LEVERAGING SCIENCE TO INFORM PROACTIVE AND REACTIVE RISK MANAGEMENT

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I. Risk Assessment as a Tool for Effective Product Stewardship

The production, transport, use, and disposal of industrial and consumer products may pose risks to human and environmental health. Workers have potential exposure to starting reagents, raw materials, and byproducts/intermediates during manufacture and transport, as well as to chemical agents in finished products. Consumers also may be exposed to chemicals from handling, using, or storing the finished product in commercial or residential settings. At each stage of a product's life cycle, potential exists for chemical release to the environment—whether through stack emissions at a production facility, spillage loss during transport, evaporative losses during use, or leaching of landfilled waste into soil or groundwater.

Product stewardship is the practice of characterizing and managing human health and environmental impacts throughout a product's life cycle. Through risk assessment, companies can understand the intrinsic hazards of chemicals and quantify the likelihood (risk) that exposures may damage human health and the environment. By understanding the hazards and potential risks throughout its product's life cycle, a company is well-positioned to maintain regulatory compliance, identify problematic chemistries or exposure scenarios that may present risks in the supply chain, and effectively manage and mitigate risks over the product's life cycle.

A. The Risk Assessment Framework

Risk assessment is a systematic evaluation of potential risks associated with a given product or activity. With respect to chemicals, risk assessment can be used to identify potential hazards and qualitatively or quantitatively evaluate the probability that exposure to those hazards will cause an adverse health effect. The risk assessment framework consists of four key components, as outlined in Figure 1: (1) hazard identification; (2) dose-response assessment; (3) exposure assessment; and (4) risk characterization. Risk assessment is an iterative process, as information learned from each step can be used to inform decisions and strategies in other steps. Each of the risk assessment framework components is briefly outlined below.

(1) Hazard identification (hazard ID) is the process of identifying the potential for adverse health outcomes for a given substance by assessing toxicological and epidemiological evidence. Through hazard ID, a company identifies the full scope of hazards that a product may pose to the worker, consumer, or environment. Initially, all adverse effects (in any species and at any dose) are evaluated, but information from dose-response and exposure assessments can inform and refine the key hazards in subsequent assessments.

(2) Through dose-response assessment, the relationship between the magnitude of exposure and the severity or frequency of an adverse health effect is studied. Generally, the higher the chemical dose, the more pronounced the effects. Dose-response relationships for the same chemical can vary significantly, however, depending on the effect, species (e.g., rat versus human), and exposure (including route, duration, and frequency). The aim of dose-response analyses is to identify thresholds below which the chemical is not expected to elicit adverse health effects or the probability of adverse effects is sufficiently low.

(3) Exposure assessment estimates the amount of chemical to which an individual could be exposed for a given exposure scenario. Exposure is impacted by many factors, including the duration and frequency of the activity of concern; the exposure pathway (e.g., inhalation, ingestion from food or water, or dermal absorption); as well as the

chemical's absorption and bioavailability (the proportion in circulation that has an active effect).

(4) Finally, in the risk characterization step, the hazard ID, dose-response, and exposure assessments are synthesized to assess the presence or absence of risk; when sufficient data are available from these initial steps, risk characterization permits a quantitative prediction of risk. In quantitative risk characterization, the estimated exposure is compared to the selected toxicity value derived in the dose-response assessment. If the exposure level falls below the selected toxicity value, then it can be concluded that there is a low likelihood of increased risk (or a low likelihood of appreciable risk, for probability-derived toxicity values) for the identified hazards and given exposure scenarios.

If the exposure level exceeds the selected toxicity value, then an increased risk of an adverse health effect may exist. In addition to quantitative estimates of risk, uncertainties and limitations in the conclusions should be addressed in any risk characterization to offer qualitative context on the strength of the risk assessment conclusions. Further, it is important to note that predicted increased risk does not necessarily mean that exposure *did* or *will* cause a health effect, but rather the effect may be *more likely* to occur.

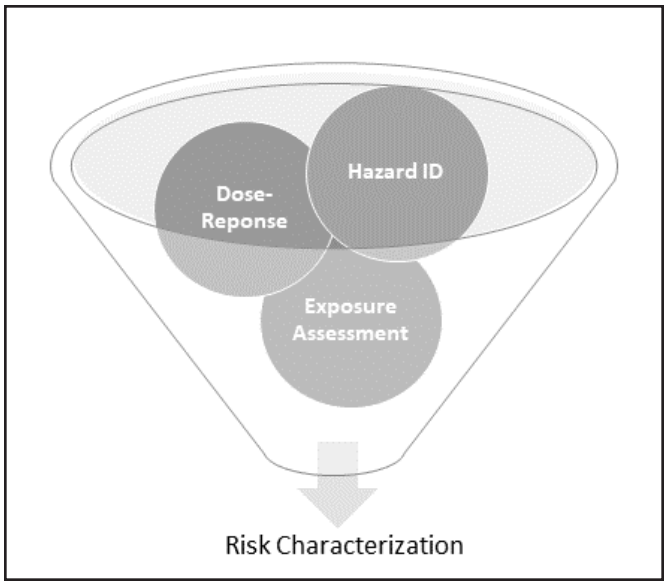
B. *Effective Product Stewardship: A Multidisciplinary Approach*

Based on the risk assessment framework, both toxicology and exposure science play an integral role in assessing risks. Effective product stewardship is multidisciplinary and draws insights from numerous scientific and technical disciplines, including toxicology, exposure science, materials science, as well as legal and regulatory affairs. Each of these fields provides a business with crucial information to identify and manage potential health and environmental risks.

- **Toxicology**. Toxicologists identify and evaluate human health and ecological hazards via animal/*in vitro* testing, modeling, and reviewing scientific literature. Through dose-response analysis, toxicologists assess the relationship between the magnitude of a chemical exposure and the severity of its effect in a given organism (e.g., bacterium; plant species; or rodent). Importantly, toxicologists determine whether the effect observed in an experimental study is relevant to human biology.

- **Exposure science**. Once a hazard is identified, exposure scientists (including industrial hygienists, environmental engineers, and others) estimate human or environmental exposures to that chemical or agent throughout the different stages of the product's life cycle. By quantifying exposure, businesses can evaluate the likelihood that observed, experimental toxicological hazards will occur in real-world scenarios, based on assumptions for work and use practices.

Figure 1. The Risk Assessment Framework



- **Materials science**. Materials science professionals have in-depth knowledge of the product's underlying chemistries. Elimination and substitution of high-risk components may be designed into the product formulation to reduce hazards or risks without affecting the product's form or function.

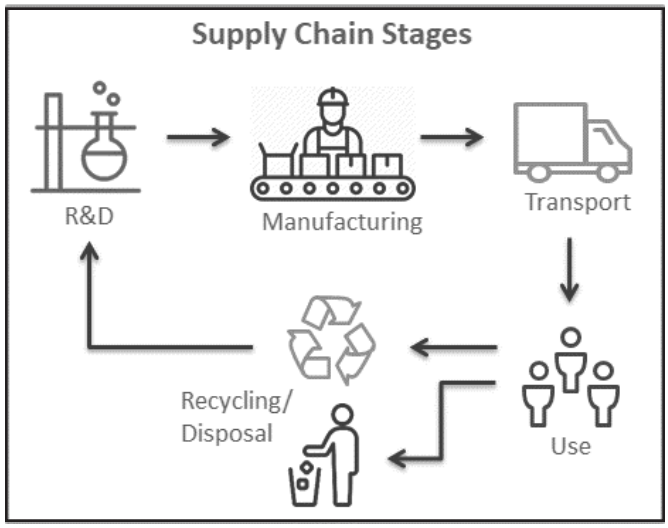
- **Legal and regulatory affairs**. The scope and application of product and chemical regulations, both in the United States and around the globe, are constantly changing. In addition to ensuring that a company's business practices maintain compliance with such laws and regulations, legal and regulatory affairs teams provide oversight on new adoptions and amendments that may significantly affect business operations. In the chemical sector, for example, compliance with the Toxic Substances Control Act (TSCA),[1] Proposition 65,[2] the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)[3] regulation, and Globally Harmonized System of Classification and Labelling of Chemicals (GHS)[4]-aligned regulations, among others, will impact product formulation, hazard communication, uses, and available markets.

1. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.
2. Safe Drinking Water and Toxic Enforcement Act, Cal. Health & Safety Code §§25249.5-25249.14 (1986).
3. Regulation (EC) No. 1907/2006 Concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals, 2006 O.J. (L 396).
4. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), U.N. Doc. ST/SG/AC.10/30/Rev.4 (2011), *available at* https://unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf.

C. *Application of Risk Assessment in Product Stewardship*

The risk assessment framework can be applied in various sectors, for numerous products or processes, and across the supply chain. Any industry in which chemical exposure may occur can benefit from the risk assessment process, including pharmaceuticals, consumer products, industrial products and chemicals, and energy. Further, this framework may be applied at any point along the supply chain (Figure 2): research and development (R&D), manufacturing, transportation, use, reuse, and disposal. By incorporating risk assessment into product stewardship, companies are better able to maintain regulatory compliance, can readily identify and screen potential hazards, and can reduce potential exposures driving these risks.

Figure 2. Overview of Supply Chain Stages



1. Regulatory Compliance

Many U.S. and international chemical regulations use risk assessment to inform policy and require that either the competent authority or business entity conduct a risk assessment to evaluate chemical safety. Under the provisions of TSCA, the U.S. Environmental Protection Agency (EPA) is currently conducting risk evaluations on existing chemicals that did not undergo assessment before being placed on the market. At any given time, the Agency designates 20 "high-priority" chemicals for health risk assessment based on various criteria, including production volume, degree of hazard, and persistence in the environment.

Under Proposition 65 in the state of California, companies selling products containing carcinogens or reproductive/developmental toxicants (as designated by the state of California) must attach a health warning label to their product as a minimum requirement. However, the law allows companies to forgo this labeling if a risk assessment demonstrates that product use does not pose health risks to the consumer. In the European Union, companies seeking to import substances at quantities of 10 or more metric tons must prepare and submit a chemical safety assessment in accordance with REACH.

2. Proactive Risk Management

A proactive product stewardship program identifies and mitigates prospective health hazards or risks *before* they can occur and possibly impact the supply chain. By implementing a hazard screen, for example, companies can phase out or substitute production chemicals that fail to meet select criteria (e.g., toxicity or environmental persistence metrics). From a regulatory perspective, companies well-informed of pending risk-based regulations are better prepared to adjust their business practices to remain compliant and also effect more favorable rulings by working with the agencies during the risk assessment process.

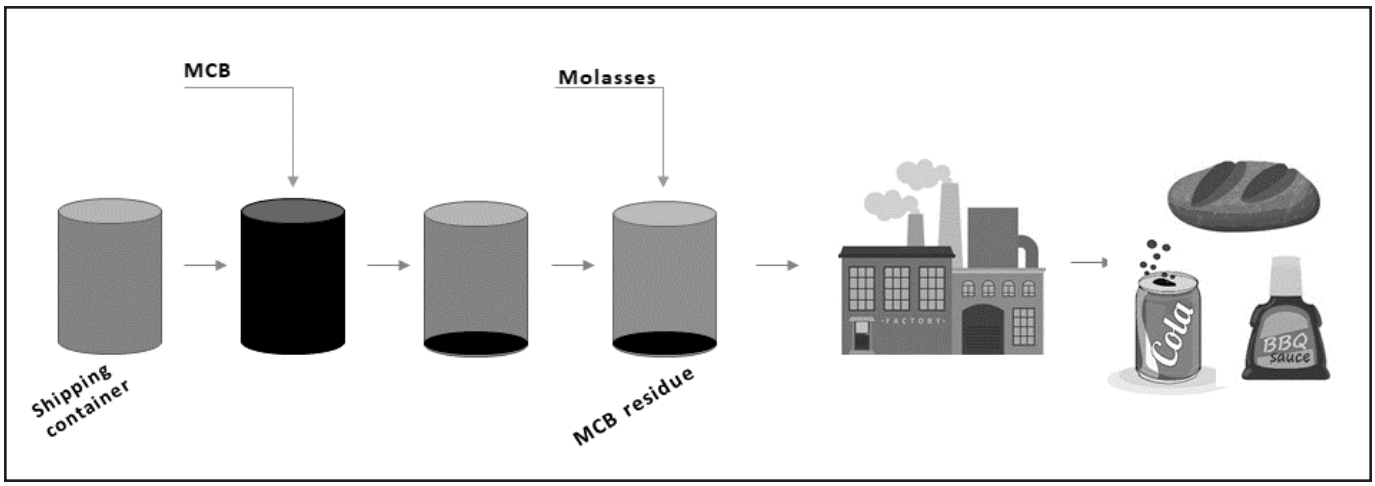
In the case of TSCA, companies whose chemicals were selected for risk evaluation by EPA could opt to supply their own exposure information rather than allow the Agency to use their more conservative, default chemical use conditions in its risk calculations. By assessing exposure potential for downstream users and consumers, businesses can identify use scenarios that might pose increased health risks. To prevent overexposure from occurring, businesses can provide engineered solutions to reduce exposures, implement effective hazard communication and training for workers, as well as provide detailed use instructions for consumers.

This section presents two case studies that demonstrate the benefits of adopting proactive risk assessment strategies into product stewardship programs. Case Study 1 discusses the development of a hazard screening tool that effectively characterizes human health and environmental hazards posed from industrial products while maintaining confidential business information (CBI). In Case Study 2, a food manufacturer or importer uses risk assessment to understand the degree of chemical contamination that could occur during production or shipping.

❑ *Case Study 1: Assessing hazard, maintaining CBI.* As discussed, a proactive product stewardship program identifies and mitigates prospective health hazards or risks before they can occur and potentially impact the supply chain; one example of this approach is the design and implementation of a hazard assessment and screening tool. However, chemical supply chains can be complex and lack transparency regarding hazard disclosure. Chemical hazard information about a substance or mixture is usually limited to safety data sheet (SDS) disclosure. Product formulation data on an SDS are often protected as CBI and, as a result, linking disclosed hazards to specific components can be difficult.

The multi-tiered structure of supply chains, where products are composed of numerous chemical mixtures and substances provided by various manufacturers and suppliers, further obstructs clear hazard ID. As such, businesses are challenged to identify and report chemical hazards in their product while maintaining the CBI of their supply chain. In this example, a third-party hazard assessment

Figure 3. Potential for Residual Chemical Carryover in Molasses



process was used to evaluate chemical-specific human and environmental health hazards within purchased industrial products without requiring public product formulation disclosure in the supply chain.

A chemical purchaser and third-party consultant developed a component-level hazard assessment tool that evaluated the complete hazard profiles of the purchaser's products while maintaining the confidentiality of its upstream suppliers and their product formulations. The purchaser and consultant designed the tool to evaluate both health and environmental hazards (e.g., carcinogenicity, reproductive/developmental toxicity, and aquatic toxicity). Hazards were identified by screening chemical components against regulatory and authoritative lists and against environmental fate and toxicity criteria. Products were then scored to reflect the presence or absence of hazards, generating a metric by which multiple products could be compared against one another. To ensure CBI during the assessment process, the third-party consultant requested formulation information from upstream suppliers and manufacturers and assessed the hazard(s) of the components; all requested information was legally protected under non-disclosure agreements and was blinded from the purchaser's review.

Through this proactive, hazard-focused approach, the chemical purchaser effectively identified hazardous products and, where possible, replaced them with less hazardous substitutes—all while maintaining supply chain and formulation confidentiality. Where less-hazardous product alternatives were unavailable or could not be obtained without imposing severe economic impacts, the hazard information gleaned from the review was applied toward a more comprehensive risk evaluation. Said differently, this hazard assessment program allowed the chemical purchaser to understand and mitigate the risk profile of its products without undertaking a risk assessment for every individual product.

❑ *Case Study 2: Addressing chemical contamination in the food supply*. The risk of chemical contamination of food supplies exists at every point in the supply chain, including production, transportation, and processing. Chemical contamination can occur naturally or be introduced by man-made processes. For example, aflatoxins are produced by fungi species like *Aspergillus* that can grow on grains and nuts stored in moist conditions.[5]

Chemicals may also be introduced to food stuffs as a result of manufacturing or transport practices. Bulk liquid food products are shipped in generic vessels that are also used to ship non-food products, introducing the possibility of chemical contamination during transport. This case study demonstrates how a molasses manufacturer can utilize risk assessment to examine the potential for health risks to consumers associated with shipping molasses in a vessel previously containing monochlorobenzene (MCB) (Figure 3).

In this hypothetical scenario, the molasses manufacturer is preparing a bulk shipment to be transported to a processing facility. However, the company is informed that the incoming vessels it will use to ship its food products were previously used to transport MCB, an industrial chemical used as a solvent and precursor molecule in chemical manufacturing. Although the cargo vessels were cleaned in between shipments, a residual level of MCB up to 100 parts per million (ppm) may be present in the molasses. The manufacturer would like to determine whether MCB contamination of molasses could cause adverse health effects in its consumers.

MCB can cause kidney and liver effects in humans following oral exposure at levels above 0.02 milligrams per kilograms per day (mg/kg/day).[6] Using the 0.02 mg/kg/day toxicity threshold and an average daily molasses consumption of 0.037 kg/day, the maximum amount of MCB

5. Department of Food Safety and Zoonoses, World Health Organization, Food Safety Digest: Aflatoxins (2018) (WHO/NHM/FOS/RAM/18.1), https://www.who.int/foodsafety/FSDigest_Aflatoxins_EN.pdf.
6. Integrated Risk Information System, U.S. EPA, Chemical Assessment Summary: Chlorobenzene; CASRN 108-90-7 (1989), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0399_summary.pdf.

residue in the molasses that does not pose human health risks is determined to be 27 ppm.[7] Because the MCB concentration in molasses (100 ppm) may exceed this level, the consumption of MCB-contaminated molasses could cause excess health risks to consumers. As a result, the molasses manufacturer opts to not use the containers that previously contained MCB to transport its foodstuffs.

By implementing risk assessment proactively, manufacturers and suppliers can quantify and mitigate health risks before a chemical hazard is introduced into their supply chain. In this scenario, the manufacturer anticipated, estimated, and mitigated MCB-related health risks *prior to* shipping its products in containers that had previously held the hazardous substance. Similarly, companies that understand the degree of chemical contamination throughout their supply chain can institute quality assurance/quality control practices to minimize product contamination (e.g., through increased sampling of pre-preparation and final products or enhanced cleaning of process equipment and shipping containers).

Proactive risk management is both economically advantageous to the business (prevents recalls and lawsuits) and protective of human health (prevents excess morbidity and mortality). The risk assessment framework can be applied to various industries, including personal care or consumer products, as well as to any step in the supply chain (e.g., manufacturing, processing, etc.).

3. Reactive Risk Management

Risk assessment is also useful in managing and mitigating hazards and risks when they do impact a supply chain. By incorporating risk assessment into emergency response scenarios, businesses can evaluate the extent to which chemical spills or contamination may cause adverse effects in workers, consumers, or the environment, and manage the risks accordingly. Companies can ensure the health and safety of their spill-response teams by providing the appropriate engineering controls (chemical isolation or encapsulation, adequate indoor ventilation); administrative controls (job rotations, shift changes); and personal protective equipment (chemical protective suits, respirators, gloves, eye protection). Additionally, companies may elect to provide consultative resources to customers and response agencies using this information to help during spill-response actions on customer sites or in public spaces.

In the case of post-life-cycle environmental cleanup efforts, risk assessment can be applied to determine the most efficient and effective strategy to reduce potential future health risks from hazardous waste sites, such as placing physical barriers to contain and bury waste, advising communities to refrain from consuming local biota, and relocating or treating contaminated soil or sediment. In addition, companies facing litigation over human health or environmental damage allegations following chemical exposures can quantify the extent of the impacts and their resulting liability.

New or existing chemicals may have toxicological data gaps that are not well characterized in the scientific literature. Toxicological studies evaluate the dose-response of chemical hazard(s) *in vivo* (in animal models) or *in vitro* (in cultured cells or organisms). Reported adverse effects may not be applicable to human health due to study limitations, such as small sample size or inadequate dosing, or key metabolic differences between the studied species and humans. However, media coverage of new toxicological findings can misinterpret the science, labeling a chemical as a "bad actor" based on insufficient data or in the face of conflicting studies.

By applying risk assessment principles, companies can quantitatively evaluate human health risks posed by a chemical to respond to negative media attention or public health concerns. The below bisphenol A (BPA) case study shows us how risk-based product stewardship can inform supply chain management when new chemical-specific health concerns come to light.

❑ *Case Study 3: Investigating BPA health concerns*. BPA was a high-production volume monomer used to manufacture polycarbonate plastics and epoxy resins found in food contact materials (FCMs). The chemical was found to be ubiquitous in humans due to its leaching from FCMs and subsequent low-dose consumption through the diet. The monomer was identified as an endocrine disrupter by several scientific and public interest organizations, but to what extent BPA caused reproductive or developmental effects in humans was largely unknown.[8]

Throughout the late 1990s and 2000s, numerous studies were published that concluded that rodents exposed to low-dose BPA exposures (similar to human dietary exposures) developed adverse health effects, including early puberty onset as well as mammary gland and prostate lesions.[9] News headlines touted BPA as a serious threat to public health: "US Cites Fears on Chemical in Plastics," "Plastics: Danger Where We Least Expect It," "The Dangers of a Food Chemical: New Evidence Against BPA."[10]

7. George A. Burdock, Fenaroli's Handbook of Flavor Ingredients (6th ed. CRC Press 2010).

8. Sarah A. Vogel, *The Politics of Plastics: The Making and Unmaking of Bisphenol A "Safety,"* 99 (Suppl. 3) Am. J. Pub. Health S559 (2008).

9. Milena Durando et al., *Prenatal Bisphenol A Exposure Induces Preneoplastic Lesions in the Mammary Gland in Wistar Rats*, 115 Env't Health Persp. 80 (2007); Shuk-Mei Ho et al., *Developmental Exposure to Estradiol and Bisphenol A Increases Susceptibility to Prostate Carcinogenesis and Epigenetically Regulates Phosphodiesterase Type 4 Variant 4*, 66 Cancer Rsch. 5624 (2006); Kembra L. Howdeshell et al., *Exposure to Bisphenol A Advances Puberty*, 401 Nature 763 (1999); Tessa J. Murray et al., *Induction of Mammary Gland Ductal Hyperplasia and Carcinoma* in Situ *Following Fetal Bisphenol A Exposure*, 23 Reprod. Toxicology 383 (2007); Bryce C. Ryan & John G. Vandenbergh, *Developmental Exposure to Environmental Estrogens Alters Anxiety and Spatial Memory in Female Mice*, 50 Hormones & Behav. 85 (2006).

10. Larry Hand, *Plastics: Danger Where We Least Expect It*, Harv. Pub. Health, Winter 2010, *available at* https://www.hsph.harvard.edu/news/magazine/winter10plastics/; John Hendel, *The Dangers of a Food Chemical: New Evidence Against BPA*, Atlantic, Oct. 4, 2010, https://www.theatlantic.com/health/archive/2010/10/the-dangers-of-a-food-chemical-new-evidence-against-bpa/63928/; Vogel, *supra* note 8.

In response to the new "low-dose" studies and negative media coverage, an FCM manufacturer sought to determine the human health and business risks posed by incorporating BPA into its supply chain. The company investigated the reliability of the low-dose rodent toxicity studies and their applicability to human health. Regarding study accuracy, the majority of the "low-dose" studies that purported to study effects at levels comparable to human dietary exposure used dosing regimens that exceeded the upper bound of human exposures.[11]

In addition, numerous publications noted that the toxicokinetics of BPA in the rat model were not representative of the chemical's metabolism and excretion in humans. In fact, BPA was found to have a longer circulation residency time, reduced metabolism to inactive compounds, and less efficient excretion in rats compared to humans.[12] The reported adverse health effects were associated with a nontraditional, U-shaped dose-response curve where effects were found at both low and high doses. However, these findings appeared to be influenced by inadequate study design; when more comprehensive and robust studies were performed that examined dose response in a larger number of rodents using a larger range of dosing, the same adverse health effects were not reported at low doses.[13]

Examining the health risk literature on BPA also provided insights into the chemical's safety at low dietary exposures. Numerous international regulatory agencies, including the European Food Safety Authority (EFSA), Health Canada, and Food Standards Australia New Zealand (FSANZ), evaluated the toxicity literature and derived tolerable daily intakes (TDIs) for BPA, concentrations that could be consumed daily over a lifetime without causing health risks. Typical estimated dietary exposures to BPA fell below even the most conservative of these TDIs (4 micrograms per kilogram per day), and there was global regulatory consensus that BPA-containing FCMs were safe for consumers of all ages.[14] However, despite this consensus of the safety of BPA at low doses, many countries continued to implement regulations that banned BPA in various products, including infant and children's bottles, toys, and food containers.[15]

This BPA case study highlights how risk assessment can help inform business practices in the face of negative media and conflicting toxicology literature. By utilizing risk assessment principles, the FCM manufacturer evaluated the merit of new low-dose toxicology literature and found regulatory consensus that BPA in FCMs did not pose health risks to consumers. However, this case example also highlights the importance of building a multidisciplinary product stewardship practice. While interpreting the science and analyzing health risks are important to business strategy, considering public perception and regulatory direction are also crucial. In the case of BPA, despite consensus of safety of low-dose exposures, the continued negative perception of the chemical in the media and push by many regulatory agencies to phase out the chemical should be weighed carefully.

D. *The Business Case for Risk Assessment-Based Product Stewardship*

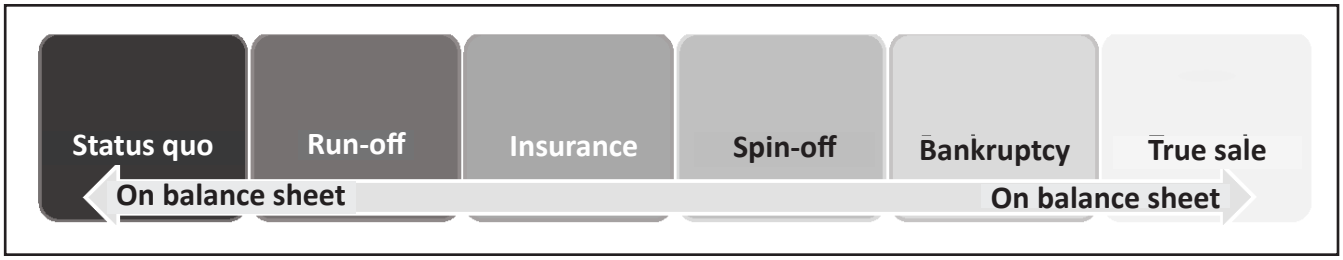
By anticipating hazards and risks of their products, companies can strategically remove health/environmental hazards before they impact the supply chain, or more effectively mitigate risks in the supply chain when they inevitably arise. Risk assessment-based product stewardship also demonstrates to consumers that a business is mindful of its potential impact on human health and the environment.

Incorporating risk assessment into a product stewardship program demonstrates alignment with global human and environmental health and safety initiatives. As consumer awareness of the sustainability and safety of products increases, building a robust product stewardship program will be necessary for business success and developing an edge over competitors. Getting ahead of this trend will position companies for both excellent customer relations and help to create trusted brands. By demonstrating through scientifically valid risk assessments that their products do not pose significant health risks at any point of the life cycle, companies can capture the attention and loyalty of the rapidly growing number of conscientious consumers.

Risk assessment can be used to eliminate hazards and manage risks in a targeted, cost-effective manner. Through iterative hazard evaluations and dose-response assessments, companies can screen and replace chemicals with less hazardous ones. In addition, these steps can be used to prioritize risk management measures, such as

11. Justin G. Teeguarden & Sesha Hanson-Drury, *A Systematic Review of Bisphenol A "Low Dose" Studies in the Context of Human Exposure: A Case for Establishing Standards for Reporting "Low-Dose" Effects of Chemicals*, 62 Food & Chemical Toxicology 935 (2013).
12. Jean Y. Domoradzki et al., *Metabolism and Pharmacokinetics of Bisphenol A (BPA) and the Embryo-Fetal Distribution of BPA and BPA-Monoglucuronide in CD Sprague-Dawley Rats at Three Gestational Stages*, 76 Toxicological Sci. 21 (2003); Lynn H. Pottenger et al., *The Relative Bioavailability and Metabolism of Bisphenol A in Rats Is Dependent Upon the Route of Administration*, 54 Toxicological Sci. 3 (2000).
13. Rochelle W. Tyl, *Abbreviated Assessment of Bisphenol A Toxicology Literature*, 19 Seminars Fetal & Neonatal Med. 195 (2013).
14. *No Consumer Health Risk From Bisphenol A Exposure*, EFSA, Jan. 21, 2015, https://www.efsa.europa.eu/en/press/news/150121; FSANZ, FSANZ Activities in Relation to Bisphenol A (2010); Bureau of Chemical Safety, Health Canada, Health Risk Assessment of Bisphenol A From Food Packaging Applications (2008); Health Canada, *Bisphenol A*, http://www.hc-sc.gc.ca/fn-an/securit/packag-emball/bpa/index-eng.php (last modified Dec. 15, 2014); Bureau of Chemical Safety, Health Canada, Health Canada's Updated Assessment of Bisphenol A (BPA) Exposure From Food Sources (2012).
15. Nadine He, *Taiwan to Ban BPA in Baby Feeding Bottles*, ChemLinked, Apr. 11, 2013, https://chemical.chemlinked.com/news/chemical-news/taiwan-ban-bpa-baby-feeding-bottles; Jan G. Hengstler et al., *Critical Evaluation of Key Evidence on the Human Health Hazards of Exposure to Bisphenol A*, 41 Critical Revs. Toxicology 263 (2011); Global Agricultural Information Network, U.S. Department of Agriculture, Belgium Bans Use of Bisphenol A (2013); Global Agricultural Information Network, U.S. Department of Agriculture, French Law Banning Bisphenol A in Food Containers Enacted (2013).

Figure 4. Contingent Liability Mitigation Strategies



engineering controls or personal protective equipment. Estimating prospective risks can protect the bottom line and demonstrate to shareholders that a company is proactive in its attempts to manage costs while also striving to protect worker and consumer health and safety. Should a health risk arise post-production, the extent of adverse health effects in consumers can be quantified, which can then inform management how to best allocate resources to communicate risk to the public, protect brand image, and/or approach potential litigation.

Virtually every company in every industry can benefit from building a product stewardship program based on risk assessment. By utilizing a scientifically robust methodology, the risks of negative impacts of a product throughout the entire life cycle can be minimized, leaving companies better prepared for the future and more likely to succeed in the long term.

II. Mitigating Risk, Armed With Science

Product stewardship requires active management throughout a product's life cycle, including the product's eventual sunset phase. When risk awareness programs identify product risks too substantial to mitigate through existing means, and/or when corresponding contingent liability exposures cannot be mitigated, a product may need to face retirement. At this point, the framework evolves from scientific risk mitigation to legal and financial risk mitigation.

Product and environmental liabilities, as well as contingent liabilities more broadly, involve an element of uncertainty, the full negative impact of which may not yet be fully understood. Yet corporate executive teams often face the challenge of making the best possible decisions to manage uncertainty. In the case of corporate exposure to potential contingent liabilities, a well-documented understanding of the scientific basis for such liabilities can provide the foundation for sound decisionmaking. Given that scientific foundation, what follows next is a process of quantifying and structuring a final resolution of that exposure to liabilities.

In order to act, management needs to leverage the same body of knowledge developed in product stewardship efforts and risk assessment programs. This basket of data includes the scope of the exposure, the timing during which the exposure occurred, and the types of impact the exposure may cause. Whether from workers' asbestos exposure or environmental pollution, contingent liabilities can cause damages that need reasonable estimation in advance. A scientific research study affords a neutral and proactive basis for decisionmaking.

A. Selecting a Strategy

With scientists helping to identify precisely which negative impacts to target, management can make informed choices about pursuing any one of six strategies for mitigating exposure to contingent liabilities. From Figure 4, in order of increasingly removing contingent liabilities from a firm's balance sheet, the options are: (1) maintaining the status quo; (2) establishing an internal run-off entity; (3) purchasing additional insurance; (4) executing a spin-off as an independent entity or via an initial public offering (IPO) to public markets; (5) bankruptcy of the subsidiary and/or parent; or (6) executing a true sale of the subsidiary with exposure to contingent liabilities to a third party. Each of the choices has benefits and risks.

In brief, a company can always opt to maintain the status quo. Leveraging its existing infrastructure, a firm can manage known risk with established resources. This approach involves several trade offs in risk and expense. Contingent liabilities pose the tail risk of large adverse judgments, in addition to ongoing reputational risk and changes in public policy. Substantial corporate resources may be consumed to defend against exposure, including legal and communications teams and/or other ongoing settlement expenses. Management focus may become distracted as it monitors strategy and outcomes. Wall Street may notice and reduce a firm's valuation as a result of the liabilities on its balance sheet. When issuing corporate debt, the firm then likely has to offer a higher interest rate to compensate for risk posed by liabilities.

Firms may opt to establish an internal run-off vehicle or leverage the balance sheet of an insurance firm via expensive coverage. Neither approach removes the contingent liability exposure from an at-risk firm's balance sheet, and insurance only covers up to policy limits (provided the insurance company itself is willing and able to pay when a claim is made). Spin-offs can theoretically achieve finality but can lack the objectivity of a negotiated arm's length sale to a single third-party buyer. Several high-profile spin-off attempts have failed and ended up in bankruptcy, a destructive but familiar option.

Bankruptcy, liquidation, and dissolution (BLD) is perceived as a form of finality, but, in fact, the true outcome of bankruptcy involves spiraling and uncer-

Table 1. Risk/Benefit Analysis of Contingent Liability Mitigation Strategies

Strategy	Benefits	Risks
Status Quo	• Less expense . . . today • Leverages existing infrastructure	• Reputational/headline risk • Adverse judgments/tail risk • Operational costs • Capital markets costs
Run-off	• Segregates liabilities from parent • Matches resources with liabilities	• Reputational • Operational costs • Capital markets costs
Insurance	• Coverage . . . up to policy limits • Perceived involvement of another balance sheet	• Expensive • Liabilities remain on balance sheet
Spin-off	• Finality . . . at a price • §524(g) or §105(a) prepackaged bankruptcy offers familiar path	• Open to challenge of insufficient funding • Potential for regulatory scrutiny
BLD	• Fast (months, not years) • Comparatively less expensive • Discrete • Final	• Reputational • Substantial time delays • Unexpected additional liabilities • Enormous execution costs
True Sale	• Fast (months, not years) • Comparatively less expensive • Discrete • Final	• Improper structuring • Inadequate funding

tain excess settlement costs, exorbitant legal and advisory fees, and frequently six to eight years or more of contentious negotiation. Prepacked bankruptcies under Bankruptcy Code §§524(g) and 105(a) promise finality via post-reorganization channeling injunctions, forcing future litigants to sue a newly established bankruptcy trust. The settlement cost of funding that trust is often much higher than the previously booked reserves for contingent liabilities pre-bankruptcy.

In part, that result stems from a consensus-based process that depends on a 75% supermajority vote of claimants, who are largely incentivized to hold out for higher payouts. Hence, both the resulting higher costs and time delays, as conflicting interests clash among insurance carriers, plaintiff creditor committees, legal representatives, the debtor company and its parent, and other potentially implicated parties that may have strategic or settlement agreements in place with the bankrupt firm.

Table 1 briefly summarizes the merits of each strategy, as well as a sixth strategy defined below.

B. Necessary Preparations for a True Sale

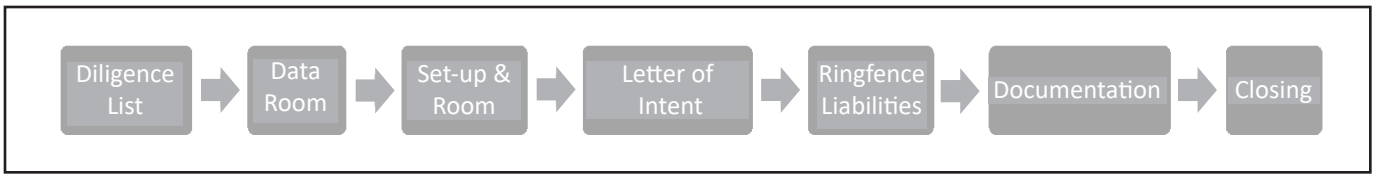
A true sale typically leverages the same materials that would exist for the other strategies. Most importantly, a proper transaction requires independent third-party actuarial and legal opinions from respected advisors. An actuarial analysis of contingent liability claims helps convert the scientific research into quantified estimates of the number of claims, their economic value, and the time period over which they are expected to be realized. Actuarial forecasters give management a sense of the magnitude of liabilities known at the time of the estimate. Having fresh estimates from forecasting teams ensures an arm's-length, economically negotiated transaction.

Lawyers utilize the actuaries' estimates as the financial basis for structuring a transaction. Legal opinions from reputable firms ensure confidence in the transaction's chosen structure. While every transaction involves a bespoke structure particular to the context of the company involved, typically a selling company chooses to dispose of either a legacy subsidiary or ringfenced entity containing the contingent liabilities. Legal teams representing seller and buyer assure precise identification of, and agreement upon, exactly what types of risk are being transferred. Risks may include product liability, environmental pollution, or other contingent liabilities. Each transaction requires that estimated liabilities are matched by contingent liability reserves or operational business lines producing reliable net income.

C. Execution of the True Sale

Given the time-specific nature of contingent liabilities estimates, they need to be relatively recent at the transaction's closing. The process for execution of a true sale is therefore necessarily rapid and efficient, at least in comparison to other alternatives. Timetables vary in the context of a given corporation's liabilities, but generally a seller can complete a true sale within two to six months, given its preparedness. The process generally operates according to the stages outlined in Figure 5 (next page).

Figure 5. True Sale Stages



❑ *Case Study 4: Mitigating risk with a true sale.* A brief case study offers insight into how a true sale mitigates risk in a business setting. Consider a firm that has ceased all active operations at what has become a brownfield site. Environmental authorities have assessed the impact and agreed to the firm's remedial action work plan as submitted. In one sense, the matter is resolved.

Yet, given the perceived uncertainties of environmental remediation costs, the firm is unable to dispose of the land at an appropriately adjusted market price, even reduced for these liabilities. The land is held in a subsidiary. Developers with plans pause; other manufacturers seeking expansion look elsewhere; and other acquirers stand by.

Despite having the subsidiary address the contingent liabilities, the firm in question is penalized. Wall Street observes the risk and increases debt financing costs accordingly. A depressed equity valuation reflects both the financial and reputational risk as well. Management is still responsible for oversight, which in turn means that this risk is not "resolved" for the firm for many years to come. The firm directly absorbs these oversight costs and spillover concerns.

A third-party acquirer now offers to purchase that subsidiary. Provided the transaction is properly structured, the selling firm definitively disposes of its contingent liabilities. Its obligations are satisfied, and it may now move on from the site and focus on core operations.

D. Science and Strategy Informing Management Decisions

Product stewardship allows a corporation to minimize human health and environmental impacts throughout a product's life cycle, using a multidisciplinary approach. Risk assessment programs and principles inform proactive and reactive strategies across multiple sectors and supply chain stages, all with an eye toward regulatory compliance and responsible corporate citizenship.

When a product's or process' impact proves too negative to mitigate, a proactive end-of-life cycle retirement strategy should include finality from any contingent liability exposure. Strategic financial and legal analysis, leveraging appropriate structuring and transactions, can ensure that a company meets its obligations, and can move forward with finality from endless and unnecessary risk exposure. In this combined framework, science and strategic financial/legal risk mitigation coordinate to ensure that management executes its plans with informed decisionmaking yielding optimal outcomes.