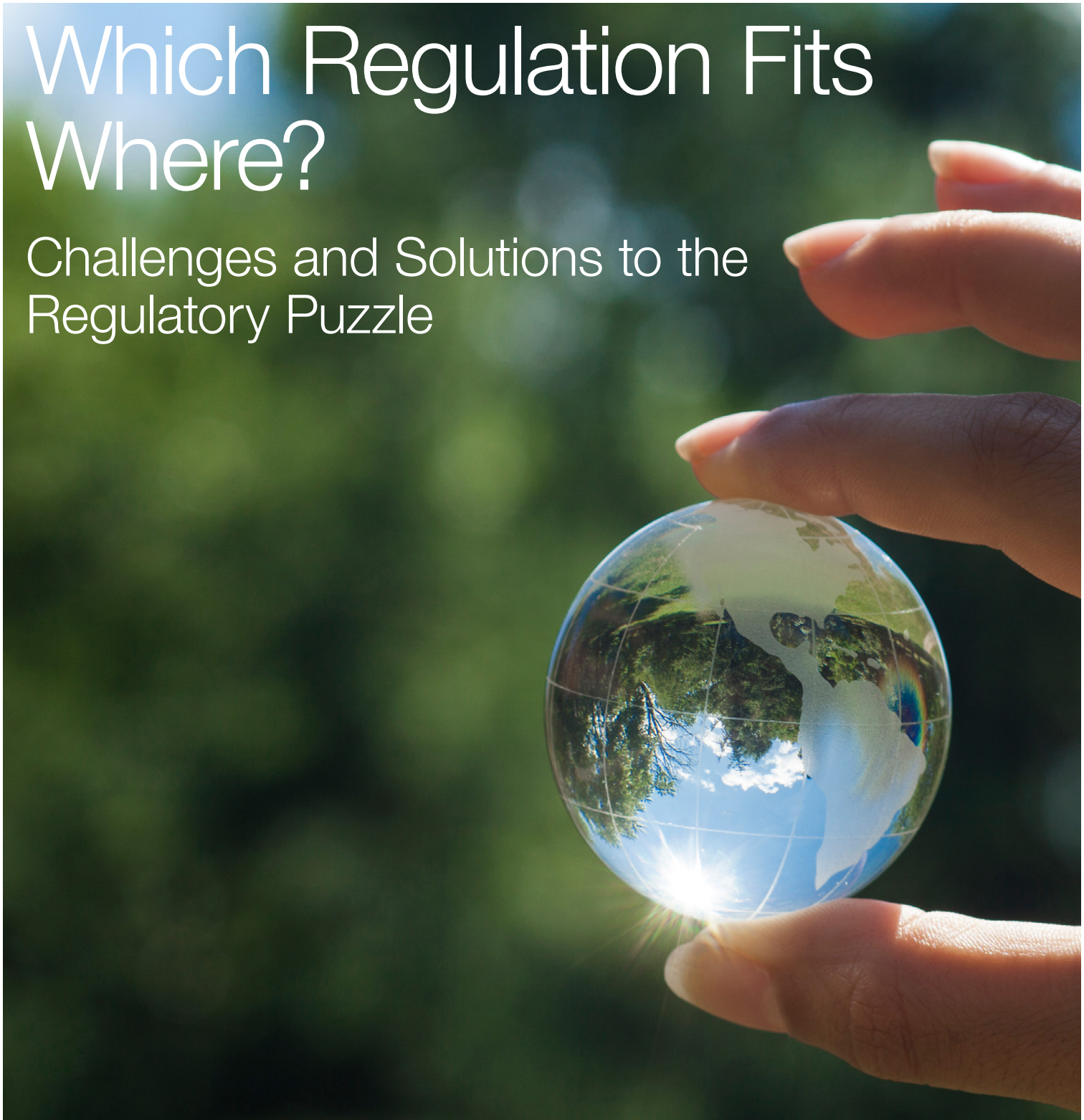
Which Regulation Fits Where?

Challenges and Solutions to the Regulatory Puzzle



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Introduction

The crux of competing within a global market is local regulatory compliance. And the speed of achieving compliance in order to launch a product can be crucial. According to a 2014 industry survey, it costs approximately $286 million to bring a single crop-protection product to market.[1] In the chemical sector, commercialization of a new product can require 2 to 4 years or more.[2] In addition, global chemical sales reached a record $5.2 trillion over the past decade; emerging economies contributed to this increase, including China where the average compound annual rate of sales growth reached 26 percent. [3]As these examples illustrate, the investment of time and money in developing a product can be substantial; effective product stewardship, which lends to a rapid and successful product launch, can speed the return on that investment.

Delivering global compliance is sometimes easier said than done. Local compliance requirements often differ in many ways, and businesses must adapt their product introduction processes to manage the submission process and avoid business delays. While all regulations are different and have their own specific challenges – both within and across regulatory schemes – there is not one unifying mode of compliance. However, in working with our clients, ERM has developed various solutions to overcome these regulatory challenges.

1. http://www.croplifeamerica.org/wp-content/uploads/2016/04/Phillips-McDougall-Final-Report_4.6.16.pdf
2. http://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/chemicals/pdfs/chemical_innovation_an_investment_for_the_ages.ashx
3. http://www.strategyand.pwc.com/perspectives/2015-chemicals-trends

Challenges of Multi-Jurisdictional Substance Registrations

The first and often greatest challenge is to understand relevant legislation. There are several reasons why there isn't a single solution for addressing the complexities of multi-jurisdictional compliance. The challenge starts with the number of regulatory schemes that have been created and adapted, such as the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation in the European Union (EU REACH), Korea (KREACH), and China (China REACH), as well as various adaptations of the Globally Harmonized System (GHS) of Classification, Labelling and Packaging. While many countries have the same general regulatory framework for product registration or hazard communication, each jurisdiction tends to choose pieces of the regulation they deem important or that require more emphasis, which causes differences in compliance demands. Demands for compliance and legislation also vary by country. For example, in some developing countries, industry may have a stronger voice than regulators as such countries grow and gain ground on the global market.

Language can also be a challenge. The availability and reliability of translated documents varies by country. At times, translated documents may not be as robust for countries that have newer regulations, such as the People's Republic of China, Republic of Korea, and the Republic of Turkey. Governing bodies may not even produce documents in different languages because of the subtle shifts in meaning and the potential errors that can result from translation; therefore, third parties are often relied upon for this task.

Further, there may be different data quality and requirement standards as some jurisdictions have firmer and more rigorously enforced regulations. For example, the European Chemicals Agency (ECHA) accepts a weight of evidence (WoE) approach, but regulators in Korea (KREACH) hesitate to accept WoE results because if new studies are required for registration in other jurisdictions, then new results can potentially trigger the need to submit updates across multiple jurisdictions. In addition, business must understand these variations and commonalities in relevant geographies and subsequently manage regulatory submissions based on those differences. For example, while REACH and KREACH are based on the same general framework, there are different endpoints and data requirements. Another example is the Biocidal Products Regulation (BPR), which is an EU directive, not a law; therefore, a central framework exists, but the directive is implemented in each individual member state.

In addition, global compliance requirements evolve over time. ERM currently is tracking developments in the United States, Turkey, and Brazil that may bring new requirements for product compliance.

Many companies face internal challenges in addition to these external challenges. A disconnect between business units or business functions within a company can lead to gaps in compliance. For example, ERM works with several clients in the Electronic and Electrical Equipment (EEE) industry requiring compliance with the Restriction of Hazardous Substances (RoHS) directive if conducting business in the EU. Departments including research & development, purchasing, manufacturing, and sales need to communicate the composition of the products and where the products will be sold in order to avoid disruption due to potential recall of non-compliant products.

In ERM's work with companies across different sectors, we rely on a series of techniques and tools to surmount these challenges. Our approach, summarized in Figure 1, is explained in more detail below.

Figure 1: Keys to Effectively Manage Product Compliance

Adaptation

Product stewards must adapt in order to create solutions in challenging situations. ERM has found in working with companies with international business needs that each jurisdiction requires a unique strategy. Time invested in developing a thoughtful strategy ultimately may increase the speed to market. One particular ERM client manufactured oleopolymers that biodegraded into inert substances. In the EU, all the monomers were registered previously under the polymer exemption; therefore, registration requirements were minimal. However, in Japan, if a polymer is biodegradable, the Japanese authorities require detailed, costly, and time-intensive bioconcentration and biodegradataion data and will not accept data waivers. Similarly, in Canada, regulatory guidance indicated that the oleopolymer did not fit the definition of a polymer of low concern, resulting in the needs for the entire spectrum of costly and time-intensive Gel Permeation Chromatography (GPC) data. In order to address the regulatory challenges, ERM subject matter experts reviewed substance chemistry in Japan and determined that the product fit the definition of an existing substance; in addition, ERM engagement with the Canadian authorities confirmed that the product did fit the definition of a polymer of low concern. Therefore, in all cases, we were able to demonstrate the case for lessened regulatory requirements.

When facing a multi-jurisdictional registration, it is prudent to identify the most demanding legislation with stringent requirements and data needs for the submission process. EU REACH is commonly used as a model because of its robust process. ERM used this approach with a nanotechnology client launching in multiple countries, including several in the business-critical, Asia-Pacific region. We found that by collecting data based on the more stringent EU model, the same data can then be used and filtered as needed for other jurisdictions such as China, Taiwan, Korea, and Japan.

While proper data collection is an important step in compliance, the appropriate use of information technology systems and regulatory databases can also ease adaptation to changing regulatory needs. It is vital to note that the quality of data ultimately affects the quality of registration dossiers – if registering across multiple jurisdictions with the same information, errors may manifest across all jurisdictions. Tracking product information with a central repository allows for careful data gap analysis to avoid such errors. Product stewards should also be aware of available databases that can help to track regulatory information in order to stay informed.

Adapting to changing and new markets is also easier when there is general awareness of what is coming along the regulatory pipeline in certain jurisdictions. There are several key emerging markets for expanding businesses, including India, Brazil, Mexico, and Indonesia. It is important to recognize what the data requirements are in key emerging markets so that registration can be addressed efficiently when needed.

Local area experts should also be utilized as they understand the regulatory framework and local language, especially in countries with newer regulations. For example, KREACH regulatory documents were not translated until recently, and Serbian biocides and chemical laws currently are not translated. Therefore, local experts are essential to understanding these regulations.

Organizational Strategies

Organizational strategies can be created to adapt to regulatory challenges. Product composition and inventory awareness are vital to a successful and valid registration. Product details must be understood at the granular level, and volumes of those products must be well documented as registration type and requirements depend on this information. Volume trackers can be as complex as a multi-system business server, or as simple as a single spreadsheet. From these volume trackers, all registrations information is pulled together and can be flagged when volumes change. Volume trackers also allow analysis of substances that will be phased out or subject to authorization. Substitutions can then be identified if necessary.

Jurisdictional needs can also be determined by use of a central map or matrix system to help identify data gaps. This can be a checklist, Visio diagram, or flowchart. Creating an outline of jurisdictional needs will allow for clearer internal communication among business units to help fill data gaps.

Prioritization will also help organize registration strategies. It is prudent for a company to understand in which countries their products and processes are compliant and then shift the regulatory focus to countries in which they do not yet have an organizational strategy in place. This method will allow product movement while also allowing product stewards to understand registration processes in different jurisdictions.

Next Steps

While there is no “silver bullet” that solves the complexities of multi-jurisdictional product compliance, there are several steps that product stewards can take to make the process manageable.

Although regulatory schemes may have overarching needs, it is important to understand the differences and nuances. Local experts can be brought in to help highlight the differences, such as exactly what documents need to be compiled for registrations. In order to make the most of local and subject matter experts, it is important to bring product stewardship to a level that is understood by all staff. One solution is creating a task force offered across jurisdictions and acknowledging the existence of learning curves. When time is initially spent engaging different audiences on the importance of product stewardship, companies can profit and ultimately accelerate a product’s time to market.

Data management is also a meaningful way to promote successful product stewardship. Each entity should create a data tracking system compatible with their business needs. The more robust the data tracking system, the easier it will be to become compliant. Another aspect of data for product stewardship is data sharing. Many product registrations require testing data to help understand chemical properties, ecotoxicity, and human toxicity. Data sharing will help decrease testing costs and the need for additional animal testing. For example, ReachCentrum[4] is creating a data brokerage option to make data currently used for EU dossiers available to KREACH dossiers. This program will allow registrants to obtain data without going through the lengthy and expensive data collection process or intensive data sharing agreements.

4. http://www.reachcentrum.eu/about.html

Conclusion

Effective product stewardship is the key to global market access. Compliance begins with a basic awareness of products and global business needs as well as subsequent understanding of local regulatory regimes. Companies can then utilize local staff and data management tools to comply with local regulations. While global compliance is often complex, investing time, money, and personnel into understanding product stewardship can improve adaptation to regulatory challenges, which ultimately will lead to rapid and successful product launches necessary to compete in global markets.

How to Learn More

Questions or comments? Email the author Kerrie Canavan at Kerrie.Canavan@erm.com.

Ms. Canavan is a Project Scientist in ERM's Manhattan office. She supports clients by providing guidance under several regulatory schemes including REACH (EU, China, Taiwan, Korea, and Japan), RoHS, various new and hazardous substance notification regulations, and country-specific inventory listing requirements. She regularly collaborates with clients handling chemicals, pharmaceuticals, polymers, nanotechnologies, and biocides to expand their access to global markets.

About ERM

Environmental Resources Management (ERM) is a leading global provider of environmental, health, safety, risk, social consulting services and sustainability related services. We have more than 160 offices in over 40 countries and territories employing more than 4,500 people who work on projects around the world. ERM is committed to providing a service that is consistent, professional and of the highest quality to create value for our clients. We have worked with many of the Global Fortune 500 companies delivering innovative solutions for business and selected government clients helping them understand and manage the sustainability challenges that the world is increasingly facing.

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