

Regulatory Readiness Framework for Commercialisation of Chemical Innovation in Malaysia

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DOI: <https://doi.org/10.47772/IJRISS.2026.100801119>

Received: 12 September 2026; Accepted: 17 September 2026; Published: 24 September 2026

ABSTRACT

The chemical industry is one of the most highly regulated sectors due to risks involving hazardous substances, environmental pollution, occupational safety, and public health. In Malaysia, the chemical sector has been prioritised under the New Industrial Master Plan 2030 (NIMP 2030) and the Chemical Industry Roadmap 2030 (CIR2030). However, the commercialisation of chemical inventions and innovations remains challenging due to fragmented regulations, overlapping approval processes, and high compliance costs. Existing commercialisation frameworks tend to focus on technological and market readiness, while regulatory readiness remains insufficiently addressed. This article develops a Regulatory Readiness Framework (RRF) for chemical innovation commercialisation in Malaysia. The study adopts a qualitative doctrinal and policy analysis approach by examining relevant statutes, regulations, industry standards and relevant policy documents governing chemical commercialisation. The article argues that chemical innovations are regulated through multiple regulatory control points across the Technology Readiness Level (TRL) pipeline, including hazard classification, product registration, environmental and occupational safety approvals, industrial licensing, and export control. The article proposes three core dimensions of regulatory readiness framework: regulatory foresight, regulatory readiness, and regulatory strategy. It concludes that regulatory readiness should be recognised as a critical capability for successful lab-to-market commercialisation of chemical innovation in Malaysia.

Keywords— Law; Regulations; Readiness; Chemical Industry; Innovation; Commercialisation.

INTRODUCTION

The commercialisation of inventions and innovations has become a critical national agenda in many innovation-driven economies. In Malaysia, strategic policy frameworks such as the New Industrial Master Plan 2030 (NIMP 2030), the Thirteenth Malaysia Plan, and the Chemical Industry Roadmap 2030 (CIR2030) emphasise the importance of strengthening industrial innovation, value-added manufacturing, technology transfer, and downstream commercialisation activities (Lee et. al, 2025; Rasiah et. al, 2024). Within this agenda, the chemical industry occupies a strategically significant position due to its broad industrial applications, contribution to manufacturing output, export potential, and strong linkages to high-value sectors such as specialty chemicals, advanced materials, agrochemicals, pharmaceuticals, petrochemicals, electronic chemicals, and sustainable chemistry.

The chemical industry encompasses a wide range of activities involving the transformation of raw materials into chemical products and industrial compounds used across multiple sectors. These include base chemicals and intermediates, petrochemicals, oleochemicals, plastics and polymers, synthetic rubber, composites, agrochemicals, construction chemicals, care chemicals, nutrition chemicals, and electronic chemicals (Foo & Eng, 2015). CIR2030 identifies many of these segments as strategic growth areas for Malaysia and highlights the need to strengthen innovation capabilities, sustainability practices, downstream industrial development, and global competitiveness within the chemical ecosystem (Lee et. al, 2025).

The commercialisation of chemical inventions and innovations generally progresses from scientific discovery and laboratory experimentation to prototype development, pilot production, industrial scale-up, market approval, and export expansion (Sternitzke, 2010). This progression is commonly represented using Technology Readiness Levels (TRLs), where innovations move gradually from early-stage research to full commercial deployment (Buchner et. al, 2019). At lower TRLs, activities focus primarily on scientific validation, proof-of-concept development, and technical feasibility. However, as innovations progress toward higher TRLs involving pilot production, industrial manufacturing, and market entry, regulatory compliance increasingly becomes a critical determinant of commercial viability (Preikschas & Pérez-Ramírez, 2024; Moussa, 2022).

This is particularly evident in the chemical industry, where issues relating to hazardous substances, toxicity, environmental pollution, occupational exposure, industrial handling, public health, and strategic trade are heavily regulated (Jahangoshai et. al, 2020; Jiang et. al, 2014). Different categories of chemical innovations are also subject to different regulatory pathways and compliance requirements (Biggi, 2024). For example, base chemicals and intermediates may require extensive industrial licensing, environmental approvals, and workplace safety compliance, while specialty chemicals such as agrochemicals, care chemicals, nutrition chemicals, and electronic chemicals may additionally require product registration, toxicological assessment, labelling compliance, and sector-specific approvals.

Consequently, the commercialisation of chemical innovation differs fundamentally from many other forms of technology commercialisation. In chemical commercialisation, regulatory readiness becomes inseparable from technological readiness. The ability to navigate complex regulatory requirements, anticipate approval pathways, and manage compliance obligations across different TRL stages has become a crucial capability for innovators, investors, universities, start-ups, and industry players seeking to successfully transition chemical innovations from laboratory research to market deployment.

PROBLEM STATEMENT

A major challenge in the commercialisation of chemical innovations in Malaysia is the existence of a “Regulatory Valley of Death”, particularly during the transition from laboratory validation to pilot production and industrial scale-up (TRL 4–7) (Loh et. al, 2025; Chow et. al, 2024). Traditionally, the Valley of Death refers to the gap between research and market deployment where innovations fail due to insufficient funding, weak market demand, or limited industrial support (Helman, 2023; Fleming, 2021). In the chemical industry, however, this gap is strongly influenced by regulatory complexity (Calza et. al, 2021; Davies, 1983).

Unlike many other industries, the chemical sector operates within a highly regulated environment due to risks involving hazardous substances, environmental pollution, occupational safety, public health, and strategic trade (Gao et. al, 2019; Fleischer et. al, 2000). In Malaysia, the commercialisation of chemical products is therefore subject to extensive regulatory controls involving multiple agencies such as the Department of Occupational Safety and Health (DOSH), Department of Environment (DOE), National Pharmaceutical Regulatory Agency (NPRA), Ministry of Investment, Trade and Industry (MITI), and the Pesticides Board. These agencies administer various laws, standards, guidelines, and approval procedures relating to chemical classification, toxicological assessment, environmental compliance, industrial licensing, product registration, and export control.

The challenge is further complicated by the diverse nature of chemical innovations. Different categories of chemical products, such as base chemicals and intermediates, plastics and polymers, and specialty chemicals,

are governed by different regulatory requirements at different Technology Readiness Levels (TRLs) (Pagani et. al, 2024; Buchner et. al, 2019). For example, early-stage innovations may require hazard classification and laboratory safety compliance, while higher TRLs involving pilot production and commercial manufacturing require environmental approvals, manufacturing licences, standards certification, and market authorisation.

As a result, many chemical innovations face delays, high compliance costs, overlapping approvals, regulatory uncertainty, and commercialisation failure (Shabanu, 2025; Makepa & Chihobo, 2024; Matus et. al, 2012). Many university-based inventions and start-up technologies fail to progress beyond the prototype stage because innovators lack regulatory expertise, financial resources, and regulatory navigation capabilities (Adomako & Tran, 2026; Szulczewska-Remi 2024).

Despite these challenges, Malaysia currently lacks a comprehensive Regulatory Readiness Framework (RRF) that systematically guides innovators and investors on regulatory requirements according to the type of chemical innovation and TRL stage. Existing commercialisation frameworks focus mainly on technological and market readiness, while regulatory readiness remains underdeveloped. Therefore, there is a need to develop a comprehensive RRF to help innovators, investors, and industry players navigate the regulatory landscape, improve regulatory coordination, reduce commercialisation barriers, and accelerate the successful commercialisation of chemical innovations in Malaysia.

METHODOLOGY

This study adopts a qualitative doctrinal and policy analysis methodology. The research gathers primary legal sources including statutes, subsidiary legislation and regulatory standards governing chemical industry activities in Malaysia. The primary legal sources include:

- Industrial Co-ordination Act 1975;
- Strategic Trade Act 2010;
- Environmental Quality Act 1974;
- Occupational Safety and Health Act 1994;
- Poisons Act 1952;
- Pesticides Act 1974,
- Classification, Labelling and Safety Data Sheet of Hazardous Chemicals Regulations 2013 (CLASS Regulations);
- Use and Standards of Exposure of Chemicals Hazardous to Health Regulations 2000 (USECHH);

Doctrinal analysis focuses on identifying the legal and regulatory mechanisms governing the commercialisation of chemical inventions and innovations. The policy analysis component evaluates how these regulations operate within the broader commercialisation ecosystem, particularly in relation to Technology Readiness Levels (TRLs), innovation governance, industrial scaling, and market entry. The study further adopts a lab-to-market analytical lens to examine how regulations influence the progression of chemical innovations from research stage to commercial deployment. In doing so, the study conceptualises the existence of sequential “regulatory control points” throughout the commercialisation pipeline.

REGULATORY LANDSCAPE GOVERNING COMMERCIALISATION OF CHEMICAL INNOVATIONS

Overview of the Regulatory Landscape

The regulatory landscape governing chemical innovation commercialisation in Malaysia is highly fragmented and multi-layered. It involves multiple ministries, agencies, statutes, technical standards, industrial procedures, and sector-specific approval systems. The major regulatory bodies include:

- Department of Occupational Safety and Health (DOSH);

- Department of Environment (DOE);
- National Pharmaceutical Regulatory Agency (NPRA);
- Ministry of Investment, Trade and Industry (MITI);
- Pesticides Board;
- Standards Malaysia;
- Companies Commission of Malaysia (SSM);
- Malaysian Investment Development Authority (MIDA);
- Chemical Industries Council of Malaysia (CICM).

These agencies regulate different aspects of chemical commercialisation including hazard classification, workplace exposure, environmental discharge, product registration, manufacturing licensing, standards compliance, export control, and industrial investment.

The regulatory framework also incorporates international standards and conventions such as the Globally Harmonized System (GHS), OECD Good Laboratory Practice (GLP), REACH (European Union), and the Chemical Weapons Convention.

Environmental and Occupational Safety Regulations

One of the primary regulatory layers governing chemical commercialisation relates to environmental protection and occupational safety.

The Environmental Quality Act 1974 regulates industrial emissions, environmental pollution, hazardous waste disposal, and scheduled waste management. Chemical manufacturing facilities may require environmental approvals, impact assessments, and compliance monitoring before operations can commence. The Occupational Safety and Health Act 1994 and subsidiary regulations govern the safe handling, storage, use, and exposure of hazardous chemicals within workplaces. DOSH administers the Classification, Labelling and Safety Data Sheet of Hazardous Chemicals Regulations 2013 (CLASS Regulations), which implement the Globally Harmonized System (GHS) for chemical classification and hazard communication.

The CLASS Regulations require hazardous chemicals to be properly classified, labelled, and accompanied by Safety Data Sheets (SDS). This regulatory requirement represents one of the earliest regulatory control points in chemical commercialisation. Similarly, the Use and Standards of Exposure of Chemicals Hazardous to Health Regulations 2000 (USECHH) establish exposure limits, workplace monitoring obligations, and chemical health risk management requirements.

Collectively, these regulations function as safety gatekeeping mechanisms that determine whether chemical inventions can progress toward industrial scale-up and commercial deployment.

Product Registration and Chemical Notification

Chemical inventions that fall within pharmaceutical, cosmetic, toxic, or agrochemical categories are subject to additional registration and market approval requirements. The National Pharmaceutical Regulatory Agency (NPRA) regulates pharmaceuticals and certain chemical-based products under the Sale of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984. Product registration, safety assessment, efficacy evaluation, and quality control are required before products may be marketed.

Similarly, agrochemical products are regulated under the Pesticides Act 1974. Products falling within toxic or controlled chemical categories may also be regulated under the Poisons Act 1952. Malaysia also utilises chemical notification systems such as Malaysia Environmentally Hazardous Substances System (MyEHS) to facilitate chemical inventory reporting and chemical management oversight.

These regulatory processes significantly influence time-to-market, compliance costs, and commercial feasibility.

Industrial Licensing and Manufacturing Regulation

A major regulatory control point arises during industrial scale-up and manufacturing. The Industrial Co-ordination Act 1975 requires manufacturing licences for certain industrial activities. Section 3 of the Act provides that no person shall engage in manufacturing activity without a licence. The Act empowers licensing authorities to impose conditions relating to industrial operations, production activities, and compliance obligations. Importantly, the Act does not merely regulate manufacturing from a technical perspective. Rather, it embeds broader industrial policy considerations into licensing decisions. Licensing approvals are influenced by national economic and social objectives, industrial coordination priorities, and orderly industrial development. Consequently, the Industrial Co-ordination Act 1975 functions as a strategic market-entry control mechanism within the chemical commercialisation ecosystem. The Malaysian Investment Development Authority (MIDA) also plays a significant role in facilitating manufacturing licence applications, industrial investment approvals, and industrial development coordination.

Export Control and Strategic Regulation

The commercialisation of advanced chemical technologies may also trigger export control obligations. The Strategic Trade Act 2010 regulates the export, transshipment, brokering, and transit of strategic items including dual-use chemicals, sensitive materials, and controlled technologies. Certain chemical inventions may require permits, end-use declarations, and export approvals before international commercialisation can occur. The Strategic Trade Act therefore operates as a downstream commercialisation control mechanism governing international market expansion. Additionally, the Chemical Weapons Convention Act 2005 regulates toxic chemicals associated with weapons production and international treaty obligations.

DISCUSSION

The complexity and fragmentation of the regulatory landscape governing chemical innovation commercialisation in Malaysia demonstrate the urgent need for a comprehensive Regulatory Readiness Framework (RRF). Existing commercialisation frameworks within innovation ecosystems primarily focus on technological readiness, financial readiness, and market readiness, while regulatory readiness remains insufficiently addressed. However, in the chemical industry, successful commercialisation depends not only on technological capability, but also on the ability to anticipate, manage, and strategically navigate regulatory requirements throughout the commercialisation lifecycle.

A Regulatory Readiness Framework (RRF) may therefore be defined as a systematic and structured framework that assists innovators, researchers, investors, start-ups, universities, and industry players in identifying, preparing for, and complying with regulatory requirements across different categories of chemical innovations and Technology Readiness Levels (TRLs). The framework should function as both a regulatory navigation tool and a strategic commercialisation guide.

The proposed RRF should incorporate a TRL-based regulatory mapping approach. Different regulatory obligations emerge at different stages of innovation development. At lower TRLs involving laboratory research and proof-of-concept development, regulatory considerations focus primarily on chemical hazard classification, toxicological assessment, laboratory safety, and chemical handling requirements under regulations such as the CLASS Regulations and USECHH Regulations. At intermediate TRLs involving prototype validation, pilot production, and industrial scale-up, additional regulatory requirements arise relating to environmental approvals, occupational safety compliance, manufacturing licences, scheduled waste management, and industrial

operational controls. At higher TRLs involving market deployment and export expansion, innovators must address product registration, standards certification, labelling compliance, strategic trade controls, and international regulatory requirements such as REACH and GHS compliance.

The framework should also recognise that different categories of chemical innovations are governed by different regulatory pathways. Base chemicals and intermediates such as fertilisers, petrochemicals, oleochemicals, and industrial feedstocks may require extensive industrial licensing, environmental approvals, and occupational safety controls. Plastics and polymer innovations involving engineering plastics, synthetic rubber, composites, and recyclable materials may additionally require sustainability compliance, circular economy considerations, and hazardous substance controls. Specialty chemicals such as agrochemicals, care chemicals, nutrition chemicals, electronic chemicals, and pharmaceutical-related chemicals are subject to more complex product registration, toxicological testing, safety assessment, and sector-specific approvals administered by agencies such as NPRA and the Pesticides Board.

Accordingly, the proposed RRF integrates three core dimensions, namely regulatory foresight, regulatory readiness, and regulatory strategy. The RRF functions as a compliance checklist as well as operating as an integrated commercialisation governance tool capable of supporting decision-making across the entire lab-to-market pipeline. The framework enables innovators and investors to assess regulatory risks, estimate compliance costs, identify approval timelines, and evaluate commercial feasibility before large-scale investment decisions are made.

In addition, the framework supports stronger coordination among regulatory agencies and commercialisation actors. The current regulatory environment in Malaysia involves multiple agencies operating independently, resulting in overlapping approvals, inconsistent procedures, and regulatory uncertainty. An integrated RRF could therefore facilitate inter-agency coordination, improve regulatory transparency, and support the development of a more innovation-friendly regulatory ecosystem.

The development of a comprehensive Regulatory Readiness Framework is therefore essential to strengthen Malaysia's chemical innovation ecosystem. By integrating regulatory considerations into the commercialisation process from the early stages of innovation development, the framework can reduce commercialisation barriers, minimise regulatory uncertainty, improve investor confidence, and accelerate the successful transition of chemical innovations from laboratory research to industrial and market deployment.

PROPOSED REGULATORY READINESS FRAMEWORK

A. Regulatory Control Points in the Chemical Commercialisation Pipeline

The regulatory landscape governing chemical innovation commercialisation may be conceptualised through sequential regulatory control points operating across the Technology Readiness Level (TRL) pipeline.

The first control point occurs during early-stage research and prototype development, where chemical identity, hazard classification, toxicity assessment, and safety profiling are evaluated under regulations such as the CLASS Regulations and USECHH.

The second control point involves product registration and pre-market approval. At this stage, innovations may require chemical notification, NPRA registration, pesticide registration, or toxic substance approvals.

The third control point arises during pilot production and industrial scale-up. Environmental approvals, occupational safety compliance, and industrial licensing requirements become dominant considerations.

The fourth control point relates to market entry and product authorisation. Sector-specific approvals, standards certification, quality assurance, and labelling compliance influence whether products can be legally sold.

The final control point concerns export regulation and international trade control under instruments such as the Strategic Trade Act 2010. These control points collectively determine whether chemical inventions can

successfully transition from laboratory innovation to marketable industrial products. The regulatory control points across Technology Readiness Level (TRL) in the chemical innovation commercialisation pipeline is illustrated in figure 1 below.

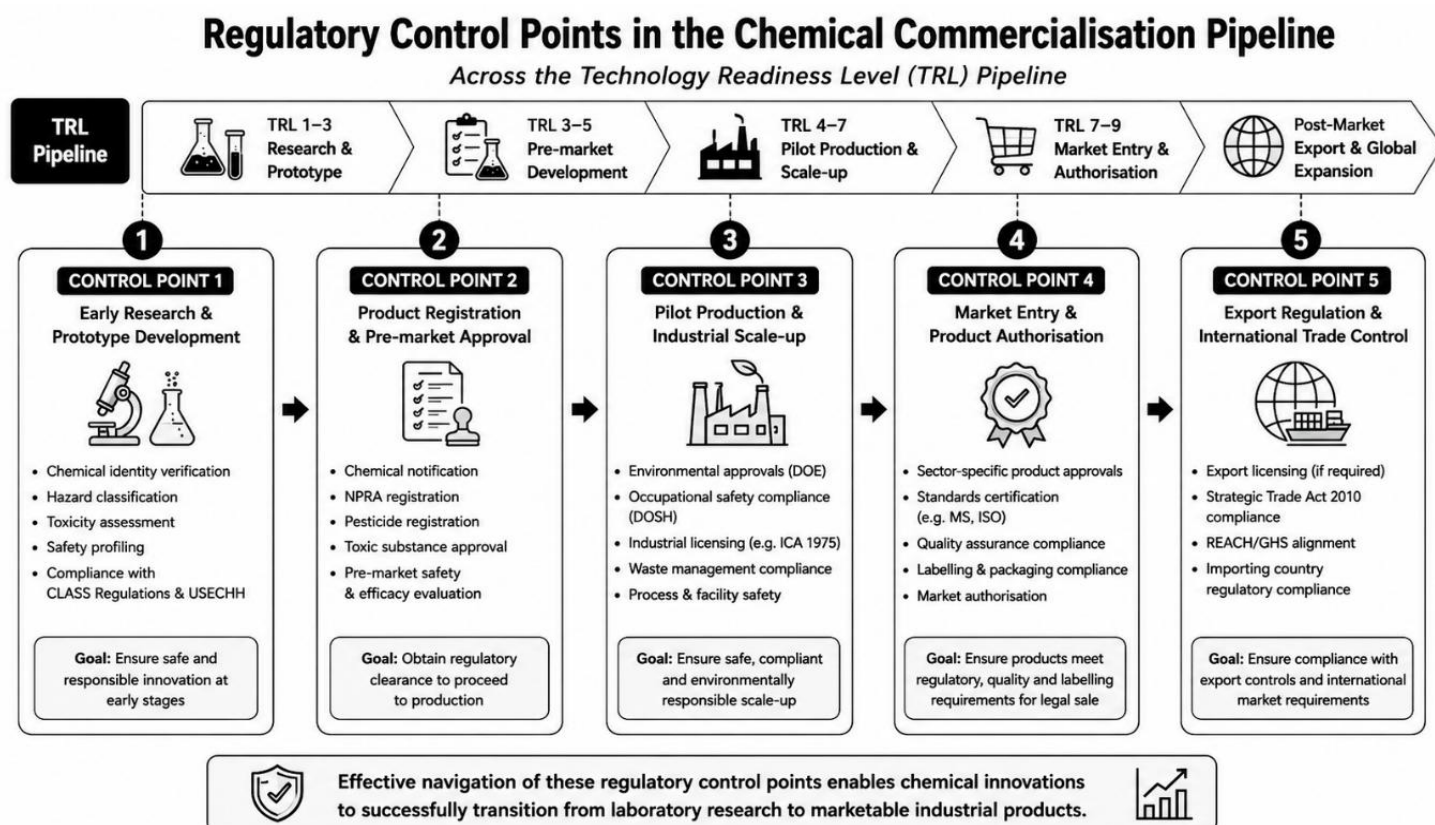


Figure 1: Regulatory Control Points Across TRL in the Chemical Innovation Commercialisation Pipeline

B. Regulatory Readiness as a Commercialisation Capability

This article argues that regulatory readiness should be recognised as a core commercialisation capability within chemical innovation ecosystems. Regulatory readiness refers to the ability of inventors, researchers, start-ups, and commercialisation actors to anticipate, prepare for, and strategically navigate regulatory requirements throughout the innovation lifecycle. Three core dimensions of regulatory readiness are proposed below.

Regulatory Foresight

Regulatory foresight refers to the ability of innovators and commercialisation actors to identify applicable laws, regulatory pathways, compliance requirements, and potential approval barriers at the earliest stages of research and development. In the chemical industry, regulatory considerations should not be treated as a post-development compliance exercise, but instead integrated into the innovation process from the beginning through a “regulation-by-design” approach.

Under this approach, chemical products and technologies are developed with early awareness of hazard classifications, restricted substances, toxicological risks, environmental obligations, occupational safety requirements, product registration procedures, and relevant national and international standards such as GHS and REACH. Regulatory foresight also involves understanding the different regulatory requirements that may arise across various Technology Readiness Levels (TRLs), from laboratory research and prototype development to industrial scale-up, market authorisation, and export activities.

For chemical innovators, early regulatory planning is particularly important because different categories of chemical innovations, such as base chemicals, polymers, agrochemicals, and specialty chemicals, are subject to

different regulatory pathways and approval processes. Failure to identify these requirements at an early stage may result in product redesign, additional testing costs, approval delays, or regulatory rejection during commercialisation.

Accordingly, regulatory foresight enables innovators to anticipate regulatory risks, prepare appropriate compliance strategies, improve investment planning, and accelerate the transition of chemical innovations from laboratory research to market deployment. It also strengthens decision-making by allowing innovators, investors, and industry partners to evaluate regulatory feasibility alongside technological and commercial viability throughout the innovation lifecycle..

Regulatory Readiness

Regulatory readiness refers to the ability of innovators and commercialisation actors to prepare the scientific, technical, and compliance evidence required for regulatory approval, industrial licensing, and market entry. In the chemical industry, regulatory approval is heavily evidence-based, meaning that products are assessed not merely on innovation potential, but on the availability of reliable data demonstrating safety, quality, performance, and regulatory compliance.

Accordingly, regulatory readiness requires innovators to systematically generate and manage regulatory documentation and compliance evidence throughout the commercialisation lifecycle. This includes toxicological data, environmental impact assessments, stability and performance testing results, Safety Data Sheets (SDS), technical dossiers, product specifications, standards certification documents, and Good Laboratory Practice (GLP)-compliant testing procedures. The scope of required regulatory evidence may vary depending on the type of chemical innovation and the applicable regulatory framework. For example, specialty chemicals such as agrochemicals, nutrition chemicals, and pharmaceutical-related products may require extensive toxicological and safety evaluations, while industrial chemicals and polymers may place greater emphasis on environmental compliance, occupational safety, and industrial operational controls.

Regulatory readiness is particularly important during intermediate and advanced Technology Readiness Levels (TRLs), where innovations move from laboratory validation to pilot production, industrial scale-up, and commercial deployment. At these stages, regulators and investors increasingly require verified compliance data before approvals, manufacturing licences, product registrations, and market authorisations can be obtained. The absence of reliable scientific and compliance evidence may result in approval delays, additional testing costs, regulatory rejection, or loss of investor confidence. Therefore, the ability to generate, organise, and maintain credible regulatory evidence should be recognised as a critical commercialisation capability within the chemical innovation ecosystem.

In practice, strong regulatory readiness enables innovators to improve approval planning, reduce regulatory uncertainty, strengthen investor confidence, and accelerate the successful transition of chemical innovations from research and development to industrial and market deployment.

Regulatory Strategy

Regulatory strategy refers to the deliberate and systematic planning of regulatory pathways, licensing requirements, industrial partnerships, and market entry approaches throughout the commercialisation lifecycle of chemical innovations. In the chemical industry, regulatory compliance should not be viewed solely as a legal obligation, but as a strategic function that directly influences time-to-market, investment decisions, industrial scalability, and global market access.

An effective regulatory strategy requires innovators to identify the most suitable approval pathways and regulatory sequencing at different Technology Readiness Levels (TRLs). This includes planning for product registration, environmental approvals, manufacturing licences, occupational safety compliance, standards certification, labelling requirements, and export controls. Since different categories of chemical innovations are governed by different regulatory regimes, innovators must develop regulatory roadmaps tailored to the nature, risk profile, and intended application of the product.

Regulatory strategy also emphasises the importance of early engagement with regulators and relevant stakeholders. Innovators should proactively consult agencies such as DOSH, DOE, NPRA, MITI, Standards Malaysia, and the Pesticides Board during the early stages of commercialisation to obtain guidance on compliance expectations, approval requirements, and potential regulatory risks. Early regulatory engagement may reduce approval uncertainty, minimise procedural delays, and improve overall commercialisation planning.

In addition, effective regulatory strategy requires strategic collaboration with industry partners, regulatory consultants, standards bodies, investors, and technology transfer offices (TTOs). Such collaborations may provide innovators with technical expertise, regulatory support, industrial infrastructure, and market access opportunities necessary for successful scale-up and commercial deployment.

Regulatory strategy should also incorporate export-readiness and international regulatory alignment. Chemical innovators seeking regional or global market access must consider international standards and regulatory frameworks such as GHS harmonisation, REACH compliance, OECD testing standards, and strategic trade requirements under the Strategic Trade Act 2010. Integrating these considerations at an early stage enables innovators to strengthen international competitiveness and avoid future regulatory barriers in export markets.

Overall, regulatory strategy enables innovators and investors to better anticipate regulatory risks, improve compliance planning, strengthen investor confidence, reduce approval delays, and accelerate the successful commercialisation of chemical innovations from laboratory research to industrial and global market deployment. The regulatory readiness framework for commercialisation of chemical innovation is illustrated in figure 2 below.

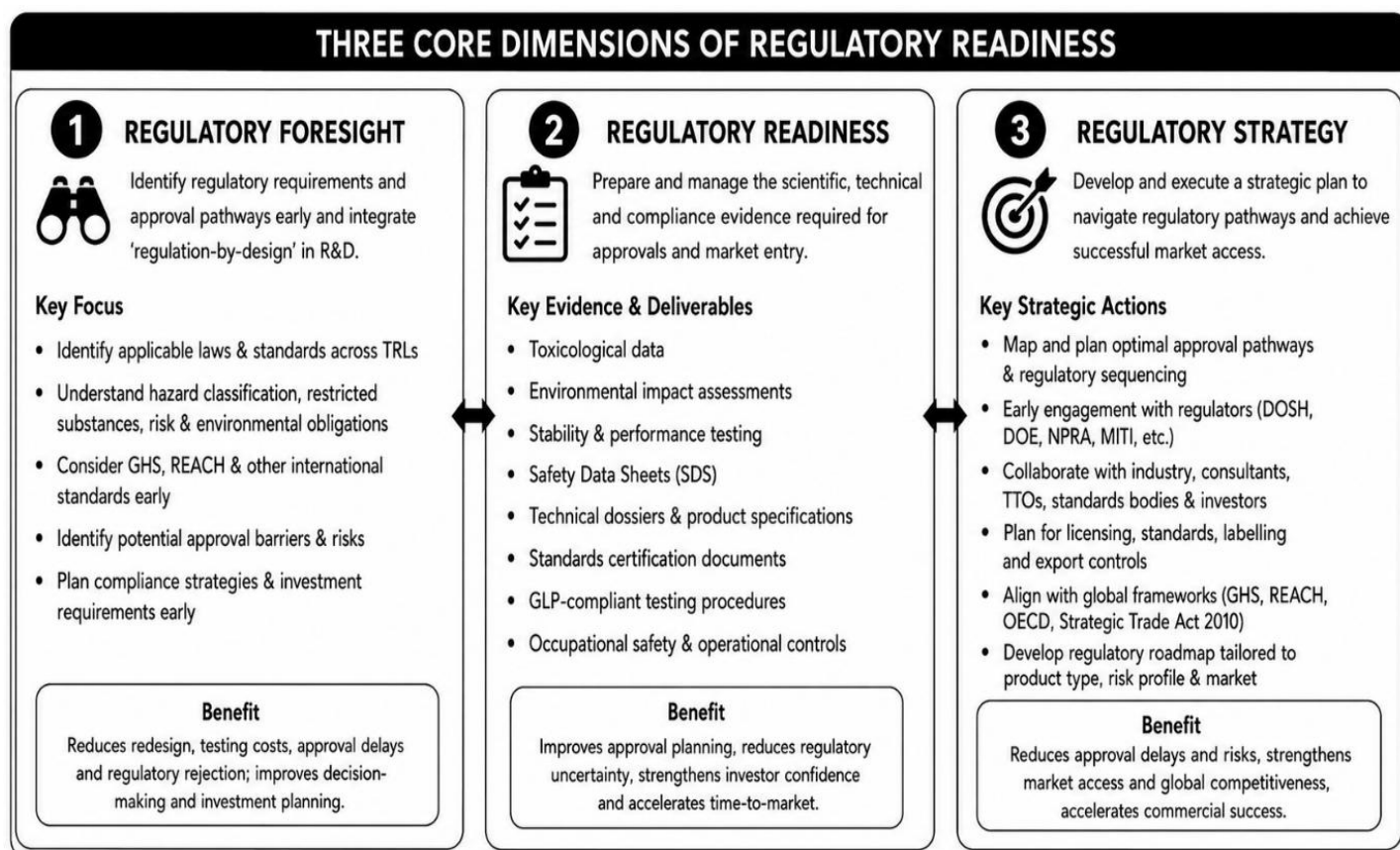


Figure 2: Regulatory Readiness Framework for Commercialisation of Chemical Innovation

PRACTICAL IMPLICATIONS

The proposed Regulatory Readiness Framework (RRF) has important practical implications for innovators, investors, universities, industry players, and regulators involved in the commercialisation of chemical

innovations in Malaysia. The framework provides a structured approach to help stakeholders understand and manage regulatory requirements throughout the commercialisation process.

For innovators and researchers, the RRF serves as a regulatory navigation tool that helps identify relevant laws, approval pathways, compliance requirements, and regulatory risks at different Technology Readiness Levels (TRLs). This is important because many researchers and start-ups have strong technical expertise but limited knowledge of regulatory processes. The framework can help reduce regulatory uncertainty, avoid delays, and improve commercialisation planning.

For investors and industry partners, the RRF improves regulatory visibility and risk assessment. Since regulatory uncertainty and compliance costs often affect investment decisions, the framework enables investors to assess regulatory readiness together with technological and market readiness before investing in chemical innovation projects.

The framework is also useful for universities and technology transfer offices (TTOs). It can support the development of regulatory advisory services, regulatory mentoring, and commercialisation support programmes for chemical-based innovations and university spin-offs.

For industry players and manufacturers, the framework helps integrate regulatory requirements into product development and manufacturing strategies. This may improve compliance management, reduce approval delays, and accelerate time-to-market.

At the policy level, the RRF may improve coordination among regulatory agencies such as DOSH, DOE, NPRA, MITI, and Standards Malaysia. It may also support the development of a Chemical Regulatory Sandbox or integrated regulatory facilitation mechanism to simplify approvals and support innovation commercialisation.

Overall, the RRF can strengthen Malaysia's chemical innovation ecosystem by reducing regulatory barriers, improving investor confidence, and accelerating the successful commercialisation of chemical innovations.

SUGGESTION FOR FUTURE RESEARCH

Future research should focus on developing a Chemical Regulatory Sandbox Framework for Malaysia to help simplify and improve the commercialisation process for chemical innovations. Future research should examine how a multi-agency regulatory sandbox involving DOSH, DOE, NPRA, MITI, Standards Malaysia, MIDA, and the Pesticides Board can be implemented to provide coordinated regulatory support for chemical innovations.

Comparative studies with countries such as Singapore, South Korea, the United Kingdom, and the European Union should also be conducted to identify international best practices in regulatory sandboxes and innovation governance. Future research should additionally examine the legal framework, governance structure, operational procedures, and risk management mechanisms required for implementing a Chemical Regulatory Sandbox in Malaysia.

Overall, future research on this area can contribute towards improving regulatory coordination, reducing commercialisation barriers, strengthening investor confidence, and accelerating the successful commercialisation of chemical innovations in Malaysia.

CONCLUSION

The commercialisation of chemical industry inventions and innovations is governed by a complex and highly regulated ecosystem involving multiple statutes, agencies, standards, and approval mechanisms. This study demonstrates that chemical commercialisation is regulated through sequential regulatory control points operating across the Technology Readiness Level pipeline. These control points influence whether innovations can progress from laboratory discovery toward industrial production, market entry, and international commercialisation.

The study further identifies the existence of a regulatory Valley of Death within chemical commercialisation, particularly during the transition from prototype validation toward industrial scale-up. The article argues that regulatory readiness must be recognised as a core commercialisation capability alongside technological readiness. Chemical innovators must develop regulatory foresight, regulatory readiness, and regulatory strategy in order to successfully navigate the commercialisation ecosystem.

Finally, the article proposes the development of a Chemical Regulatory Sandbox Framework to facilitate coordinated regulatory governance, reduce fragmentation, improve regulatory certainty, and accelerate chemical innovation commercialisation in Malaysia. Strengthening regulatory governance within the chemical commercialisation ecosystem will not only improve commercialisation outcomes but also contribute toward Malaysia's broader industrial transformation agenda under NIMP 2030 and CIR2030.

Conflict of Interest

The author(s) declare that there are no conflicts of interest regarding the publication of this article. The author(s) have no financial, professional, personal, or institutional relationships that could have influenced the research, analysis, or conclusions presented in this study.

Funding Statement

This research received no external funding and did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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