Leveraging Science to Inform Proactive and Reactive Risk Management

Part I: Risk Assessment as a Tool for Effective Product Stewardship

Cardno ChemRisk

Authors: Caroline Gillie and Allison Killius

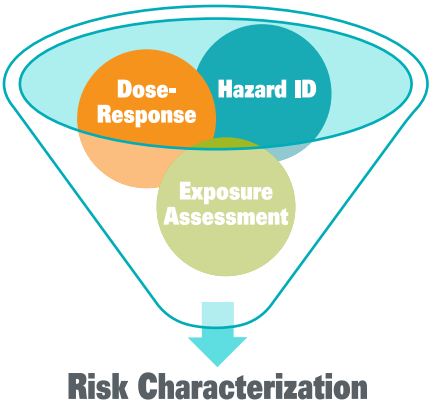
The production, transport, use, and disposal of industrial and consumer products may pose risks to human and environmental health. Workers have exposure potential to starting reagents, raw materials, and byproducts/intermediates during manufacture and transport, as well as to chemical agents in finished products. Consumers also may be exposed to chemicals from handling, use, 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.

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 quantitatively evaluate the probability that exposure to those hazards will cause an adverse health effect. The risk assessment framework consists of four key components: (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 hazard criteria 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 effect. Dose-response relationships for the same chemical can vary significantly, however, depending on the species (rat vs. human) and exposure (route, duration, frequency). From these analyses, thresholds are identified 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, for a given use scenario, the amount of chemical to which an individual could be exposed. 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 via a quantitative model to assess the presence or absence of risk. In this step, 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 no increased risk (or no appreciable risk, for probability-derived toxicity values) for the identified hazards. If the exposure level exceeds the selected toxicity value, then an increased risk of an adverse health effect likely does exist. 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.

EFFECTIVE PRODUCT STEWARDSHIP: A MULTIDISCIPLINARY APPROACH

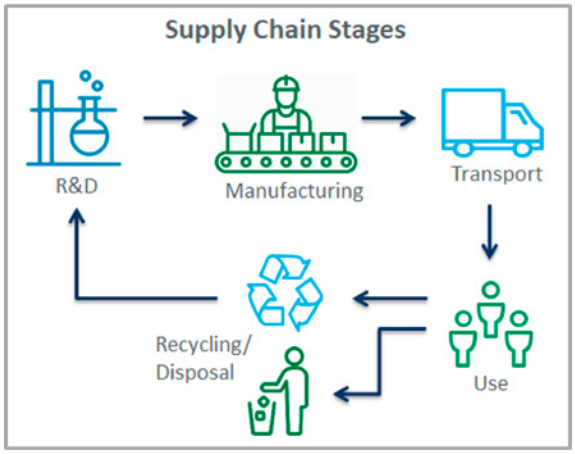
Based on the risk assessment framework, both toxicology and exposure science play an integral role in assessing risks. Effective product stewardship is multidisciplinary and draws insights from numerous scientific and technical disciplines, including toxicology, exposure science, materials science, as 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..
- **Materials Science:** Materials science professionals have in-depth knowledge of the product's underlying chemistries. Elimination and substitution of at-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 U.S. 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 TSCA[1], Proposition 65[2], REACH[3], and GHS[4]-aligned regulations, among others, will impact product formulation, hazard communication, uses, and available markets..

[1] Toxic Substances Control Act (1976); amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016)
[2] Safe Drinking Water and Toxic Enforcement Act (1986)
[3] Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (2006)
[4] Globally Harmonized System of Classification and Labelling of Chemicals

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. Furthermore, this framework may be applied at any points along the supply chain: research and development, 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 the exposure potentials driving these risks.



- **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 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 E.U., companies seeking to import substances at quantities of ten or more metric tons must prepare and submit a chemical safety assessment in accordance with REACH.

- **Proactive and Reactive Risk Management**

  Beyond regulatory compliance, risk assessment is fundamental to building a robust product stewardship program that proactively and reactively manages risks throughout a product's life cycle. 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). By assessing the 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. As an example, a food product manufacturer or importer may need to understand what degree of cross-contamination with allergens could occur during production or shipping without causing allergic responses in consumers. They could then institute QA/QC practices to minimize product contamination through increased sampling of pre-preparation and final product or enhanced cleaning of process equipment and shipping containers.

  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 reform, companies whose chemicals were selected for risk evaluation by the 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.

  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 clean-up 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.

THE BUSINESS CASE FOR RISK ASSESSMENT-BASED PRODUCT STEWARDSHIP

By anticipating hazards and risks of their products, companies can strategically remove any 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 creating 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 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 long-term.

Part II: Mitigating Risk, Armed with Science

Author: Holland Sullivan

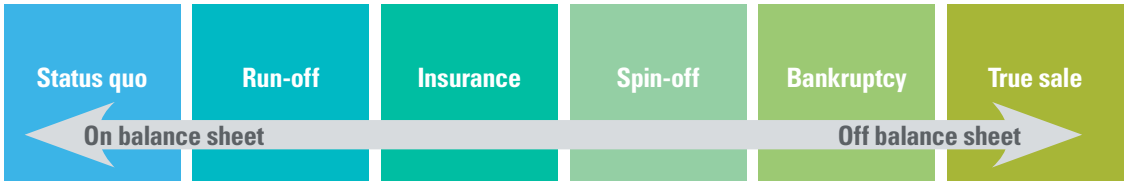
Product stewardship requires active management throughout a product's life cycle, including the product's eventual sunset phase. When risk awareness programs identify product risks too substantial to mitigate through existing means, and/or when corresponding contingent liability exposures cannot be mitigated, 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 decision-making. 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 decision-making.

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. 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 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.

BLD (bankruptcy, liquidation, and dissolution) is perceived as a form of finality, but, in fact, the true outcome of bankruptcy involves spiraling and uncertain excess settlement costs, exorbitant legal and advisory fees, and frequently six to eight years or more of contentious negotiation. Prepacked bankruptcies under Bankruptcy Code Sections 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.

The table below briefly summarizes the merits of each strategy, as well as a sixth strategy defined below:

Strategy	Benefits	Risks
Status Quo	> Less expense… today > Leverages existing infrastructure	> Reputational / headline risk > Adverse judgements/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	> May remove from balance sheet	> Open to challenge of insufficient funding > Potential for regulatory scrutiny
BLD (Bankruptcy, Liquidation, & Dissolution)	> Finality… at a price > 524(g) or 105(a) prepackaged bankruptcy offers familiar path	> 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

NECESSARY PREPARATIONS FOR 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.

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 true sale within two to six months, given its preparedness. The process generally operates according to these stages:

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 or process's impact proves too negative to mitigate, a proactive end-of-lifecycle 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 decision-making yielding optimal outcomes.

PREPARED BY

Cardno ChemRisk

www.cardnochemrisk.com

FARA RECOVERY
FINANCIAL ASSET RECOVERY ANALYTICS, LLC

www.fararecovery.com