporate name-recognition and product "branding" may influence a company's decisions concerning future commercial activities involving a PBT chemical. Thus, a business's valuable intellectual property in a product name might be compromised when downstream users link that name to potential health or environmental risks. This situation most likely will arise with respect to chemicals that are associated with consumer products, particularly those marketed as being somehow "green" or otherwise safe for consumers and the environment. And although this factor typically will not operate independent of the others mentioned above, it can be a powerful motivator for company decision makers, particularly those who are commercially downstream from the producers or primary processors of a PBT chemical.

In light of these and similar drivers, plus the various interests that might weigh in on the issue, risk management decision-making for PBT chemicals is complex, dynamic and unpredictable. Several scenarios, drawn from real-world experiences involving PBT chemicals, demonstrate this point.

If EPA states outside a rulemaking that a particular chemical might present certain PBT-type health or environmental risks, that statement alone may prove sufficient for tort claimants and/or commercially downstream business interests to take actions that effectively restrict, or altogether ban, that chemical. Further, even if senior EPA officials do not make such statements, others at the agency, including persons outside the chain of command from the key regulators, can speak out or make other communications which, once issued, have the practical consequence of being "official" EPA statements.

Activities by academic and other nongovernmental organizations outside the United States concerning PBT chemicals can have a significant impact upon risk management decisions in this country. For example, technical and scientific materials published abroad may be used effectively to support proposed chemical controls in the United States, even if the underlying protocols and data are not available for full external review and validation, or do not meet U.S. standards for the development of such data. Further, other countries, using such data and applying their own legal standards, may issue controls that subsequently are proffered to U.S. regulatory officials as evidence of the need to take the same actions in this country. If U.S. regulators conclude that similar controls are not authorized under U.S. law, at least based upon currently available information, they may well be criticized as being lax on risks that other countries have moved to address. In response, the U.S. officials may seek to engage the relevant chemical manufacturers in nonregulatory, "voluntary" programs whose basic goal is the same as the regulatory controls adopted outside the United States (i.e., the limitation or total phase-out of the PBT chemical at hand).

EPA may sponsor a "stakeholder workshop" concerning a PBT chemical, to be attended by representatives of government, manufacturers of the chemical, downstream commercial users, producers of alternative technologies (chemical and otherwise), consumer organizations, and academic and other third-party scientists. During the workshop, participants may be asked their opinions (including via straw votes) on a variety of technical, business, and policy matters, including many that pertain to moving the chemical out of the market. In fact, chemical phase out may be a fundamental premise of the workshop as organized. Following the workshop, EPA (or a contractor) may prepare, for public dissemination and with the agency's imprimatur, a proceedings document that

includes attendees' statements and written materials and that purports to summarize workshop outcomes and next steps. Thus, although the entire program is conducted outside the scope of any notice-and-comment or other due-process framework, EPA fosters the development of substantive commentary and opinion making concerning fundamental risk management decisions.

EPA's conduct of proceedings for the development of Enforceable Consent Agreements (ECAs) provides an example of the government playing a key role in hybrid voluntary/regulatory actions. As an alternative to regular APA-style rulemaking for the development of test data, EPA's TSCA rules authorize the agency to convene a group of interested parties whose job it is to reach consensus on the contents of a test program that will be enshrined in an ECA and sponsored by relevant chemical manufacturers. The ECA concept is a workable one, and several successful ECA test programs have been negotiated between industry and EPA. However, the ECA process itself creates certain obstacles to the successful development of test programs for high profile, controversial PBT chemicals. Most notably, any organization or person may declare itself to be an interested party and thereby secure the right to participate in the negotiation of test standards and other requirements for industry. According to EPA, this process is required because, in order for an executed ECA to be a legally binding and enforceable alternative to a TSCA test rule, the ECA must be negotiated in a fully transparent manner in which all members of the public have a right to participate. This has led, at times, to a situation in which EPA chairs ECA negotiating sessions attended by the affected chemical manufacturer(s), government officials and, as interested parties, plaintiffs and their counsel who currently are suing the manufacturer over health risks and injuries allegedly caused by the manufacturer's PBT chemical. Understandably, full and free discussions, let alone negotiations, are severely curtailed by this dynamic.

A foreseeable consequence of minimal or no risk management action at the federal level is states' enactment of bans or use restrictions on PBT chemicals. Absent federal preemption, and in the face of demands by local constituents, state legislators may pass such laws without taking account of the types of scientific assessments that federal regulators must consider as a predicate for imposing controls on chemical production and use. And because of the tort, commercial deselection, and other external drivers, it may take no more than a few such state laws, typically coupled with scientific-sounding "findings," for the subject chemical(s) to be effectively restricted or banned nationally.

Once a PBT chemical becomes the subject of substantial scientific attention, it may develop a life of its own in terms of the scientific and technical resources that are generated for further studies and reviews. Perhaps an ultimate indication that a chemical is destined for eventual phase-out is its appearance as the centerpiece of international scientific conferences, particularly if the conferences become regular events. The combination of scientific attention, and the funding to support that attention, may create a momentum that does not dissipate until well after commercial activities involving the chemical have been severely limited, if not eliminated.

Given this unsettled regulatory and liability context, environmental lawyers who become involved with PBT chemicals may find the following observations of some utility:

Define, and maintain focus on the key potential liability scenarios for particular PBT chemicals, whether they are regulatory, tort, or contractual in nature. A lawyer adds significant value by clarifying and emphasizing both end-game liability concerns for PBT chemicals, and appropriate measures to address them.

Concerning business interests and liability drivers, learn the trees but understand the forest. As described above, a significant number of players and interests likely will be involved in addressing and resolving PBT health and environmental matters, and their interactions will create dynamics often not present in more conventional regulatory situations. Having a sound grasp of those dynamics is essential to formulating and executing legal and business strategies that limit and manage potential liabilities.

Gain a thorough understanding of the core scientific issues involved, including the status of data development and knowledge, plus key uncertainties and work-in-progress, for all key toxicity and exposure parameters.

Regularly anticipate (with scientific experts) where the science is leading and likely to end up. Though this may necessarily involve a fair amount of crystal ball gazing and supposition, it nonetheless will prove useful in formulating compliance and liability strategies.

Stay ahead of the game. Notwithstanding the many uncertainties associated with existing PBT chemicals, it is reasonable to anticipate the types of products and activities that should be minimized or avoided in order to limit future PBT-related adversities. For example, several lists exist of substances that already either have been found to be, or are suspected of being, PBT chemicals. Also, the basic characteristics of persistence and bioaccumulation, along with tests to score or otherwise evaluate particular substances' persistence and bioaccumulation characteristics, are available in the published literature.

In sum, a lawyer's contributions to decision-making about PBT chemicals should cover a range of business considerations and legal theories, with regulatory matters occupying an important, but not necessarily dominant, role in the overall picture. Although much can be learned from risk-management experiences with non-PBT chemicals, the combination of chemical persistence and bioaccumulation often presents significant risk scenarios, with corresponding enhanced potential liabilities. An environmental lawyer therefore must look well beyond applicable statutes and regulations in framing clients' potential legal challenges and the options for addressing them.