Summary
In the chemicals industry, increasing regulations are putting pressure on R&D and technology leaders to find effective ways to minimize safety and other manufacturing risks early in the R&D process. Companies that successfully enhance how EHS considerations are integrated into NPD decisions and processes will increasingly have the competitive edge.
A highly competitive market

For chemical companies, the first decade of the 21st century came with dramatic transformations in the business environment. For instance, there’s been a tremendous expansion of the output and research and development (R&D) capabilities in China that are now approaching those of the U.S. and the E.U (Figure 1). As economies continue to develop around the world, new talent, more funding, and valuable raw materials are moving more fluidly and over longer distances. The U.S. chemical industry has shown minimal change in R&D/sales and S&M/sales indexes over the last ten years, and hard target cost and profitability ratios will likely continue to dampen any increased investment in R&D. In this highly competitive market, top executives are looking for opportunities to increase revenue and profitability from constrained investments in new product development (NPD).

Figure 1. Gross Domestic Expenditures on R&D by US, EU and selected other countries 1981-2011.

EU = European Union; PPP = purchasing power parity.

NOTES: Data are not available for all countries in all years. Data for the United States in this figure reflect international standards for calculating gross expenditures on R&D, which vary slightly from the National Science Foundation’s approach to tallying U.S. total R&D. Data for Japan for 1996 onward may not be consistent with earlier data because of changes in methodology. EU data for all years are based on the current 27 EU member countries.

SOURCE: Organisation for Economic Co-operation and Development, Main Science and Technology Indicators.

Throughout the development phase of different projects, heads of R&D are already juggling conflicting interests like technical feasibility and manufacturability, profitability, customer demand, competition, intellectual property protection, and regulatory shifts. Savvy innovation portfolio management, combined with improved market insights and validation, are critical levers for increasing commercial success rates. Still, with enhanced regulations and the 2015 TSCA reform, it’s becoming equally important to address environmental health and safety (EHS) issues early in NPD in order to increase ROI and business sustainability. In addition to addressing regulatory and EHS factors during NPD, the chemical industry is also trying to drive business sustainability by paying more attention to the interface between companies and their customers, aiming to ensure the safe end-to-end delivery of hazardous substances to end-customers, to offer transparent communication of product safety throughout their value and development chain, and to identify alternate chemicals and materials to improve the safety of certain products or manufacturing processes. Competing by launching new chemical products to the market becomes even more complex when one considers the increasing volume of new and existing information from which chemists, engineers, and researchers have to cull market and technical insights and opportunities.

Christina Valimaki, senior director of Chemicals Industry Marketing at Elsevier R&D Solutions, notes, “Along with an overall increase in both the number and complexity of regulations across the world, not to mention the fact that these laws are being more strictly enforced, there’s been an extraordinary increase in the volume of chemical products and technology developments that require market and technical evaluation as part of a thorough stage-gate development process. For example, there are currently over 80,000 chemical products in the U.S. market alone, and this number will continue to grow as western-owned chemical companies move down the value chain toward offering targeted specialty product portfolios.”
The combination of accelerating regulatory shifts, chemical product proliferation, and chemistry research volume means that R&D leaders must face the challenge of keeping up with information.

For chemical companies, the exponential increase in product launches narrows white-space opportunities and increases the need to evaluate alternative technologies that customer markets are considering. In addition, as chemical R&D departments experience regulatory escalation and competitive product proliferation, they should also consider the rapid increases in academic research about potential chemistries and engineered solutions for practical market applications (Figure 2). As Valimaki points out, “Smart literature and synthesis databases offer answers to everything from materials characterization and pricing information to reaction pathways and detailed insights into technical practices and challenges faced by industrial customers.”

The combination of accelerating regulatory shifts, chemical product proliferation, and chemistry research volume means that R&D leaders must face the challenge of keeping up with information, and also shift their internal resources and processes to support their organizations’ ability to comply with those changes. For any chemical company, not being able to account for these market shifts can lead to delays in production and commercialization, insurance premium increases, non-compliance penalties, or litigation impact.

Figure 2. Number of Chemistry-Related Research Articles Published from 1945-2016. Includes documents tagged for relevant subject areas such as Chemistry, Biochemistry, Chemical Engineering, Materials Science, Agricultural and Biological Sciences, and Environmental Science. SOURCE: Scopus Database, Elsevier, February 2016
Regulatory shifts: Navigating a new map

The forty-year-old Toxic Substances Control Act (TSCA) is just one of many laws that the U.S. Congress has passed to regulate the chemical industry. But while the TSCA was intended to give the Environmental Protection Agency (EPA) broad oversight over all aspects of chemical risk management, from manufacturing to disposal, the law is extremely complex and difficult to implement, especially for existing chemicals. For instance, the TSCA’s provisions are applied differently to “new” and “existing” chemicals (defined under the TSCA as those included in the TSCA Inventory, a list of all chemical substances in the market prior to December 1979). As a result, 62,000 chemicals were automatically approved for commercial use without being evaluated for how they might potentially harm human health or the environment. There are reportedly about 83,000 chemicals in active use in the U.S. today.²

Pressure to address TSCA shortcomings intensified when REACH (Registration, Evaluation and Authorization and Restriction of Chemicals) was launched in the E.U. in 2007 to bolster the continent’s involvement in the industry, and required chemical manufacturers to generate data under a principle of “no data, no market.” The EPA announced a new approach in 2009 to enhance the chemicals management program, addressing gray areas in the existing legislation, including the requirement for risk-management actions, chemical action plans, information about chemical risks, and increased public access to information. In addition to the EPA move, there has been legislative activity at the state level driven by public demand, resulting in a surge of regulations specific to different states. This only adds to the difficulty for companies to implement clear and cost-effective regulatory compliance.

Since 2010, the Senate has considered a number of legislative amendments to the TSCA, culminating with the passing last December of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Additionally, the similar TSCA Modernization Act of 2015 (H.R. 2576) was passed by the House of Representatives last June. The bills set up a new standard for the EPA, allowing the organization to investigate and take action on a chemical based on “health only,” effectively prohibiting the consideration of costs when determining chemical safety. The law also allows the EPA to establish a requirement to ensure that vulnerable populations (like pregnant women and children) are protected from dangerous chemicals, to require toxicity testing on any chemical with a simplified process, and to allow Confidential Business Information (CBI) to be shared with states, first responders, and healthcare providers. With a shift toward requiring evidence of a chemical’s safety in order to enter or remain in the market, the effects of TSCA reform on the chemicals industry are expected to be profound.

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—Robert Najjar, EHS Expert

A two-prong approach to enhancing EHS compliance support in R&D

With so many increasing and changing regulations, the immediate challenge for any competitive chemical company is to achieve and maintain compliance. Heads of R&D committed to maximizing ROI in the overall process must make an effort to address EHS-related factors in the earlier stages of the chemical development chain though a dual approach:

1. Enabling and improving EHS risk assessments in early phases of NPD.
   In addition to regulatory complexity, the amount of data about potential chemistries related to substances and processes will only increase. R&D teams must discover effective ways to develop safe products using safe processes, not only to control risks and costs associated with safety issues, but also to show value in the short term. There will be additional efforts to dissect and identify the regulatory impact on both operations and especially on new products, and heads of R&D must account for this as they design their long-term strategies. Even companies with compliance under control are challenged to step up to the next level of environmental, health, and occupational safety, by applying a “risk lens” to their implementation of EHS principles. EHS expert Robert Najjar stated that “a risk lens means looking beyond the prevention of accidents and focusing on reducing the risks that have the potential to cause those accidents.” Companies like Dow have already drawn up frameworks for product safety assessment that focus on gathering information and identifying hazards at multiple points of the process, including the early stages of development. With the massive regulatory changes affecting the market, even tried-and-true processes for chemical risk assessments will require updates and enhancements.¹

2. Fully integrating EHS resources and processes into R&D idea-generation and feasibility phases.
   Critical to managing EHS risk is a robust focus on ensuring that the necessary resources and processes are in place to accurately profile the chemistry and manufacturability of a new substance. The EPA’s first administration principle for its 2014 Chemicals Management Program is that “chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment.”² To make properly informed go/no-go decisions from ideation to feasibility for new chemical products, it’s essential to conduct an early evaluation of the properties, potential interactions, and environmental impact of both end-products and intermediate compounds, and to also obtain an early view on EHS-related concerns during manufacturing, so as to design appropriate mitigation tactics. Solutions for identifying previously unknown risks and for developing safe production must start early in the R&D phase through processes established between chemists, manufacturing engineers, and EHS specialists.

Conclusion

In a landscape of substantial overproduction and excess capacity, enhanced productivity and capacity no longer provide chemical companies with a competitive edge. Other factors, like safe product delivery and post-sale support, are becoming increasingly useful and even necessary for advancement, and companies that can transition from product-centered to market-oriented organizations will be better-positioned for sustainability. Chemical companies must address safe manufacturing early in the R&D process, and stay in compliance with increasing regulations. To top it off, EHS considerations need to be part of the NPD approval process, along with the usual evaluation of technical feasibility and capabilities, IP protection, or marketability. A proactive and collaborative approach between R&D, manufacturing, and EHS departments will increasingly be a cornerstone in minimizing obstacles to commercial success.
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