Since 1953
AMCHAM
American Chamber of Commerce in Korea

2025 Business Environment Insight **Report**

APEC Special Edition

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American Chamber of Commerce in Korea

About AMCHAM Korea

The American Chamber of Commerce in Korea (AMCHAM Korea) was founded in 1953, with a broad mandate to encourage the development of investment and trade between Korea and the United States.

AMCHAM Korea is the largest foreign chamber in Korea with approximately 800 member companies and affiliates with diverse interests and substantial participation in the Korean economy.

For any inquiries regarding the report, please contact gov@amchamkorea.org.

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Industry	Key Issues	Recommendations
Aerospace & Defense	Need Clarity Over DAPA's Request for Industrial Cooperation (IC) Plans NEW	Provide guidance and clarification regarding the Industrial Cooperation plans to enable OEMs to deliver the best solutions for Korea's defense industry.
	Onerous Penalty Provisions in Offset Terms & Obligations UNRESOLVED	Incorporate an additional provision in the Offset Guidelines so DAPA could consider replacement projects by the contractor that has greater offset value than the shortfall.
Agriculture, Food & Beverage	Agricultural Biotechnology UNRESOLVED	Streamline the approval process for genetically modified crops, eliminate unnecessary steps, and ensure regulations on gene editing align with global standards and the KORUS FTA to support innovation and trade.
	Negative Perception of Non-Sugar Sweeteners NEW	Reconsider regulations on NSS to ensure a level playing field and remove the stigma associated with NSS created by said regulations.
	On-site Inspections of the OEM Manufacturers UNRESOLVED	Ease the mandatory on-site inspection requirements.
	Packaging Materials and Methods UNRESOLVED	Reconsider packaging regulations and align with Global Plastics Treaty negotiations, adopting industry standards like the Consumer Goods Forum Global Design Rules, as recommended by the Business Coalition.
Alcoholic Beverage	Proposed Plan to Revise Health Warnings on Alcoholic Beverages NEW	Maintain the current health warning labels that already inform the harms of excessive drinking to health.

Automobiles	Auto GHG/CAFE Rules for 2026-2030 UNRESOLVED	Adopt transparent procedures and foster open communication with industry stakeholders in setting realistic GHG/CAFE rules for 2026-2030.
	Discriminatory EV Subsidy Policy Against Non-Target Companies Under the Low-Emission Vehicle Supply Mandate (LEVSM) NEW	Revise the LEVSM eligibility criteria to reflect recent EV sales instead of 2009 vehicle sales record, fostering EV adoption, market participation, and Korea's carbon neutrality goals.
	Duplication of Penalty Systems: LEV/ZEV Mandate and GHG Regulations NEW	Reconsider the LEV/ZEV Supply Target Policy, either by abolishing it or revising the associated penalty system to eliminate redundant regulatory burdens.
	End-of-Life Vehicle & Extended Producer Responsibility UNRESOLVED	Grant an exemption to U.S. end-of-life vehicles from the hazardous materials requirement and reconsider the EPR extension.
	NACS Charging Standard Adoption NEW	Revise the Act on the Promotion of Development and Distribution of Environment-Friendly Automobiles to include NACS as an accepted charging standard.
	Overlapping Regulations on Electric Vehicles UNRESOLVED	Minimize industry burden and avoid redundant rules through government-wide consultation and review.
	Recognition of U.S. Safety Standard (FMVSS) in Korea UNRESOLVED	Grant full recognition of FMVSS-certified vehicles regardless of its origin of production.
	Sale of Pre-certified Vehicles UNRESOLVED	Allow imported vehicles, including EVs, used for marketing and development to gain sale certification post-use.
	Type Approval Requirements for EVSE NEW	Align regulations with global standards, recognizing the proven accuracy of remote displays in showing energy values; and lower the sample ratio for metering accuracy checks on certified EVSE models to streamline deployment and accelerate EV adoption.
	Warranty/Recall Requirements UNRESOLVED	Notify recalls exclusively for vehicles or parts sold by automakers in Korea and adhere to international norms in determining the deadline.

Chemicals	Colorless Coated Glass Bottle Recyclability Assessment NEW	Regulate coated glass as easy to recycle and seek alternatives to enhance sorting capability of glass waste.
	Detailed Criteria to Distinguish Chemical Substances from Articles UNRESOLVED	Detail criteria in distinguishing an article or a chemical substance for registration exemption.
	Difficulties for Confidential Business Information Approvals of Trade Secret Ingredients in R&D Samples NEW	Exempt the process of Non-Disclosure Approval for trade secret ingredients in R&D samples under OSHA
	Disclosure of Confidential Business Information UNRESOLVED	Minimize confidential business data disclosure requirements and punitive penalties for non-registration.
	Discrepancies in the List of Existing Chemicals between K-REACH and OSHA UNRESOLVED	Amend Article 85 of the Enforcement Decree of the OSHA to include all existing chemicals under the K-REACH and revise Article 147 of the Enforcement Rules to relax the registration criteria for new chemicals.
	Easing Hazards and Risk Data Submission Criteria for Fragrances in Biocidal Products NEW	Modify submission criteria for hazard data and expand and recognize data scope of submittable data for biocidal product approval.
	Easing Pre-notification Requirement for New Technology Biocide Introduction in Korea NEW	Adjust the pre-notification requirement.
	Expanded Scope of Consumer Chemical Product Regulations UNRESOLVED	Eliminate registration requirements for changes that have no relevance to human health.
	Redundant Regulations under the Chemical Control Act (CCA) UNRESOLVED	Eliminate duplicate regulatory requirements.
	Test Methods for Consumer Chemical Products UNRESOLVED	Harmonize testing methods for safety standards for consumer chemical products with global standards.

Digital Economy	Online Platform Regulations UNRESOLVED	Discontinue the legislative discussions to allow for thorough consultation with the U.S. Government, Korean consumers, civil society, academia, and industry, given the potential risk of significant trade friction arising from the regulation.
	Application of the Cloud Security Assurance Program (CSAP) UNRESOLVED	Extend logical network separation to the Moderate tier, broaden the range of non-sensitive public sector information, and revise Korea-specific requirements to align with global technological standards.
	Artificial Intelligence UNRESOLVED	Eliminate overly burdensome AI requirements, align with international best practices, and implement a proportionate, risk-based approach that enables responsible and safe development of AI.
	Designation of a Local Representative UNRESOLVED	Reconsider the requirement for foreign service providers to designate a local agent in Korea.
	Legislative Bill on Safety Management of Digital Disasters and Failures UNRESOLVED	Reevaluate the Bill to better reflect unique capabilities and characteristics of each service provider and to minimize undue burdens on businesses.
	National Core Technologies (NCTs) NEW	Expedite the release of the cloud use guideline for NCT at earliest convenience.
	Personal Information Protection Act (PIPA) UNRESOLVED	Align personal information protection regulations with global standards.
	Telecommunications Business Act: Value-Added Service Provider Regulations NEW	Adopt transparent, predictable guidelines and ensure that any supplementary or enhanced obligations extended to VSPs remain reasonable and do not restrict business freedom.

Energy & Environment	Bilateral Agreements for CO_2 Transport and Storage and the Establishment of Common CO_2 Storage Standards UNRESOLVED	Accelerate the advancement of proposed bilateral agreements and forge additional agreements with nations possessing pertinent storage capacity.
	Domestic Certification Requirements for Large- and Medium-Sized Wind Turbines UNRESOLVED	Allow mutual recognition of safety certification.
	Equity Investment Commitment Letter in Electricity Business License Evaluation Process UNRESOLVED	Modify the requirements in the Equity Commitment Letter to avoid discouraging foreign investment.
	Fast-Track Approach to Delayed Interconnection Analysis NEW	Prioritize delayed grid reviews for projects meeting key requirements, including financial, technical, and community acceptance, during the EBL review stage.
	Need for Strengthening the Hydrogen Sector NEW	Need to focus on enhancing the industrial ecosystem by restructuring the auction evaluation process.
	Opportunities for Private Investment in Grid Infrastructure UNRESOLVED	Invite private investors to help improve grid capacity to facilitate the growth of renewable energy and ease KEPCO's financial burdens.
	Policy Improvement for the Distributed Power Sector NEW	Grant microgrids more independence, set clear regional pricing regulations, and establish guidelines for differential tariffs based on transmission costs and regional demand.
Financial Services	Adherence to Regulatory Transparency UNRESOLVED	Ensure consistency between administrative guidance and current regulations to enhance regulatory predictability and uniformity.
	Differentiation of Information Handling for Corporate vs. Consumer Clients UNRESOLVED	Provide differentiated information processing guidelines for corporate client information vs. individual client information.
	Excessive Regulatory Control on Financial Products NEW	Adopt a principles-based approach that balances consumer protection with innovation, allowing flexibility in product design while ensuring USD-denominated financial products receive fair treatment vis-à-vis KRW-denominated products to enhance choice and market efficiency.
	Liberalization of Firewall Standards among Financial Entities within Korea UNRESOLVED	Relax the firewall standards among financial entities within Korea to facilitate the exchange of information.
	Measured Liberalization of Korean Data Protection Standards for Financial Companies UNRESOLVED	Ease the data protection standards to a level comparable to the U.S. and other developed OECD nation standards.

	Relaxation of Korean Network Segregation and Cloud Computing Standards for Financial Companies[UNRESOLVED]	Relax network segregation and cloud computing standards for financial companies to a level comparable to those of the U.S. and other developed OECD nations.
	Relaxation of Restrictions on the Short Sale of KTB[UNRESOLVED]	Relax the short sale rule so that banks can cover KTB position on the bond settlement.
Labor[NEW]	Expansion of Parental Leave Pay & Substitute Workforce Support	Further improve parental leave policies, including increased subsidies for substitute workforce programs and incentives for companies that actively promote parental leave.
	Labor Flexibility	Consider reforms that offer flexibility in adjusting workforce in response to economic conditions, while safeguarding worker protections.
	Reform of Working Hours System	Ensure that any reforms in working hours align with international best practices, support business growth, and maintain employee well-being.
Medical Devices	Accelerating Patient Access to Innovative Medical Technologies[UNRESOLVED]	Accelerate the reimbursement and pricing approval process to comply with the 100-day timeframe, and integrate these approvals into the PR process.
	Exclusion of Advanced Medical Equipment Companies from Relevant Policy Discussions [UNRESOLVED]	Encourage open communication with medical equipment companies to discuss policies concerning medical equipment.
	Reimbursement Coverage for Innovative Medical Technologies[UNRESOLVED]	Adopt flexible reimbursement approaches and activate the “New Conditional Reimbursement” system to enhance patient access, with more flexibility in the nHTA system for smoother adoption.
	Policy Support for Medical Devices Necessary for Cancer Diagnosis and Treatment[NEW]	Establish appropriate reimbursement rates for medical devices used in cancer diagnosis and treatment, and cover technologies with proven safety and clinical efficacy.
	Activation of Home-based Treatment and Expansion of the Digital Health Industry[NEW]	Establish mutual communication between stakeholders and policymakers to address concerns and foster collaboration.
	Global Harmonization in the Medical Device Approval System[NEW]	Harmonize product and manufacturing site registration regulations with international standards.

Pharmaceutical	Lack of Transparency and Predictability UNRESOLVED	Establish and disclose clear criteria for the pricing and reimbursement evaluation to ensure transparency and predictability of policies.
	Pricing of Global Innovative Drugs UNRESOLVED	Assess the value of new and innovative medicine in a more swift and appropriate manner.
	Necessity of Dual Pricing for Access to Innovative Medicines and Sustainable Supply NEW	Revise the current dual pricing regulations in Korea to ensure the practical applicability of Dual pricing
	Need for Implementation of Indication-Based Pricing for Pharmaceuticals NEW	Implement a P&R system that acknowledges the value of multiple indications, starting with a pilot program for indication-based pricing and progressing to full-scale adoption.
	Establishing a National Immunization System and Improving the National Immunization Program (NIP) Policy NEW	Establish clearer process, timeline and guideline in the NIP system and vaccine tender standard.
	Intellectual Protection Challenged by the Amendment to the Patent Act NEW	Engage with key stakeholders to halt the enactment of the Patent Act Amendment Bill or revise it to ensure alignment with U.S. practices.
Taxation NEW	Predictability in Tax Enforcement	Expand opportunities for tax rulings and streamline the advance pricing agreement process.

Note: "New" refers to new regulatory issues that have arisen since last year's AMCHAM report, while "Unresolved" refers to issues that remain unresolved from the previous year.

INTRODUCTION

As the largest foreign chamber of commerce in Korea, the American Chamber of Commerce (AMCHAM) is pleased to present the 2025 edition of our annual *Business Environment Insights* report. Amid a rapidly evolving geopolitical and economic landscape, the U.S.-Korea commercial relationship continues to expand, navigating both opportunities and challenges.

In 2024, economic ties between the two nations reached new heights, with significant growth in bilateral trade and investment. As Korea's role in global trade, investment, and supply chain resilience continues to rise, so does the need to enhance its regulatory framework to remain competitive with other leading economies.

This report highlights key regulatory challenges that hinder the entry of U.S. goods and services and impede U.S.-Korea industrial collaboration. These challenges range from policies that may not fully align with the spirit of the KORUS FTA to overly complex regulations that could stifle innovation and bilateral cooperation.

AMCHAM remains committed to advocating for Korea's transformation into a regional innovation hub. Achieving this vision requires a business-friendly regulatory environment that aligns with global best practices and enhances Korea's attractiveness to foreign investors. Strengthening Korea's investment climate will not only drive economic growth but also promote more balanced and sustainable trade between our two nations.

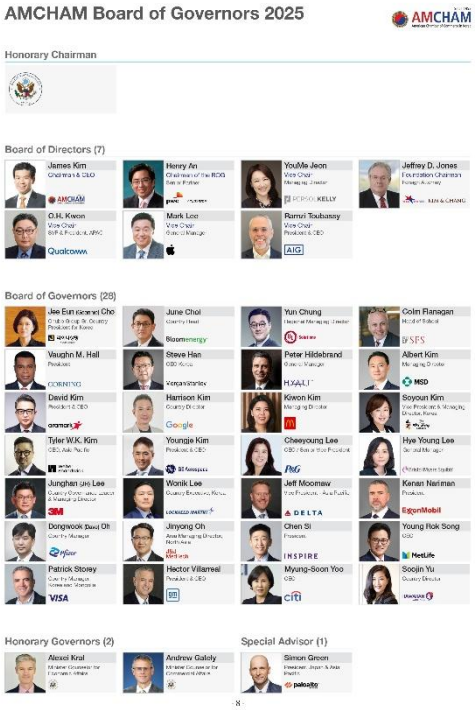
Mission of AMCHAM Korea

Promote the expansion of trade and investment partnerships between the U.S. and Korea by:

1. Supporting U.S. companies in Korea
2. Helping U.S. SMEs to enter the Korean market
3. Facilitating Korean companies' investment in the U.S.

AMCHAM at a Glance

- **72** years in history
- **800+** corporate members and affiliates
- **1,500+** individual members
- **31** industry committees
- Board of Governors



ECONOMIC IMPACT OF KORUS FTA

The year 2025 marks the 13th anniversary of the implementation of the KORUS FTA, a landmark agreement that has profoundly shaped the U.S.-Korea economic relations. KORUS, with its renegotiation in 2018, remains one of the most comprehensive free trade agreements for both nations, serving as the foundation for bilateral commercial ties. Over the past decade, both countries have benefited significantly from KORUS, with the total trade in goods increasing by 93% - from $104 billion in 2013 to $200 billion in 2024[1]. Despite challenges such as the pandemic and geopolitical tensions, trade between the U.S. and South Korea has continued to expand. U.S. exports to South Korea grew from $56 billion in 2019 to $66 billion in 2024. Korean exports to the U.S. grew from $77 billion in 2019 to $127.8 billion in 2024.[2]

Source: Korea International Trade Association (KITA)

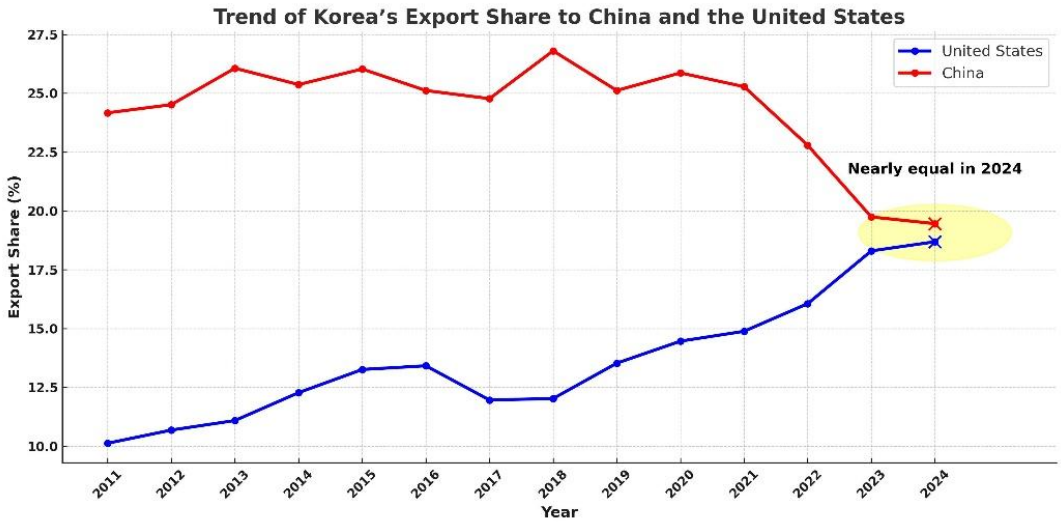
Trade flows between the U.S. and Korea have undergone notable transformations. Before KORUS, the largest U.S. exports to Korea were machinery and electrical components. By 2024, crude oil, natural gas, and semiconductor equipment had become the primary export categories. South Korea's top exports to the U.S. have also evolved. While automobiles remained the top export, computer accessories surged to second place – more than doubling from 2023 – driven by increased AI-

[1] 2024 Trade Trends Between South Korea and the U.S., Korea International Trade Association (KITA)

[2] "United States Exports to South Korea - 2025 Data 2026 Forecast 1991-2024 Historical" & "South Korea Exports to United States - 2025 Data 2026 Forecast 1988-2023 Historical", Trading Economics

related investments in the U.S. and growing demand for DRAM modules. Automotive parts and accessories followed as the third-largest export category.[3]

A major shift in South Korea's export landscape is the reorientation of its primary export market from China to the U.S. As of December 2024, South Korea's cumulative exports to the U.S. reached $123 billion, closely approaching its exports to China at $133 billion[4]. If this trend continues, the U.S. will surpass China as South Korea's largest export market for the first time since 2001. This development underscores the deepening economic interdependence between South Korea and the U.S.



Source: Korea Export-Import Bank

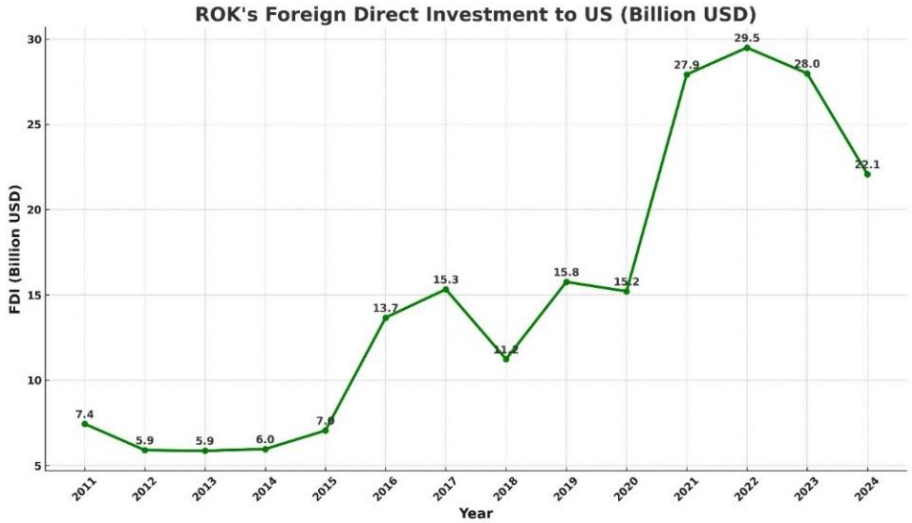
Investment flows have also expanded significantly under KORUS. U.S. investment in Korea grew from $1 billion in 2011 to $5.24 billion in 2024[5] while Korean investment in the U.S. surged from $7.4 billion in 2011 to $22 billion in 2024[6]. Notably, South Korea became the largest foreign investor in the U.S. for the first time, further solidifying the strength of the bilateral economic partnership.

[3] "2024 Trade Trends Between South Korea and the U.S.", Korea International Trade Association (KITA)

[4] Ibid.

[5] Ibid.

[6] "Statistics of Foreign Direct Investment", Korea Export-Import Bank



Source: Korea Export-Import Bank

KOREA'S BUSINESS ENVIRONMENT AMID UNCERTAINTIES

As bilateral trade and investment continue to grow, American businesses in Korea remain key stakeholders in both economies. Despite significant political and economic challenges, including the martial law incident last December, Korea has demonstrated resilience by maintaining a clear separation between business and politics. Meanwhile, the new U.S. administration under President Trump has expressed concerns over the growing trade deficit with Korea, emphasizing the need to eliminate non-tariff barriers in Korea. Close coordination between both governments will be crucial to ensuring stability in bilateral commercial relations.

Amid these uncertainties, new opportunities for deeper cooperation are emerging across key sectors, including the digital economy, energy, shipbuilding, MRO (maintenance, repair, and overhaul), and defense. To strengthen Korea's shipbuilding industry, the Ministry of Trade, Industry, and Energy (MOTIE) has committed KRW 260 billion—a 40% increase from the previous year—stimulating further investment. Meanwhile, the defense sector is gaining momentum as a focal point of U.S.-Korea collaboration, creating new avenues for investment and partnership.

LOOKING AHEAD: 2025 APEC, A STRATEGIC OPPORTUNITY FOR KOREA

The 2025 APEC Summit presents a critical opportunity for Korea to shape the future of economic cooperation in the Asia-Pacific region. Hosting APEC for the first time in two decades gives Korea a platform to strengthen its role as a regional economic leader and to drive initiatives centered on connectivity, innovation, and sustainability.

This report serves as an APEC Special Edition, highlighting regulatory issues unique to Korea that impact U.S. businesses. Key APEC 2025 themes, including digital transformation, supply chain resilience, and sustainability, are particularly relevant to American companies and the broader U.S.-Korea economic partnership. AMCHAM is actively engaging with U.S. and Korean stakeholders to ensure private sector perspectives are central to APEC policy discussions and to advocate for Korea's position as a strategic business destination for multinational corporations.

A transparent and predictable regulatory environment is essential for fostering a stable business environment and encouraging AMCHAM members to invest in and export to Korea. AMCHAM remains committed to working closely with both governments to implement the policy improvements outlined in this report. We believe that these policy recommendations will help level the playing field for foreign and domestic businesses, while reinforcing the vital trade and investment ties between the U.S. and Korea.

AEROSPACE & DEFENSE

- Overview
- Need Clarity Over DAPA's Request for Industrial Cooperation (IC) Plans[NEW]
- Onerous Penalty Provisions in Offset Terms & Obligations[UNRESOLVED]

AEROSPACE & DEFENSE

OVERVIEW

South Korea remains a primary market for U.S. aerospace and defense exports. From April 2023 to March 2024, U.S. civil aerospace and defense exports to South Korea recorded a total of $3.76 billion, thereby establishing South Korea as the 5th largest destination for these exports among APEC member economies, excluding China and Russia. In parallel, South Korea has recently emerged as one of the world's fastest-growing defense exporters, rising from its 31st place in 2000 to become the ninth-largest arms exporter globally. With a strategic emphasis on defense exports, the Korean government aims to elevate Korea to among the top four defense exporters worldwide by 2027.

Recently, the Aerospace and Defense industry has witnessed significant strides in cooperation between the United States and South Korea, marked by the signing of the Security of Supply Arrangement (SOSA) in November 2023, to enable priority delivery requests for defense-related goods between the two countries. Furthermore, both the U.S. and Korean governments are engaged in discussions concerning the Reciprocal Defense Procurement (RDP) Agreement. This agreement will provide a structured framework for continuous dialogue on market access and procurement issues, aimed at fostering more effective defense collaboration between the two countries.

In light of these developments, AMCHAM strongly believes that the efficient reform of Korea's defense acquisition policy will serve to promote robust, high-value industrial collaboration between the U.S. and Korea. AMCHAM remains committed to supporting Korea's national security interests and industrial objectives as well as the U.S.-ROK Alliance. AMCHAM urges both governments to collaborate closely with the industry to refine acquisition policies, thereby enhancing Korea's long-term capacity to advance its defense industry objectives globally. Such efforts will also bolster Korea's strategic deterrence capabilities.

INDUSTRY ISSUES

Need Clarity Over DAPA's Request for Industrial Cooperation (IC) Plans

Recently, for several large-scale programs, DAPA IPTs (Integrated Project Teams) have been exempting offset requirements in order to optimize program cost, while requesting OEMs to submit Industrial Cooperation (IC) plans. These IC plans, according to the IPTs, are non-binding and captured in the form of an MOU between DAPA and the OEMs, and we understand that these MOUs will be part of the overall approval process for DAPA's procurement source selection and contract execution.

As far as we are aware, the IC plan is not currently part of any regulation or guidelines from the Korean government. It is being requested on a case-by-case basis by individual DAPA IPTs for each program. Because of this, one business area within one OEM is being requested to submit IC plans in lieu of offset, while another business area in the same OEM may be required to develop the traditional offset proposal. This is causing confusion among OEMs and therefore AMCHAM requests the following clarification from DAPA:

- ❑ Even though IC plans are intended to be non-binding, is there expectation from the Korean government that OEMs make significant effort to implement IC initiatives described in the plans?
- ❑ Do IC plans need to be directly connected to the system being procured? (e.g. For a fighter procurement, do IC plans need to be related to that fighter platform?)
- ❑ Do IC plans need to have a fixed period of performance?
- ❑ Do IC plans need to be evaluated by KRIT (Korea Research Institute for Defense Technology planning and advancement)?
- ❑ Is there any long-term plan by DAPA to eventually codify IC plan requirements in their regulation?
- ❑ What happens if offset is waived for a program, but OEMs fail to submit IC plans as requested by the IPT?

- **Issue**
  DAPA's inconsistent requests for Industrial Cooperation plans generate confusion among OEMs

- **Relevant Agencies**
  Defense Acquisition Program Administration (DAPA)

- **Recommendation**
  AMCHAM requests DAPA to provide guidance and clarification regarding the Industrial Cooperation plans in order for the OEMs to deliver the best solutions for Korea's defense industry while ensuring compliance with the rules and requirements of each procurement.

Onerous Penalty Provisions in Offset Terms & Obligations

DAPA's most recently released Offset Guidelines in October 2024 maintains Articles 23.3. and 23.4. (see below) which state that, in the event of non-performance, 10% of residual offset obligation will be confiscated from the offset performance bond if the obligation is not completed by the end of the agreed Proof of Performance (PoP); if the Overseas Contractor is still unable to perform the remainder of the obligation within the one additional year from the end of PoP, then 50% of the residual offset value will additionally be confiscated, and the remainder of the offset obligation will be liquidated.

This topic has been discussed between DAPA and AMCHAM on a number of occasions, and we very much appreciate DAPA's willingness to engage and provide detailed explanation for the continuation of the current penalty provision. However, it is nevertheless an unavoidable reality for OEMs that these articles pose an undue financial burden and make the U.S.-ROK industrial collaborations challenging as detailed below:

The total amount of confiscation if the contractor fails to perform, while liquidating, is very high. For example, for a $100m offset program, the bond will be placed at $10m; if $20m remains at the end of PoP, $2m will be confiscated at that point, and after one year, additional $10m will be confiscated, making it a total of $12m in terms of the confiscated amount. A contractor therefore would have completed 80% of their obligation, but still be subject to a payout of additional $12m in an actual cost to close out the remaining $20m offset value. In addition, the performance bond is not sufficient to cover the total amount of confiscation, while performance bonds cost money and impact the overall procurement cost.

This issue is compounded by the fact that DAPA's credit award for completed performance does not take place immediately, but rather several weeks or even months afterwards due to: offset implementation reports needing to wait until the preceding performance period is over before being prepared; DAPA's administrative backlog for individual managers; and occasional personnel changeovers on either side.

The restrictive penalty provision in the Offset Guidelines binds the DAPA as much as it binds overseas contractors. A contractor may fail to perform its offset obligation for a variety of causes that are not directly attributable to the contractor, and some may not be readily covered under the Force Majeure clause: there may be unforeseen downturn in market conditions which reduce expected production quantities; or there may be ambiguities or mistakes in the Offset Memorandum of Agreement (MOA) or

Technical Assistance Agreement (TAA) that are interpreted differently or even disputed by successive project managers, forcing the contractor to deviate from the original plan. At that point, it may be in the interest of all parties (DAPA, an overseas contractor, and the ROK industry alike) to seek alternative offset projects that may deliver an equal or greater benefit to Korea rather than resorting to punitive measures. However, because of Article 23, DAPA Offset Division (OD) has no choice but to impose the prescribed penalties.

AMCHAM strongly believes that a viable alternative or supplementary provision in the Offset Guidelines can be introduced, which reduces undue risk for OEMs while delivering greater value to Korea's beneficiaries in the event of non-performance. We respectfully request DAPA to review the inclusion of the following provision as Article 23.5:

- *Notwithstanding the preceding Article 23.3 and 23.4, if the Foreign Contractor submits a replacement offset project which is evaluated by KRIT to be of higher value than the amount of unfulfilled offset value caused by non-performance solely attributable to the Foreign Contractor, DAPA may negotiate and accept the replacement offset project without requiring confiscation from the Foreign Contractor.*

Article 23.3. and 23.4 of DAPA Offset Guidelines, October 2024

(3) " If the Foreign Contractor fails to fulfill its Offset obligation within the implementation period of the Offset MOA, the Director General shall confiscate 10% of the unfulfilled portion of said obligation from Offset performance bond as a penalty for contract violation.

(4) Even in case of above paragraph (3), the Foreign Contractor shall be obligated to continue to implement its unfulfilled obligation for 1 year upon the expiry of the implementation period. If the Foreign Contractor fails to complete its unfulfilled obligation, the Director General shall additionally confiscate 50% of the unfulfilled portion of the said obligation and extinguish the remaining unfulfilled value.

- **Issue**
  Onerous and excessive penalty terms in Offset Guidelines

- **Relevant Regulations**
  October 2024 DAPA Offset Guidelines, Offset Memorandum of Agreement, Technical Assistance Agreement, Offset Guidelines

- **Relevant Agencies**
  Defense Acquisition Program Administration (DAPA)

- **Recommendation**
  An additional provision needs to be included in the Offset Guidelines so that DAPA would have the option to consider replacement projects proposed by the contractor that have a greater offset value than the shortfall.

AGRICULTURE, FOOD & BEVERAGE

- Overview
- Agricultural Biotechnology UNRESOLVED
- Negative Perception of Non-Sugar Sweeteners NEW
- On-site Inspections of the OEM Manufacturers UNRESOLVED
- Packaging Materials and Methods UNRESOLVED

AGRICULTURE, FOOD & BEVERAGE

OVERVIEW

Agricultural trade is a prime example of how expanded U.S.-Korea economic and commercial ties have benefited both countries. While Korea imposes high tariffs, averaging 57%, on agricultural goods from non-FTA partners, the majority of U.S. agricultural products are exempt from import duties under the KORUS FTA. U.S. agricultural exports to Korea have increased by over 30% since the KORUS FTA entered into force in 2012. In 2024, exports of U.S. agricultural and related products to South Korea amounted to over $8 billion, making the country the fifth-largest single-country export market by value for the U.S.

According to the Ministry of Agriculture, Food and Rural Affairs (MAFRA), agricultural exports to the U.S. reached a record high in 2024, totaling $15.93 billion, marking a 21.2% increase from the previous year. This surge has been fueled by increased demand for U.S. agricultural products, including instant noodles, which have experienced explosive growth fueled by the global popularity of K-Wave content and targeted marketing strategies. Additionally, the U.S. has become the leading export market for Korean frozen rice rolls, with growth rates exceeding 20%. With new product entering major U.S. retail stores this year, continued growth is expected.

Although the KORUS FTA amendment negotiations did not address agricultural trade, U.S. agricultural exports are expected to benefit from improvements made to customs and origin verification procedures that were agreed upon as part of the amendment package. The Korea Rural Economic Institute (KREI) has recently suggested that increased imports of U.S. food products could become a key part of efforts to improve the trade balance. Additionally, there is growing support within Korea for increasing the purchase of U.S. agricultural products to align with U.S. requests.

AMCHAM hopes that the U.S. and Korean governments will continue to work together to promote mutually beneficial trade in agricultural goods, driving further growth and sustainability in the sector.

INDUSTRY ISSUES

Agricultural Biotechnology

Agricultural biotechnology is essential for increasing crop yields, contributing to health and environmental sustainability, as well as conserving energy, soil, and water resources. However, certain Korean laws and regulations, especially the Act on Transboundary Movements of Living Modified Organisms and Other Related Matters ("the LMO Act"), continue to create significant barriers for U.S. agricultural biotechnology exports.

The Ministry of Food and Drug Safety (MFDS) and the Rural Development Administration (RDA) under the Ministry of Agriculture, Food and Rural Affairs (MAFRA) are primarily responsible for ensuring the safety of biotech crops imported for food and feed use. However, under the LMO Act, three additional agencies—the Korea Disease Control and Prevention Agency (KDCPA) under the Ministry of Health and Welfare (MOHW), the National Institute of Fisheries Science (NIFS) under the Ministry of Oceans and Fisheries (MOF), and the National Institute of Ecology (NIE) under the Ministry of Environment (ME)—are also mandated to be part of the consultation process. This results in as many as five agencies conducting safety reviews for each new biotech crop.

The Risk Review Consultations (RRC) conducted by these three additional agencies have created unnecessary complications, as each agency imposes specific data requirements that cannot be justified based on risk assessment principles. These agency-specific data requirements add no value to the assessment but instead create issues of non-transparency and unpredictability in Korea's biotech crop safety assessment process. As the LMO Act mandates participation from all five agencies, it limits the potential for streamlining the system without legislative changes.

Since 2008, major grain-exporting countries and their value chain stakeholders have consistently requested improvements to these regulations by amending the LMO Act to streamline the consultation process with the three additional agencies in the RRC. The U.S. government has also held multiple discussions with the Ministry of Trade, Industry and Energy (MOTIE) and other relevant agencies regarding this critical issue. However, there have been no meaningful improvements or substantial progress thus far. Instead, the issue has entrenched itself as a significant non-tariff barrier in U.S.-Korea trade, stifling the growth and innovation potential of agricultural biotechnology.

- **Issue**
  The excessively complicated process for risk review on agricultural

biotech import approval creating redundancy and lack of predictability and transparency

- **Relevant Regulations**
  The Act on Transboundary Movements of Living Modified Organisms and Other Related Matters (LMO Act)

- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE), Ministry of Food and Drug Safety (MFDS), Ministry of Agriculture and Rural Affairs (MAFRA), Ministry of Health and Welfare (MOHW), Ministry of Fisheries (MOF), Ministry of Environment (ME)

- **Relevant KORUS Provisions**
  Chapter 8 (Sanitary and Phytosanitary Measures) Article 3 (Committee on Sanitary and Phytosanitary Matters), Subparagraph 3(a)

- **Recommendation**
  Korea should streamline the burdensome approval process for the safety review of genetically modified crops by eliminating redundant and unnecessary procedures while increasing transparency and predictability. To prevent non-tariff barriers in Korea's biotech grain trade, which amounts to $2.5 billion a year, MOTIE, the competent national authority for the LMO Act, should take responsibility and lead the initiative. It is also important for the Korean government to clarify its position on the proper regulation of agricultural products increasingly developed through innovative breeding techniques such as gene editing (e.g., CRISPR). Such a policy should be firmly rooted in scientific principles, globally harmonized, and aligned with the terms stipulated in the KORUS FTA, ensuring that its implementation promotes both innovation and trade.

Negative Perception of Non-Sugar Sweeteners

In recent years, the Ministry of Food and Drug Safety (MFDS) has shown increasing interest in regulating non-sugar sweeteners (NSS), particularly after the International Agency for Research on Cancer (IARC)'s classiciation of aspartame as "possibly carcinogenic." This classification stands in contrast to decades of consistent safety assessments by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which is responsible for evaluating food additive safety, including NSS. Most recently, new labeling requirements have been introduced for products containing NSS, necessitating package redesigns and incurring associated costs. More broadly, these requirements risk reinforcing negative perception of NSS, despite their established safety profile.

NSS plays a valuable role in providing consumers with low-sugar alternatives, supporting healthier dietary choices. Regulations should allow for the continued use of these food technologies without creating unnecessary stigma, ensuring consumers can make informed choices based on balanced, science-driven policies.

- **Issue**
  Regulatory measures that disproportionately target products deemed safe and effective by global food safety organizations, such as JECFA, risking creating sigma and market distortions.

- **Relevant Regulations**
  Food Labeling Regulations

- **Relevant Agencies**
  Ministry of Food and Drug Safety (MFDS)

- **Recommendation**
  AMCHAM urges the Korean government to reconsider regulations on NSS to ensure a level playing field and remove the stigma associated with NSS created by said regulations.

On-site Inspections of the OEM Manufacturers

Under the Special Act on Imported Food Safety Control, the Ministry of Food and Drug Safety (MFDS) requires that any business entity importing and selling food products, including those involved in original equipment manufacturing (OEM) for food processing or production, must undergo on-site inspections by an imported food sanitation audit institution. This inspection must be conducted at the manufacturing or processing facility in the exporting country. According to Article 10 of the Special Act, the MFDS may designate an institution to carry out these professional on-site inspections. Notably, unless a business entity is registered as a "good importer" under Article 7 of the Special Act, it must undergo these inspections every two years, regardless past positive audit results. The business entity is responsible for covering all inspection-related expenses, including travel expenses, interpretation, and other associated costs. This imposes a significant financial and administrative burden for U.S. companies importing OEM food products and health functional foods to Korea, increasing import costs and complicating the regulatory process.

- **Issue**
  Burdensome requirements mandating OEM manufacturers to have an on-site inspection every two years
- **Relevant Regulations**
  Special Act on Imported Food Safety Control
- **Relevant Agencies**
  Ministry of Food and Drug Safety (MFDS)
- **Recommendation**
  We urge the Korean government to ease the mandatory on-site inspection requirements.

Packaging Materials and Methods

Currently, Korea aims to save resources and protect the environment by controlling excessive packaging and banning the re-packaging of commodities. Article 9 of the Act on the Promotion of Saving, Recycling, and Resources states that manufacturers, importers, or sellers must comply with the standards for packaging methods, including the rate of packaging space and layers. According to the Standards of Product Packaging Materials and Packaging Methods, the detailed standards for food and beverage products are as follows:

Products	**Standards**	
	Rate of packaging space	Number of package layers
Processed food	15% or less	2 or fewer
Beverages	10% or less	2 or fewer
Alcohol	10% or less	2 or fewer
Confectioneries	20% or less (For decoration cake: 35% or less)	2 or fewer
Health functional food	15% or less	2 or fewer

However, due to the varying sizes and heights of products, it is difficult to apply a uniform method to all packaging. U.S. companies have raised concerns about the lack of clarity regarding the calculation method for packaging space ratios used by Korean government authorities. Additionally, partial amendments to the Recycling Act proposed in 2020 mandate pre-inspections of packaging materials to ensure compliance with specified packaging requirements. Such regulations place an onerous financial burden on industry stakeholders and could delay product releases, weakening companies' competitiveness in the market.

It is worth noting that ongoing negotiations for the Global Plastics Treaty - the last round of which took place in Busan last year - may influence Korea's packaging regulations. The Business Coalition for the Treaty advocates for globally harmonized standards to ensure all plastics are safe to use, reuse, and recycle. They also emphasize that mandatory design-for-recycling requirements should be paired with targets for scaling systems and infrastructure to extend plastics' lifecycle and reduce

environmental leakage. These views could help inform a review of Korea's packaging regulations.

The Korean government has strongly supported a legally binding instrument on plastic pollution. During the Busan session, it emphasized the need for global cooperation to establish an ambitious treaty that covers the full lifecycle of plastics. Korea highlighted its experience with Extended Producer Responsibility (EPR) and the new Act on Promotion of Transition to Circular Economy as effective models for resource circulation. The Business Coalition advocates for EPR policies that require industry players to fund the collection and treatment of packaging and short-lived products, considering Korea's experience a valuable example for other countries in the treaty negotiations.

- **Issue**
  Excessive regulations on packaging materials and methods

- **Relevant Agencies**
  Ministry of Environment (ME)

- **Relevant Regulations**
  Act on the Promotion of Saving and Recycling of Resources

- **Recommendation**
  AMCHAM urges the Korean government to reconsider regulations on packaging methods and materials and align them with global efforts, particularly those being advanced through the Global Plastics Treaty negotiations. Additionally, we recommend adopting internationally recognized industry standards, such as the Consumer Goods Forum Global Design Rules, in line with the recommendations of the Business Coalition for a Global Plastics Treaty, to ensure consistency and facilitate compliance during UN negotiations.

ALCOHOLIC BEVERAGE

- Overview
- Proposed Plan to Revise Health Warnings on Alcoholic Beverages[NEW]

ALCOHOLIC BEVERAGE

OVERVIEW

The South Korean alcohol market continues to evolve, driven by shifting consumer preferences towards premium, low-alcohol, and non-alcoholic beverages. As of 2024, the market size for spirits reached approximately $6.67 billion. The rise of health-conscious trends, particularly among younger generations, has fueled an increasing demand for lower-calorie and non-alcoholic drinks. This global trend has continued to expand, driven by the growing acceptance of non-alcoholic drinks among younger generations, particularly Gen Z. This generation is increasingly drawn to health-conscious choices, including low and non-alcoholic options, a trend that has influenced global markets, including the United States. Social media platforms play a key role in promoting these products, enhancing brand awareness and attracting new consumer bases.

In South Korea, this trend is reflected in the growing popularity of lower-alcohol soju and flavored spirits, which cater to the health-conscious market. Soju, traditionally a high-alcohol spirit, has secured a new position through the introduction of low-alcohol and lower-alcohol variants. This innovative shift in product offerings is resonating with consumers both domestically and in key export markets like the United States.

Whisky, especially premium brands and highball cocktails, is at the forefront of this change, contributing to South Korea's position as the world’s fastest-growing whisky market. Notably, whisky imports reached a record 30,586 tons in 2023, marking a 13.1% increase from the previous year. Whisky has also captured a significant market share among younger consumers who favor highball cocktails and premium single malts. Gin and other craft spirits are gaining traction, driven by an expanding cocktail culture and curiosity about Western spirits. As global trends shift towards healthier drinking habits, South Korea’s alcohol industry stands at a crossroads, with opportunities to innovate and meet evolving consumer preferences.

In terms of trade, South Korea’s alcohol imports in 2023 totaled $1.13 billion, with the United States ranking third among the top five import markets, accounting for $140.6 million. Meanwhile, South Korea’s alcohol exports reached $0.33 billion, with the United States ranked second among the top export destinations for Korean liquor, totaling $63.7 million.

INDUSTRY ISSUES

Proposed Plan to Revise Health Warnings on Alcoholic Beverages

South Korea currently obligates alcoholic beverage products to include health warning labels that specify harms of 'excessive drinking.' According to the National Health Promotion Act, alcoholic beverages in South Korea must contain one of the three health warning label options that link excessive consumption of alcohol to certain types of diseases, including cancer.

"Excessive Drinking Health Warnings for Alcoholic Beverage Containers"
(Option 1) Alcohol is a carcinogen, and excessive drinking of alcohol causes liver cancer and stomach cancer. Drinking alcohol during pregnancy increases the risk of birth defects.
(Option 2) Excessive drinking of alcohol causes cancer. Underage drinking impedes growth and brain development, and drinking during pregnancy increases the risk of birth defects of miscarriage.
(Option 3) Excessive drinking causes stroke, memory impairment or dementia. Drinking alcohol during pregnancy increases the risk of birth defects.

The current health warnings already highlight the association between excessive consumption of alcohol and certain cancers, identified well over a century ago. However, the proposed change by the government attempts to denigrate any and all alcohol usage as harmful, by changing the "excessive drinking warning labels" into "drinking warning labels" as the first step.

Such proposed change implies that alcohol is harmful to health not only in excessive amounts but also in any amount. These claims lack sufficient scientific evidence, and contradict the NASEM[7] report, which concluded that there can be health benefits, as well as risks, for some consumers who drink in moderation. The NASEM report in 2024 re-affirmed the existence of a "J-shaped" relationship between drinking alcohol and all-cause mortality, meaning that across a population, light to moderate drinkers

[7] NASEM is the US National Academies of Science, Engineering & Medicine which was commissioned and funded by the US Congress to provide scientific expert advice for the US Dietary Guidelines review process.

will on average live longer than heavy drinkers and also than those who choose not to drink at all.

In this regard, maintaining the already-informative warnings on alcoholic beverages in South Korea will guide the consumers with more accurate information than the proposed changes.

- **Issue**
  Proposed plan to change “excessive drinking” health warnings to “drinking” health warnings on alcoholic beverages

- **Relevant Regulations**
  National Health Promotion Act (NHPA)

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW)

- **Recommendation**
  AMCHAM urges the Korean government to maintain the current health warning labels that already inform clearly the harms of excessive drinking to health.

- Overview
- Auto GHG/CAFE rules for 2026-2030 UNRESOLVED
- Discriminatory EV Subsidy Policy Against Non-Target Companies Under the Low-Emission Vehicle Supply Mandate (LEVSM) NEW
- Duplication of Penalty Systems: LEV/ZEV Mandate and GHG Regulations NEW
- End-of-Life Vehicle & Extended Producer Responsibility UNRESOLVED
- NACS Charging Standard Adoption NEW
- Overlapping Regulations on Electric Vehicles UNRESOLVED
- Recognition of U.S. Safety Standard (FMVSS) in Korea UNRESOLVED
- Sale of Pre-certified Vehicles UNRESOLVED
- Type Approval Requirements for EVSE NEW
- Warranty/Recall Requirements UNRESOLVED

AUTOMOBILES

OVERVIEW

The revised KORUS FTA contains a number of outcomes with positive implications for the U.S. automotive industry. These improvements reflect a willingness by the Korean government to improve market access for U.S. automobile exports in response to concerns voiced by the U.S. government and business community. Improved market access under the amended KORUS FTA has contributed to expanded exports of U.S. automobiles to Korea, while the extension of the U.S. truck tariffs by 2041 will provide significant protection for the U.S. industry and potentially encourage further investment by Korean automakers in the U.S.

Against this backdrop, U.S. automakers have seen significant benefits under the KORUS FTA in large part due to a reduction in tariff rates. Korea's tariff rate on U.S. automobile imports fell from 8% in 2011 to 0% in 2016. In comparison, the U.S. tariff rate on Korean automobiles fell from 2.5% in 2011 to 0% in 2016. Korean companies have also benefited significantly from the KORUS FTA, particularly through increased access to the U.S. market and the elimination of tariff barriers, facilitating their exports to the United States. In 2024, South Korea's automotive exports to the U.S. continued to grow, reaching a total value of $36.6 billion. From January to December 2024, South Korea shipped a total of 1,535,616 vehicles (passenger vehicles and light trucks) to the U.S., marking a 23.55% increase from the previous year.

While technical measures imposed in the name of environmental or safety reasons continue to create an uneven playing field for U.S. automobiles in Korea, AMCHAM anticipates growth in U.S. automobile exports as these non-tariff barriers are addressed. AMCHAM urges both U.S. and Korean governments to cooperate with the industry to remove remaining barriers and refrain from imposing new barriers to the bilateral automotive trade.

INDUSTRY ISSUES

Auto GHG/CAFE rules for 2026-2030

As part of the KORUS FTA amendment, Korea committed to considering U.S. regulations when setting future fuel economy targets and to adopting more flexible targets for small manufacturers. However, in early 2021, the Korean government announced a 40% reduction in national emissions by 2030 (NDC, Nationally Determined Contribution) from the 2018 baseline to strengthen its climate change commitments. Since the current Corporate Average Fuel Economy (CAFE) targets for 2026~2030 are set based on the previous NDC, the government decided to revise CAFE. Leveraging the mid-term review scheduled for 2025, as stipulated in the existing regulations, the government aims to introduce stricter CAFE targets for 2026-2030. The Ministry of Environment (ME) began working with academic institutions in 2022 to conduct commissioned research, which culminated in a stakeholder meeting in November 2023 to discuss the findings. The study recommended more stringent targets, with improvements ranging from 18% to 40% compared to current benchmarks, such as the 2030 passenger car target of 70g/km. ME initially planned to draft the new targets by 2024, hold negotiations with stakeholders, and finalize the CAFE targets by 2025. However, the negotiation process has been delayed until 2025, raising concerns that it will be challenging to finalize the detailed implementation plans on time.

- **Issue**
  Korea's stringent greenhouse gas emissions standards
- **Relevant Regulations**
  Regulations for Motor Vehicle Average Fuel Economy Standards, Greenhouse Gases Emission Standards, and Their Application and Management
- **Relevant Agencies**
  Ministry of Environment (ME)
- **Relevant KORUS Provisions**
  September 2018 KORUS Amendment and Modification Texts: Agreed Minutes
- **Recommendation**
  Korea should adopt transparent procedures and maintain open communication with the industry when developing new GHG/CAFE regulations for 2026-2030. It is also crucial to set reasonable targets,

considering factors such as automakers' current compliance status, shifts in domestic EV demand, and adjustments to U.S. CAFE standards.

Discriminatory EV Subsidy Policy Against Non-Target Companies Under the Low-Emission Vehicle Supply Mandate (LEVSM)

Every year, the Korean government implements an EV subsidy program to reach a cumulative target of 4.2 million EVs by 2030. However, as of the end of 2024, only around 700,000 EVs are on Korean roads. Under the subsidy program, companies subject to the LEVSM receive an additional subsidy of up to 1.4 million KRW per EV. However, eligibility is restricted to companies that sold more than 4,500 vehicles in 2009. Given that mass-produced EVs were first introduced in Korea in 2010, and the EV market only began to expand significantly in the mid-2010s, this policy unfairly disadvantages new entrants in the Korean EV market.

- **Issue**
  The LEVSM eligibility criteria should be revised to eliminate barriers for new vehicle manufactures that did not sell more than 4,500 vehicles in 2009. This adjustment will help the Korean government more effectively promote EV adoption and advance sustainability goals.

- **Relevant Regulations**
  Clean Air Conservation Act

- **Relevant Agencies**
  Ministry of Environment (ME)

- **Recommendation**
  AMCHAM recommends revising the eligibility criteria for the LEVSM to better support the expansion of EV adoption and the achievement of carbon neutrality in Korea. Instead of basing eligibility on total vehicle sales in 2009 – a period before EVs were introduced in Korea – the criteria should be updated to reflect more recent EV sales data, such as the past three years. This revision would encourage greater participation from new entrants in the EV market, aligning with Korea's goals for increased EV adoption and long-term sustainability.

Duplication of Penalty Systems: LEV/ZEV Mandate and GHG Regulations

With the revision and promulgation of the Clean Air Conservation Act in 2021, Korea introduced the Low and Zero-Emission Vehicle (LEV/ZEV) Mandate alongside its existing Greenhouse Gas (GHG) regulation system, making it the only country to enforce both policies simultaneously. Currently OEMs are complying with GHG regulations to meet the government's eco-friendly vehicle supply targets.

However, the LEV/ZEV Mandate and GHG regulations have separate penalty systems, meaning that companies facing unavoidable circumstances, such as a pandemic or other business challenges, may incur overlapping penalties under both the CAFE (Corporate Average Fuel Economy) standards and the LEV/ZEV Mandate. Furthermore, the selective adoption of the highest-level regulations from various countries, without due consideration of global trends or the unique industrial and market characteristics of Korea, has resulted in an exceptionally burdensome environmental regulatory framework.

This creates one of the highest environmental compliance burdens globally, posing significant barriers to entry and growth for foreign companies while introducing uncertainty due to the complex and unique regulatory landscape. In contrast, other countries tailor their regulations to better align with their own industrial and market conditions.

Regulation	US	JPN	EU	KOR
Exhaust Gas Emission	O	O	O	O
CAFE/GHG	O	O	O	O
LEV/ZEV Mandate	△ (in some states such as California)			O

- **Issue**
  The separate penalty system for the LEV/ZEV mandate duplicates the existing greenhouse gas regulations

- **Relevant Regulations**
  Clean Air Conservation Act, Greenhouse Gases Emission Standards, Low and Zero-Emission Vehicle Mandate

- **Relevant Agencies**
  Ministry of Environment (ME)

- **Recommendation**

  AMCHAM recommends that the Korean government reconsider the LEV/ZEV Supply Target Policy, either by abolishing it or revising the associated penalty system to eliminate redundant regulatory burdens.

End-of-Life Vehicle & Extended Producer Responsibility

Korea implements restrictions on hazardous materials in end-of-life vehicles (ELV). As the U.S. does not have such restrictions on hazardous materials, it is difficult for U.S. vehicles to comply with ELV requirements, and this will restrict vehicle exports.

- **Issue**
  Regulations on hazardous materials in end-of-life vehicles and extended producer responsibility of vehicle recycling that are unfairly burdensome to U.S. automakers
- **Relevant Regulations**
  Act on the Promotion of Saving and Recycling of Resources
- **Relevant Agencies**
  Ministry of Environment (ME)
- **Relevant KORUS Provisions**
  Chapter 9 (Technical Barriers to Trade) Article 7 (Automotive Standards and Technical Regulations)
- **Recommendation**
  AMCHAM urges the Korean Government to grant an exemption to U.S. vehicles from the hazardous material requirement and to reconsider the Extended Producer Responsibility (EPR) extension.

NACS Charging Standard Adoption

Korea remains the only country that continues to recommend CCS Combo1 (CCS1) as the preferred charging standard, while North America is transitioning to the North America Charging Standard (NACS). The majority of global automakers have announced their shift to NACS, contributing to market standardization and enhancing customer experiences to accelerate EV adoption. Moreover, Korean regulations require parking lots above a certain size to install Electric Vehicle Supply Equipment (EVSE) for either 2% or 5% of total parking spaces, with penalties of up to 30 million KRW for non-compliance. However, installing NACS-compatible EVSE does not count toward this requirement, meaning property owners must install CCS1, CCS2, or Type 1 chargers separately to meet regulatory compliance.

- **Issue**
  Korea is the only country globally using CCS1. Automakers selling EVs in Korea face the inefficiency of having to produce CCS1-standard EVs exclusively for the Korean market. Additionally, regulations only recognize CCS1, CCS2 and Type1 chargers for mandatory EVSE installations in parking spaces, further complicating the compliance process.

- **Relevant Regulations**
  Act on the Promotion of Development and Distribution of Environment-Friendly Automobiles

- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE)

- **Recommendation**
  AMCHAM recommends that the Act on the Promotion of Development and Distribution of Environment-Friendly Automobiles be revised to include NACS as an accepted charging standard, allowing it to count toward the obligation to install a specified amount of EVSEs in parking lots.

Overlapping Regulations on Electric Vehicles

As the spread of electric vehicles expands in the Korean market, various new regulations for electric vehicles are being established by relevant ministries. Recently, the Ministry of Land, Infrastructure and Transport has planned to implement follow-up management of electric vehicles' driving distance on a single charge, energy consumption efficiency and a preliminary certification system for electric vehicle battery safety through the revision/promulgation of the Automobile Management Act. The Ministry of Trade, Industry and Energy plans to implement an electric vehicle energy consumption efficiency rating system from the beginning of April this year. The Ministry of Environment is also seeking to strengthen verification of electric vehicle certification (mileage per charge, etc.) and subsidy evaluation by revising related laws. These regulations carry strong penalties for violation (imprisonment/fines, penalty surcharge, and consumer compensation, etc.), acting as a major obstacle to the industry's efforts to popularize electric vehicles.

- **Issue**
  Regulations related to electric vehicles and batteries are diversifying and strengthening, and these regulations are being indiscriminately established by each ministry without prior coordination, which is acting as a major obstacle to the industry's spread of electric vehicles.

- **Relevant Regulations**
  Clean Air Conservation Act, Motor Vehicle Management Act, Act on Promotion of Development and Distribution of Environmentally Friendly Vehicles

- **Relevant Agencies**
  Ministry of Environment (ME), Ministry of Land, Infrastructure and Transport (MOLIT), Ministry of Trade, Industry and Energy (MOTIE)

- **Relevant KORUS Provisions**
  Chapter 9 (Technical Barriers to Trade) Article 7 (Automotive Standards and Technical Regulations)

- **Recommendation**
  In relation to the establishment of new electric vehicle and battery regulations by ministries, it is necessary to minimize the burden on the industry’s efforts to popularize electric vehicles by only promoting core policies after sufficient consultation and review at

the government-wide level to ensure that there are no duplicate regulations.

Recognition of U.S. Safety Standard (FMVSS) in Korea

Inconsistencies with global standards increase costs/complexity and may result in product restrictions without any meaningful benefits to the customer. Thus, the automotive industry agrees on the ideal standard of “test once, certify once and sell anywhere.”

Under KORUS-FTA, the U.S.-made vehicles certified under the Federal Motor Vehicle Safety Standards (FMVSS) can be imported into Korea without meeting Korean Motor Vehicle Safety Standards (KMVSS), up to a limit of 50,000 units per year. However, same vehicles certified with FMVSS but manufactured outside the U.S. cannot be sold in Korea. They must meet KMVSS requirements, forcing U.S. OEMs to bear additional engineering costs despite limited sales volume.

This not only exacerbates the trade imbalance between the U.S. and Korea in the automotive sector, but also prevents global brands from competing fairly with dominant local players. In particular, the high homologation costs hinder U.S. automakers from expanding their business and diversifying their product line-ups in the Korean market.

- **Issue**
  Vehicles certified under FMVSS but manufactured outside the U.S. cannot be sold in Korea. To be imported, they must comply with KMVSS, resulting in additional engineering costs for U.S. OEMs despite limited sales volume.

- **Relevant Regulations**
  Motor Vehicles Management Act

- **Relevant Agencies**
  Ministry of Land, Infrastructure and Transport (MOLIT)

- **Relevant KORUS Provisions**
  Section B: Safety Standards, Protocol between the government of the Republic of Korea and the government of the United States of America amending the February 10, 2011 exchange of letters

- **Recommendation**
  AMCHAM recommends that the Korean government fully recognize FMVSS-certified vehicles, regardless of their production origin.

Sale of Pre-certified Vehicles

The Korean government requires all new vehicle models imported into Korea to obtain their emissions certification prior to clearing customs to be eligible for sale. However, the government does permit automakers to clear customs without an emission certification if the vehicle is used for marketing and development-related activities. Korea's strict interpretation does not allow automakers to obtain the necessary emissions certifications for these specific vehicles. As a result, once these specific vehicles have completed their marketing and development purposes, they must be shipped back to their country of origin or be scrapped because they are not eligible for sale in Korea. Likewise, in the case of electric vehicles exempt from certification that have undergone a subsidy evaluation and fuel efficiency test (including driving distance on a single charge) by a domestically certified agency, they are also not eligible for sale in Korea.

- **Issue**
  Vehicles (including electric vehicles) imported into Korea for marketing and development-related purposes that are not eligible for sale due to the strict interpretation of the regulation

- **Relevant Regulations**
  Clean Air Conservation Act, Motor Vehicle Management Act

- **Relevant Agencies**
  Ministry of Environment (ME), Ministry of Land, Infrastructure and Transport (MOLIT)

- **Relevant KORUS Provisions**
  Chapter 9 (Technical Barriers to Trade) Article 7 (Automotive Standards and Technical Regulations)

- **Recommendation**
  We encourage the Korean government to permit vehicles (including electric vehicles) that are imported into Korea for specific marketing and development-related activities to be able to obtain the necessary certification needed for sale once the vehicle has completed its intended use.

Type Approval Requirements for EVSE

Korea's Metering Regulation uniquely requires Electric Vehicle Supply Equipment (EVSE) manufacturers to install a hard-wired display to show energy values for commercial operation. While global industrial standards focus on ensuring meter accuracy to maintain fairness in commercial transactions, Korea remains the only country enforcing this hard-wired display requirement. This regulation imposes unnecessary design constraints, forcing manufacturers to develop Korea-specific models that deviate from widely accepted global practices. Additionally, Korea mandates a 100% sampling test for metering accuracy verification prior to the installation of each EVSE unit, whereas most other regions rely on certification processes and statistical, partial sampling methods.

- **Issue**
  Regulations mandate unreasonable hard-wired display requirement and 100% sampling for meter accuracy testing.

- **Relevant Regulations**
  Measuring Act

- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE), Korea Agency for Technology and Standards (KATS)

- **Recommendation**
  AMCHAM recommends that Korea align its regulation with global standards and industry practices. Remote displays are widespread already, and their accuracy in showing energy values has been proven secured. Moreover, if an EVSE model has been tested and certified, reducing the sample ratio for metering accuracy check would accelerate the process of EVSE deployment, and consequently, EV adoption.

Warranty/Recall Requirements

Current recall regulations obligate automakers and importers to recall defective vehicles indefinitely. By comparison, Korea-made cars that are exported to the U.S. face only ten years of recall regulations. Korea requires notification of all voluntary recalls and all recalls ordered by any other foreign country, even if the recall covers vehicles not sold by the automaker in Korea. Moreover, Korea requires the automaker to provide this notice within 14 days of the initial recall announcement.

The indefinite recall period imposes unreasonable financial costs on auto companies and discourages voluntary recall efforts. Requiring an automaker to notify a recall involving vehicles not sold by the automaker in Korea is unreasonable and unduly burdensome. It also may create confusion in the Korean market, undermining consumer confidence in the automaker. (For example, a car sold in India has different homologation requirements from those for a car sold in Korea. A recall of the Indian version of the vehicle would not necessarily affect the Korean version.)

In 2021, the Korean government revised a related recall regulation under the Motor Vehicle Control Act (MVCA). As a result, the recall definition has been revised in a manner similar to the U.S. definition, but the penalty has increased from 1% of the revenue to 3%. In the case of voluntary recalls, the financial penalty could be reduced by 50% of the original amount. However, the U.S. does not impose penalties for voluntary recalls.

Furthermore, the reporting deadline of 14 days is unreasonably short and inconsistent with the deadline in other countries.

- **Issue**
  Korea's unreasonably stringent warranty/recall requirements for global automakers.

- **Relevant Regulations**
  Motor Vehicle Management Act

- **Relevant Agencies**
  Ministry of Land, Infrastructure and Transport (MOLIT)

- **Relevant KORUS Provisions**
  Chapter 9 (Technical Barriers to Trade) Article 7 (Automotive Standards and Technical Regulations)

- **Recommendation**
  Automakers should be required to notify recalls only for vehicles

or parts that are sold by the automaker in Korea. Moreover, the deadline for giving notice should conform to international norms and not be less than 30 days.

CHEMICALS

- Overview
- Colorless Coated Glass Bottle Recyclability Assessment NEW
- Detailed Criteria to Distinguish Chemical Substances from Articles UNRESOLVED
- Difficulties for Confidential Business Information Approvals of Trade Secret Ingredients in R&D Samples NEW
- Disclosure of Confidential Business Information UNRESOLVED
- Discrepancies in the List of Existing Chemicals between the K-REACH and the OSHA UNRESOLVED
- Easing Hazards and Risk Data Submission Criteria for Fragrances in Biocidal Products NEW
- Easing Pre-notification Requirement for New Technology Biocide Introduction in Korea NEW
- Expanded Scope of Consumer Chemical Product Regulations UNRESOLVED
- Redundant Regulations under the Chemical Control Act (CCA) UNRESOLVED
- Test Methods for Consumer Chemical Products UNRESOLVED

CHEMICALS

OVERVIEW

The U.S. chemical exports to Korea continue to benefit from the duty-free access under the KORUS FTA, with exports to South Korea remaining strong in 2025. However, the regulatory landscape for chemical products in Korea remains complex and increasingly stringent. While tariff-related barriers are low, the non-tariff regulatory challenges have intensified, and Korea's "chemophobia" culture, fueled by high-profile incidents such as the 2011 toxic humidifier disinfectant crisis, continues to shape public perception and policy.

Examples include a series of tightened regulations on chemical products introduced by the Ministry of Environment (ME) and the Ministry of Employment and Labor (MOEL). Korea's Act on Registration and Evaluation of Chemicals (K-REACH), Chemical Substances Control Act (CCA), Consumer Chemical Products and Biocides Safety Act (K-BPR), and Occupational Safety and Health Act (OSHA) are also cases of Korean standards that are overly strict compared to regulations in the U.S. and the EU. Such regulations create an uneven playing field by imposing regulatory barriers that inhibit U.S. companies' access to the Korean market.

INDUSTRY ISSUES

Colorless Coated Glass Bottle Recyclability Assessment

The Ministry of Environment (ME) initially removed colorless coated glass bottles from the ‘difficult to recycle’ category in 2021, as stated in Ministry of Environment Notice No. 2021-3. However, in 2023, ME reversed this decision, designating colorless coated glass bottles as “difficult to recycle” again, creating confusion in the industry ['6th Packaging Materials/Structure Review Committee’(2023.11.13.)]. This shift is particularly concerning given that globally, colorless coated glass bottles are considered easy to recycle. When properly sorted, the coating pigment evaporates during recycling, and the recyclability of coated glass bottles remains intact. This inconsistency conflicts with global sustainability regulations aimed at plastic reduction, potentially undermining Korea’s competitiveness in the industry.

- **Issue**
  Korea's unique approach to the recyclability of colorless coated glass bottles
- **Relevant Regulations**
  Act on the Promotion of Saving and Recycling of Resources
- **Relevant Agencies**
  Ministry of Environment (ME)
- **Recommendation**
  AMCHAM recommends that the Korean government reclassify coated glass as easily recyclable and focus on improving capabilities of glass waste, rather than lowering the recyclability rating of glass bottles.

Detailed Criteria to Distinguish Chemical Substances from Articles

K-REACH Article 11 stipulates that chemicals contained in specific solid forms, serving particular functions, and not leaking during use are exempt from registration. The industry views this provision as a key exemption criterion for “articles”. However, certain products cannot be clearly classified as either chemical substances or articles based solely on this condition. This ambiguity, coupled with a lack of alignment with global standards, poses significant challenges for companies striving to ensure compliance.

- **Issue**
  Unclear conditions for registration exemption
- **Relevant Regulation**
  Korea’s Act on Registration and Evaluation of Chemicals (K-REACH) article 11
- **Relevant Agency**
  Ministry of Environment (ME)
- **Recommendation**
  More elaborate criteria are needed to distinguish between an article and a chemical substance for registration exemption.

Difficulties for Confidential Business Information Approvals of Trade Secret Ingredients in R&D Samples

MOEL requires that any person who manufactures or imports a material controlled under the MSDS system must prepare and submit an MSDS to KOSHA prior to manufacturing or importing. Additionally, they must obtain Non-Disclosure Approval for any confidential business information regarding trade secret ingredients in MSDS Section 3. This approval allows for the use of alternative name(s) and the alternative content(s) and content descriptions instead of revealing the hazardous ingredients names and contents that are considered trade secrets.

While MSDS submission is exempted for R&D samples, the requirement for Non-Disclosure Approval for trade secret ingredients in MSDS Section 3 applies to these samples. R&D samples are usually urgent materials used in new products or technology development. The time spent waiting for Non-Disclosure Approval for trade secret ingredients can significantly delay R&D activities in Korea, hindering the timely development of new products and technologies.

- **Issue**
  Korean regulations that require the disclosure of confidential business information
- **Relevant Regulations**
  Occupational Safety and Health Act (OSHA) Article 112
- **Relevant Agencies**
  Ministry of Employment and Labor (MOEL)
- **Recommendation**
  Non-Disclosure Approval for trade secret ingredients in R&D samples should be exempted under OSHA to accelerate R&D activities in Korea.

Disclosure of Confidential Business Information

K-REACH, CCA, and OSHA all require the disclosure of chemical mixture composition to authorities, creating overlapping regulations with varying requirements and systems. This complexity places a burden on U.S. chemical exporters to Korea, who may face challenges in disclosing this information due to confidentiality concerns or incomplete data from third-party suppliers. Non-compliance can restrict U.S. exports to Korea.

Under the amended K-REACH, the Ministry of Environment (ME) provides the Only Representative (OR) method for third-party importers to comply with the registration and notification process. This is currently the only method available for registering or notifying chemical substances imported by third parties. However, the relatively small size of the Korean market compared to the global market makes it difficult for global companies to justify the cost and burden of complying with this process. Additionally, under the newly amended K-REACH, the penalty for manufacturing, importing, or selling chemicals without proper registration has been increased to up to 5% of a company's average annual sales for the three years prior to the violation, further raising the stakes for non-compliance.

- **Issue**
  Korean regulations that require the disclosure of confidential business information

- **Relevant Regulations**
  Act on Registration and Evaluation of Chemicals (K-REACH), Chemical Control Act (CCA), Occupational Safety and Health Act (OSHA)

- **Relevant Agencies**
  Ministry of Environment (ME), Ministry of Employment and Labor (MOEL)

- **Relevant KORUS Provision**
  Chapter 9 (Technical Barriers to Trade) Article 1 (Affirmation to TBT Agreement)

- **Recommendation**
  AMCHAM acknowledges the necessity of transparency to protect consumers from hazardous chemicals. However, AMCHAM recommends that companies should only be required to disclose information that is essential to safeguarding public health, while

allowing them to protect confidential business data. Additionally, AMCHAM suggests adjusting penalties for non-registration of substances to make them less punitive, ensuring they are more aligned with practical compliance efforts.

Discrepancies in the List of Existing Chemicals between the K-REACH and the OSHA

The definitions of new chemical substances differ between the K-REACH and the OSHA. Under K-REACH, substances previously designated as existing chemicals through hazardousness assessments under the former Toxic Chemicals Control Act are considered registered. However, OSHA does not recognize those substances unless separately registered under OSHA. Consequently, compliance requirements vary between the two laws when handling these substances, due to the inconsistency between the two chemical inventories. Furthermore K-REACH mandates registration of new chemicals imported or manufactured in quantities of 1 ton or more, while OSHA mandates the submission of a Hazardousness and Risk Assessment Report for substances imported or manufactured in quantities of 100 kg or more. Additionally, the exemption criteria for new chemicals differ between K-REACH and OSHA. This dual regulatory situation poses challenges for companies in managing compliance for these substances.

- **Issue**
  Inconsistent existing chemicals between K-REACH and OSHA, leading to compliance challenges in handling the substances

- **Relevant Regulations**
  Korea's Act on Registration and Evaluation of Chemicals (K-REACH), Occupational Safety and Health Act (OSHA)

- **Relevant Agencies**
  Ministry of Employment & Labor (MOEL), Ministry of Environment (ME)

- **Relevant KORUS Provision**
  Chapter 9 (Technical Barriers to Trade) Article 1 (Affirmation to TBT Agreement)

- **Recommendation**
  The hazardousness data for chemicals designated as existing chemicals under the former Toxic Chemicals Control Act is already secured by the government. Registration of existing chemicals in quantities of 1 ton or more is ongoing under the Chemical Substance Control Act until 2030, which will gradually provide additional hazardousness and risk information. Therefore, AMCHAM recommends the following:

- Amend Article 85 of the Enforcement Decree of the OSHA to include all existing chemicals under the K-REACH
- Revise Article 147 of the Enforcement Rules to align the registration criteria for new chemicals under OSHA with K-REACH by raising the threshold to 1 ton.
- Modify Article 147, 150 and 151 of the Enforcement Rules to align with Article 11 of the Enforcement Decree of K-REACH, ensuring greater regulatory consistency and simplifying compliance for companies.

Easing Hazards and Risk Data Submission Criteria for Fragrances in Biocidal Products

The 'Notice on Hazards and Risk Data Submission Criteria for Fragrances in Biocidal Products' by National Institute of Environmental Research (NIER) mandates that for products with inhalation exposure, hazard data submission is exempt if the substance is present in less than 0.1% of the product. However, for all substances of concern (SoC) and allergens present in more than 0.01% of the product, hazard data must be submitted, regardless of the exposure route. These new requirements are stricter than previous ones, making compliance difficult, especially with the approval grace period for group 1 products set for late 2025. Furthermore, the Notice lacks clarity on the recognition scope of hazard data.

- **Issue**
  Unclear conditions for registration exemption and excessive requirements compared to general consumer chemical products

- **Relevant Regulations**
  Consumer Chemical Products and Biocides Safety Control Act Notice on hazards and risk data submission criteria for fragrances in biocidal products (NIER, 2024.04.18.)

- **Relevant Agencies**
  Ministry of Environment (ME), National Institute of Chemical Safety (NCIS), National Institute of Environmental Research (NIER, previous responsible authority)

- **Recommendation**
  - Modify Submission Criteria: Hazard data should only be submitted when fragrances and allergens are present at 0.1% and 0.01%, respectively, as individual components in products, rather than the total sum.
  - Expand the Recognize Data Scope:
    - Expand the scope of acceptable data for biocidal product approval, allowing open data (e.g., URLs) from sources such as ECHA, RIFM, etc., to confirm classification labels or toxicological values, without requiring additional information such as reference purchase certificates.
    - Apply end points used in risk assessment to substances already evaluated and designated as hazardous chemicals by the ME.

Easing Pre-notification Requirement for New Technology Biocide Introduction in Korea

K-BPR regulates the approval and management of biocidal products, including those incorporating new technologies. This legislation mandates that all biocidal products obtain prior approval from the Ministry of Environment (ME) before being introduced to the market. The approval process involves a comprehensive evaluation of both the safety and efficacy of the active substances and the biocidal products themselves. Concerns have been raised regarding the pre-notification requirement, which places an excessive burden on manufacturers and importers. This requirement includes submitting information such as product delivery confirmation, contracts, cost verification, and reaction mechanisms, among other details.

- **Issue**
  Excessive pre-notification requirement for new technology biocide introduction to Korea

- **Relevant Regulations**
  Korea's Consumer Chemical Products and Biocides Safety Act (K-BPR)

- **Relevant Agencies**
  Ministry of Environment (ME), Ministry of Employment and Labor (MOEL)

- **Recommendation**
  AMCHAM recommends that the Korean government align the pre-notification requirements for new technology biocides with those that were in place when submitting notifications for existing biocidal products in 2019.

Expanded Scope of Consumer Chemical Product Regulations

K-BPR significantly broadens the scope of consumer chemical products subject to registration and/or safety confirmation. The definition of “Consumer Products” now encompasses not only household items but also industrial and professional products. Consequently, U.S. companies importing or manufacturing consumer chemical products must adhere to safety and labeling standards, incurring substantial costs and assuming significant regulatory responsibilities. These responsibilities include biennial reporting, testing at designated labs every three years, and so on. Moreover, frequent and redundant registrations are necessary even for minor formula changes, posing specific challenges for imported products. Some products that were previously not subject to these requirements may fail to pass the newly mandated tests, risking the discontinuation of their import and sale. This could affect both U.S. exporters and Korean end users, particularly if suitable alternatives that meet the new safety and labeling standards are not readily available.

- **Issue**
  Recent legislation that expands the scope of registration and/or safety confirmation, burdening U.S. companies

- **Relevant Regulations**
  Korea’s Consumer Chemical Products and Biocides Safety Act (K-BPR)

- **Relevant Agencies**
  Ministry of Environment (ME), Ministry of Employment and Labor (MOEL)

- **Relevant KORUS Provision**
  Chapter 9 (Technical Barriers to Trade) Article 1 (Affirmation to TBT Agreement)

- **Recommendation**
  Companies should not be required to register changes that have no direct relevance to human health, such as minor percentage changes, changes in non-hazardous ingredients like perfume, or inert chemical modifications in formulas. Redundant registration requirements, such as those between CCA and K-BPR, should be eliminated. Additionally, a sufficient grace period should be provided for registration of such changes to minimize challenges for businesses.

Redundant Regulations under the Chemical Control Act (CCA)

The Chemical Control Act (CCA) is designed to manage chemical substances and prevent chemical accidents. According to Article 3 (Scope of Application) of the CCA, products regulated under other laws are exempt from its control. However, household chemical products regulated by the “Chemical Control Act on Consumer Chemical Products and Biocides Safety Control” and hygiene products regulated by the “Hygiene Control Act” remain subject to CCA regulations, creating redundancy and unnecessary regulation overlap.

- **Issue**
  Redundant regulations under the Chemical Control Act (CCA)
- **Relevant Regulations**
  Chemical Control Act (CCA)
- **Relevant Agencies**
  Ministry of Environment (ME)
- **Relevant KORUS Provision**
  Chapter 9 (Technical Barriers to Trade) Article 1 (Affirmation to TBT Agreement)
- **Recommendation**
  The Korean government should eliminate duplicate regulatory requirements to streamline the regulatory process and reduce unnecessary burdens on businesses.

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Test Methods for Consumer Chemical Products

Under K-BPR, the Ministry of Environment (ME) uses its own safety testing methods for the safety and labeling standards of consumer chemical products, which differ from globally recognized standards. ME only accepts testing from certified testing agencies within Korea, primarily semi-governmental organizations, and does not recognize internationally certified agencies. This creates an additional burden for global companies, requiring them to conduct extra rounds of testing and modify products to meet ME's safety standards when importing consumer chemical products into Korea. These requirements can act as a barrier for global companies seeking to enter the Korean market.

- **Issue**
  Korea's lack of recognition of globally standardized testing methods
- **Relevant Regulations**
  Korea's Consumer Chemical Products and Biocides Safety Act (K-BPR)
- **Relevant Agencies**
  Ministry of Environment (ME)
- **Relevant KORUS Provision**
  Chapter 9 (Technical Barriers to Trade) Article 1 (Affirmation to TBT Agreement)
- **Recommendation**
  Korea should align its testing methods for safety and labeling standards for consumer chemical products with globally recognized standards. Testing results from globally certified agencies should be accepted in Korea to streamline compliance for global companies.

DIGITAL ECONOMY

- Overview
- Online Platform Regulations UNRESOLVED
- Application of the Cloud Security Assurance Program (CSAP) UNRESOLVED
- Artificial Intelligence UNRESOLVED
- Designation of a Local Representative UNRESOLVED
- Legislative Bill on Safety Management of Digital Disasters and Failures UNRESOLVED
- National Core Technologies (NCTs) NEW
- Personal Information Protection Act (PIPA) UNRESOLVED
- Telecommunications Business Act: Value-Added Service Provider Regulations NEW

DIGITAL ECONOMY

OVERVIEW

Free movement of data across borders and nondiscriminatory treatment of global technology service companies are essential to 21st-century commerce and the Fourth Industrial Revolution. Unfortunately, Korea's regulations impose highly stringent and globally unique requirements on cloud providers, internet service providers, and other digital service providers, including "online platforms", that diverge from international standards. Such regulations restrict market access opportunities for U.S. and other global service providers and serve to discriminate against them in favor of domestic providers. Additionally, these regulations isolate Korean businesses and consumers from accessing a broader array of innovative technologies and services, which could stimulate greater economic productivity and innovation within Korea.

AMCHAM supports digital trade regulations that enable and facilitate the cross-border flow of data, avoid data localization requirements, and reflect the law and spirit of key international trade agreements including the U.S.-Korea Free Trade Agreement (KORUS). Mandating that data be kept or processed within national boundaries does not make it safer from cybersecurity threats or natural disasters. U.S. industries are making significant investments in cloud data centers worldwide to provide globally integrated services and achieve data storage security. Decisions on where data is stored and how it is processed should be determined by the free market and consumer choice rather than through government mandates.

AMCHAM applauds the Korean government's intent to align Korea's regulations on digital services with global standards which would be counterproductive and impinge on the Fourth Industrial Revolution. In particular, we welcome the establishment of the Presidential Committee on Digital Platform Government with the initiative to create a data-based digital platform where the government could collaborate with the public and firms to solve social problems. However, we are concerned about legislation imposing requirements that restrict the free movement of data across borders such as mandating the localization of certain components of the cloud industry in Korea. We hope that the Korean government will work closely with international businesses and the U.S. government to address these and other concerns as a means to create a truly level playing field for domestic and multinational companies in the digital economy sector.

INDUSTRY ISSUES

Online Platform Regulations

Digital platform innovations have played an important role in driving Korea's economic growth and enhancing the consumer experience for millions. However, a growing number of legislative proposals, led by some policymakers and the KFTC, have specifically targeted digital platform businesses. These proposals have raised concerns about the imposition of disproportionately strict regulations on select digital platform companies, creating an uneven regulatory landscape. These measures could risk violating Korea's commitments under international trade agreements, including the U.S.-Korea Free Trade Agreement (KORUS).

On September 9, 2024, the KFTC unveiled a new roadmap for online platform regulation legislation, outlining plans to amend the Monopoly Regulation and Fair Trade Act (MRFTA) to establish new criteria for determining supposedly market-dominant platform operators and to define specific prohibited behaviors. This bill is similar to legislation proposed in July 2024 by Democratic Party lawmakers that would require targeted companies to prove that the identified conduct is pro-competitive in order to *remove* KFTC sanctions *after* they have been applied ex-ante.

Leading U.S. online platform companies have expressed concerns about these proposals by the KFTC and the Democratic Party given: (1) the adverse consequences for Korean consumers and small businesses, such as app developers by creating restrictive market conditions; (2) the disproportionate targeting of major U.S. digital services providers, which could accelerate market share gains for Chinese technology giants in Korea and violate Korea's international trade and national security commitments; (3) the compliance requirements that threaten digital innovation by mandating the sharing of proprietary algorithms and trade secrets with third parties, and prohibiting self-preferencing for select market players; and, (4) that the bills are unnecessary as there is existing enforcement authority under current law.

While some U.S. digital service providers view the proposed regulations as a means to promote competition, interoperability, and consumer choice, most leading U.S. digital service providers and technology industry associations strongly oppose the proposals and point to growing empirical evidence that such regulation negatively impacts SME's pricing for consumers, innovation, and economic growth.

- **Issue**
  Overall, the proposed regulatory criteria and thresholds for digital platform regulation disproportionately affect certain U.S.

companies and reflect a potentially discriminatory approach that senior U.S. officials have indicated would violate Korea's international trade commitments. If implemented, this regulatory approach would disadvantage targeted U.S. companies and establish de facto non-tariff barriers for U.S. digital service providers. Such a policy could provoke substantive trade tensions between the U.S. and Korea, and risk significant disruption to vital bilateral economic relations.

- **Relevant Regulations**
  Monopoly Regulation and Fair Trade Act (MRFTA), Online Platform Monopoly Regulation Act (OPMRA), Fair Online Platform Intermediary Transactions Act and related proposals in the National Assembly

- **Relevant Agencies**
  Korea Fair Trade Commission (KFTC), Ministry of Trade, Industry and Energy (MOTIE), Ministry of Science and ICT (MSIT), Korea Communications Commission (KCC)

- **Relevant KORUS Provisions**
  Chapter 12 (Cross-border trade in services) and Most Favored Nation, Chapter 16 (Competition-related matters)

- **Recommendation**
  Given the potential risk of significant trade friction arising from this regulatory approach, AMCHAM urges the Korean government to discontinue the legislative discussions and, instead, engage in robust consultation with the US Government, Korean consumers, civil society, academia, and industry to ensure harmonized approaches to technology regulation between Korea and the U.S.

Application of the Cloud Security Assurance Program (CSAP)

Korea's unique data protection standards for public cloud services, enforced by the Ministry of Science and ICT (MSIT) and the National Intelligence Service (NIS), require public agencies to only use SaaS and IaaS from providers certified under the Cloud Security Assurance Program (CSAP) operated by the Korea Internet & Security Agency (KISA), which is a public entity subsidiary of MSIT.

As of April 2025, leading U.S. cloud service providers all have obtained CSAP Low-tier certification (Group C) from the KISA. AMCHAM anticipates that these certifications will enable U.S. cloud service providers to actively contribute to innovation within the public sector, and we foresee enhanced collaboration with public institutions and agencies.

Nevertheless, as highlighted in the introduction, the entire public sector market continues to be governed by strict data residency requirements under the CSAP framework across all impact level categories – High, Moderate, and Low. This data localization requirement significantly hinders the adoption of AI and various cloud-based SaaS applications, even when dealing with non-critical government data used to deliver citizen services through cloud computing.

In addition, due to the NIS's Security Verification Scheme for Public Sector IT Security Products, even the U.S. cloud service providers who obtained CSAP-Low tier certification can serve only Group C public sector customers such as local governments and K-12 institutions (including privately owned).

Considering that most cloud service providers offer sophisticated data control mechanisms, irrespective of data storage location, public institutions could concentrate on their fundamental roles and core values, such as the delivery of more innovative and efficient public services, while retaining comprehensive control over data migrated to cloud platforms.

- **Issue**
  Data residency requirements and Security Verification Scheme for Public Sector IT Security Products for public cloud hinder the wider adoption of AI and SaaS services in the public sector

- **Relevant Regulations**
  Cloud Security Assurance Program (CSAP) certification

- **Relevant Agencies**
  Ministry of Science and ICT (MSIT), National Intelligence Service (NIS)

- **Relevant KORUS Provisions**
  Chapter 12 (Cross-Border Trade in Services), Chapter 15 (Electronic Commerce) & Chapter 17 (Government Procurement)

- **Recommendation**
  AMCHAM urges the Korean government to extend logical network separation to the Moderate tier, broaden the range of non-sensitive public sector information, and revise Korea-specific requirements, including the strict data residency rule, to align with global technological standards. This would promote regulatory reform in the cloud computing sector.

Artificial Intelligence

On December 26, 2024, the Korean National Assembly passed the AI Basic Act, positioning South Korea the second country after the European Union to enact a comprehensive AI law. The Act aims to promote AI development while addressing potential risks, such as biases and safety concerns, and it will come into effect one year after its promulgation. The Act defines “High-Impact AI” and establishes a National AI Committee to oversee governance and infrastructure investments. Also on January 31, a new amendment to the Personal Information Protection Act was proposed regarding AI development. The proposed amendment is not sufficient to encourage AI development due to overly strict conditions. The proposed amendment’s strict requirements for using personal information for AI development could in fact potentially hinder the AI innovation and Korea’s AI competitiveness. The amendment allows the use of personal information for AI development only if the Personal Information Protection Committee (PIPC) approves it, and under narrow conditions such as public or social benefit. Mandatory PIPC approval is impractical and unduly burdensome. The amendment requires that any use of personal information for AI development, outside of its original collection purpose, must be approved by the PIPC. This requirement introduces a significant procedural hurdle for any AI development. Requiring PIPC approval every time personal data is used for AI development is impractical given the fast-paced nature of AI development. This will slow down AI innovation, rather than facilitate it, as the bureaucratic process becomes a significant bottleneck.

The Act may impose a greater burden on AI-related businesses, particularly those engaged in high-risk sector AI. AMCHAM is concerned that American companies exploring the Korean AI market could face high market barriers following the passage of the bill, along with various other regulatory initiatives recently announced by the Korea Communications Commission (KCC) and the PIPC, among others.

AMCHAM understands and supports the Korean government’s efforts to ensure the spread of safe and reliable AI. However, we are concerned that the government's increasing efforts to regulate the use of AI on multiple fronts may hinder opportunities for American companies in Korea, including opportunities for collaboration with Korean companies.

- **Issue**
  Ongoing debate on how to regulate the risks associated with AI without limiting AI’s potential for growth, with particular emphasis on deepfakes, disinformation, data governance and privacy, copyright, and supply chain and chips.

- **Relevant Regulations**
  AI Basic Act, Proposed amendments to the Copyright Act, Anticipated AI bill driven by the KCC, Anticipated guidelines driven by the PIPC, KCC, and the Ministry of Culture, Sports and Tourism (MCST)

- **Relevant Agencies**
  Ministry of Science and ICT (MSIT), Korea Communications Commission (KCC), Personal Information Protection Commission (PIPC), Ministry of Culture, Sports and Tourism (MCST)

- **Relevant KORUS Provisions**
  Chapter 12 (Cross-Border Trade in Services)

- **Recommendation**
  We urge the Korean government to eliminate overly burdensome requirements for AI and adopt a balanced, risk-based regulatory approach aligned with international best practices. By fostering responsible and safe development, Korea can strengthen its competitive edge in the global AI landscape.

Designation of a Local Representative

In May 2020, the National Assembly amended the Telecommunications Business Act (TBA) to require large content providers to ensure network stability and appoint local representatives. However, industry stakeholders have raised concerns that this regulation places an undue burden on content providers for network quality issue beyond their control. Meanwhile, the Korean Fair Trade Commission (KFTC) has proposed amendments to the E-Commerce Act, which would require foreign business operators to designate local representatives responsible for managing consumer complaints and responding to information requests under the Fair Trade Act.

Additionally, recent legislative activity in the National Assembly's National Policy Committee has led to amendments to the Personal Information Protection Act. The bill mandates that overseas businesses with domestic entities designate those entities as their domestic agents. This provision places an undue burden on foreign businesses with local subsidiaries, compelling them to handle user complaints under the law – regardless of their original purpose for establishing a domestic presence – thereby restricting business flexibility and potentially disadvantaging international companies operating in Korea.

AMCHAM understands the intent of the amended TBA and subsequent legislative proposals mandating the appointment of a local representative is to promote the development of domestic e-commerce and to protect the rights and benefits of Korean users of online services provided by global service providers. However, such a regulation would have the unintended consequence of making it practically impossible for certain U.S. service providers to operate in Korea, particularly smaller U.S. internet companies that cannot designate an agent in Korea.

The regulation contradicts Article 12.5 of the KORUS FTA, which stipulates that neither party may require a service supplier of the other party to establish or maintain a representative office or any form of enterprise, or to be resident, in its territory as a condition for the cross-border supply of any service. Requiring the designation of a domestic agent would yield results similar to requiring the establishment of a representative office.

- **Issue**
  Recent legislation that requires foreign service providers to designate a domestic representative

- **Relevant Regulations**
  Act on Promotion of Information and Communications Network

Utilization and Information Protection, Etc. (Network Act), Telecommunication Business Act (TBA), Personal Information Protection Act (PIPA), Amendments to the E-Commerce Act (KFTC)

- **Relevant Agencies**
  Ministry of Science and ICT (MSIT), Korea Communications Commission (KCC), Personal Information Protection Commission (PIPC), Korea Fair Trade Commission (KFTC)

- **Relevant KORUS Provisions**
  Chapter 12 (Cross-Border Trade in Services)

Legislative Bill on Safety Management of Digital Disasters and Failures

In the aftermath of the fire and service outage at the Pangyo data center in late 2022, the Legislative Bill on Safety Management of Digital Disasters and Failures was proposed in the National Assembly's Science, ICT, Broadcasting, and Communications Committee on December 31, 2024.

By consolidating dispersed safety management regulations into a single legislative framework, the Bill mandates major digital service providers to develop annual digital safety management plans, report incidents and cooperate with investigations into the causes of digital disasters or failures upon request by the Ministry of Science and ICT.

However, AMCHAM raises concerns about the Bill's uniform enforcement across all value-added telecommunications business operators, regardless of the distinct nature of their services. This blanket application is seen as both impractical and unfair, as it fails to consider the unique nature and varying impacts of different digital services. Also, the Bill could significantly increase compliance costs and complexity, and risk exposing trade secrets due to excessive documentation demands.

- **Issue**
  The bill does not distinguish between the various services provided by value-added telecommunications operators, imposing redundant regulations that significantly raise compliance costs and complexity. This approach contradicts self-regulation principles and may risk exposing trade secrets due to excessive documentation requirements.

- **Relevant Regulations**
  The proposed Legislative Bill on Safety Management of Digital Disasters and Failures

- **Relevant Agencies**
  The National Assembly’s Science, ICT, Broadcasting, and Communications Committee, the Ministry of Science and ICT (MSIT)

- **Relevant KORUS Provisions**
  Chapter 15 (Electronic Commerce) and Chapter 18 (Intellectual Property Right)

- **Recommendation**

  AMCHAM urges the National Assembly to thoroughly reevaluate the bill. Our regulatory approach supports tailored obligations that reflect the unique capabilities and characteristics of each service provider, aiming to preserve constitutional principles while minimizing undue burdens on businesses.

National Core Technologies (NCTs)

Korean companies that own NCTs (“NCT companies”) are prohibited from adopting U.S. cloud services by the Ministry of Trade, Industry and Energy (“MOTIE”). NCTs are designated by MOTIE based on the criteria and process described in the Notice on NCT designation, including sectors such as semiconductor, automotive, electronics, robotics, and aircraft. NCT companies must either report or seek approval from MOTIE before exporting NCT-related technology to other countries, as per the Act on Prevention of Divulgence and Protection of Industrial Technology (“regulation”).

In the context of cloud computing, MOTIE considers the use of U.S. Cloud Service Providers (CSPs) for NCT workload as an export, even if the CSPs operate data centers within Korea. In contrast, there are no restrictions for using domestic CSPs, meaning no prior report or approval is required when utilizing domestic cloud services for NCT workloads. The obstacles include: a) a complicated approval process, b) the lack of clear guidelines from MOTIE for adopting global cloud services, and c) uncertainty over whether MOTIE will approve the application once submitted.

In response to strong demand from NCT companies, including Korean conglomerates and others, MOTIE indicated in July 2023 that it would allow the use of U.S. cloud services for NCTs. To prepare for this, a task force was formed with U.S. CSPs to develop a set of security measures and draft a cloud use guideline for NCTs. After a series of meetings, a draft guideline was completed, but as of February 2025, it has not been published, with no clear indication provided. (It is worth noting that the MOTIE director and deputy director overseeing this matter have changed.) U.S. CSPs and Korean NCT companies have been awaiting the release and implementation of the guideline, as it would provide a clear process for adopting U.S. cloud services.

- **Issue**
  Discriminatory Standards on Approval of Export Reports on National Core Technologies

- **Relevant Regulations**
  Act on Prevention on Divulgence and Protection of Industrial Technology

- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE)

- **Relevant KORUS Provisions**
  Chapter 9 (Technical Barriers to Trade)

- **Recommendation**
  We urge the Korean government to promptly release the cloud use guideline for NCTs, a document that has been developed through extensive collaboration between all stakeholders, including U.S. CSPs, Korean NCT companies, MOTIE.

Personal Information Protection Act (PIPA)

Following the amendment of PIPA in 2023, the updated law introduces several significant implications for global companies, including: (1) the expansion of data subject rights, such as data portability and the right to refuse or request an explanation on automated decision-making, and (2) a shift towards economic sanctions, with increased administrative penalties and fines based on “total revenue” rather than “relevant revenue.”

PIPA imposes strict regulations on the overseas transfer of personal data. Data controllers must inform users of the destination, intended use by third parties, transfer method and timing, and retention period when obtaining consent for such transfers. Additionally, the amended law grants the Personal Information Protection Commission (PIPC) the authority to halt a company's cross-border data transfers in cases of significant violations or insufficient protection of transferred personal data, raising concerns among U.S. stakeholders.

The PIPC’s current stance on providing personal information to overseas third parties requires separate consent for both “cross-border transfer” and “third-party provision of personal information.” AMCHAM understands that the regulator also mandates these items to be separately outlined in the privacy policy. This requirement persists despite the only distinction being the involvement of an overseas third party in the former, thereby creating an additional burden for businesses.

PIPA also mandates that personal information controllers implement physical and technical measures to protect personal data, including the separation of internal and external networks. This stringent network separation rule is particularly demanding in Korea, requiring financial institutions and other critical sectors to physically separate their internal networks from external ones. While the goal is to prevent data breaches and enhance cybersecurity, this regulation can lead to operational inefficiencies and increased costs for businesses. The network separation requirements also pose barriers to adopting cloud services and modern technologies, as they necessitate local data storage and limit the integration of external systems. This could reduce the global competitiveness of Korean businesses and stifle innovation.

Furthermore, PIPA treats third-party processors the same as data controllers/data owners under the broad concept of a “personal information handler.” As a result, all types of data-processing delegates are subject to nearly the same legal obligations as data owners. CSPs, in particular, are included in this blanket rule despite having no access, visibility or control over customer’s data.

These regulations create an uneven playing field for U.S. data storage and processing service providers and are inconsistent with the principle of the most-favored-nation treatment under the KORUS FTA and the World Trade Organization (WTO) General Agreement on Trade in Services (GATS). Requiring global content providers to install servers in Korea and offer services effectively mandates data localization.

- **Issue**
  Strict requirements on handling the collection, usage, disclosure, and other processing of personal information

- **Relevant Regulations**
  Personal Information Protection Act (PIPA)

- **Relevant Agencies**
  Ministry of Science and ICT (MSIT), Personal Information Protection Commission (PIPC)

- **Relevant KORUS Provisions**
  Chapter 12 (Cross-Border Trade in Services)

- **Recommendation**
  We urge the Korean government to align its personal information protection regulations with global standards and explore more effective ways to facilitate cross-border transfer of data in line with international best practices.

Telecommunications Business Act: Value-Added Service Provider Regulations

Value-added service providers (VSPs) face broad prohibitions and a lack of predictability in law enforcement under the Korea's Telecommunications Business Act (TBA). In February 2025, amendments to the TBA introduced enhanced and onerous customer service requirements, targeting primarily large companies, many of which are U.S.-based, that fall under the VSP classification. These requirements include the implementation of both online and telephone automated response systems (ARS) and the processing of customer requests in real-time and in Korean during business hours. These regulatory challenges are further complicated by the National Assembly's consideration of additional obligations for VSPs, potentially classifying them as essential services.

- **Issue**
  The Telecommunications Business Act's imposition of onerous and unpredictable regulations on VSPs, resulting in regulatory uncertainty and operational burden.

- **Relevant Regulations**
  Telecommunications Business Act

- **Relevant Agencies**
  Korea Communications Commission (KCC), Ministry of Science and ICT (MSIT), National Assembly

- **Recommendation**
  AMCHAM recommends that the Korean government adopt enforcement guidelines that are both transparent and predictable to reduce regulatory uncertainty. In addition, any supplementary or enhanced obligations should be imposed only on services deemed essential, particularly given the current lack of consensus regarding the classification of VSPs as essential. If additional obligations are introduced, they must be reasonable and should not hinder the freedom of business operations.

ENERGY & ENVIRONMENT

- Overview
- Bilateral Agreements for CO_2 Transport and Storage and the Establishment of Common CO_2 Storage Standards[UNRESOLVED]
- Domestic Certification Requirements for Large- and Medium-Sized Wind Turbines[UNRESOLVED]
- Equity Investment Commitment Letter (ECL) in Electricity Business License (EBL) Evaluation Process[UNRESOLVED]
- Fast-Track Approach to Delayed Interconnection Analysis[NEW]
- Need for Strengthening the Hydrogen Sector[NEW]
- Opportunities for Private Investment in Grid Infrastructure[UNRESOLVED]
- Policy Improvement for the Distributed Power Sector[NEW]

ENERGY & ENVIRONMENT

OVERVIEW

South Korea continues to make significant strides toward its ambitious goal of achieving Zero Carbon Emissions by 2050, a commitment that is shaping its energy policies and environmental initiatives in 2025. The government's focus remains on reducing its reliance on coal, with an increased emphasis on nuclear energy, LNG, and renewable energy sources as part of a diversified energy mix during the transitional period.

In 2025, South Korea's renewable energy-related laws are expected to be more closely aligned with carbon neutrality goals, with a stronger legal foundation for technological innovation and market activation. This is anticipated to lead to the expansion of renewable energy deployment and increased economic efficiency.

The NDC (Nationally Determined Contribution) represents the greenhouse gas (GHG) reduction targets each country sets as part of its commitment under the Paris Agreement. Countries are required to update these targets every five years. South Korea submitted its 2030 target (NDC 2.0) in 2020, and the 2035 target (NDC 3.0) is due for submission in 2025.

South Korea's current 2030 target is to reduce emissions by 40% from 2018 levels, equating to 436 million tons. However, as of last year, emissions totaled 624.2 million tons, achieving only a 14% reduction. The 2035 target must demonstrate further progress while considering the current situation and implementing improvements to ensure the goal is met.

AMCHAM urges the Korean government to actively engage with relevant industry stakeholders throughout this process to develop more sustainable and practical measures that address the impact of rising energy costs while advancing toward the Zero Carbon Emissions goal.

INDUSTRY ISSUES

Bilateral Agreements for CO_2 Transport and Storage and the Establishment of Common CO_2 Storage Standards

Given South Korea's limited storage capacity, capturing CO_2 from local emitters, transporting it, and storing it in foreign facilities will be crucial for the country to meet its emissions reduction targets for 2030 and 2050. While South Korea has ratified the London Protocol, it has actively pursued bilateral agreements with various countries to enhance its carbon capture and storage (CCS) capabilities. Notable examples include the Green Economy Partnership Arrangement with Australia in December 2024 and collaboration initiatives with Malaysia in November 2024. To further advance its CCS efforts, the Korean government should continue to actively explore additional bilateral partnerships with other countries in this field.

Additionally, as South Korea looks to store CO_2 abroad, establishing a common set of standards and requirements is essential. This would expedite transport permits and approvals, as well as enable private companies to replicate projects across various regions or countries.

- **Issue**
  Need for bilateral agreements to enable timely CO_2 transport from South Korea and common standards to accelerate the issuance of CO_2 transboundary transport permits

- **Relevant Regulations**
  Carbon Dioxide Capture, Transportation, Storage, and Utilization Act

- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE)

- **Recommendation**
  Accelerate the proposed bilateral agreements and establish additional timely agreements with countries that have relevant storage capacity, while aligning on CCUS standards to drive the market development in collaboration with Korean stakeholders.

Domestic Certification Requirements for Large- and Medium-Sized Wind Turbines

The Korea Energy Agency (KEA)'s KS Certification system, implemented in 2014, hinders the smooth entry of foreign suppliers into the market. Companies must obtain KS Certification to qualify for government subsidies, as products without the certification are excluded from receiving Renewable Energy Certificates (RECs). Since Korea's regulatory environment does not recognize international safety certification standards, the KS Certification requirement creates a barrier for foreign companies seeking to enter the Korean market.

- **Issue**
  Domestic Certification Requirements for large-and medium-sized wind turbines
- **Relevant Regulations**
  Electric Utility Act
- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE)
- **Relevant KORUS Provisions**
  Chapter 9 (Technical Barriers to Trade)
- **Recommendation**
  AMCHAM urges the Korean Government to establish mutual recognition of safety certification to enhance the industrial partnership and synergy between the Korean and foreign companies.

Equity Investment Commitment Letter (ECL) in Electricity Business License (EBL) Evaluation Process

In December 2022, the Electricity Regulatory Committee (ERC) revised the standard evaluation guidelines for the EBL to include the legally binding ECL as a demonstration of commitment to support equity injection of at least 15% of the total project cost during construction. This amendment was designed to filter out disingenuous developers, including speculators. Furthermore, in August 2023, ERC raised the evaluation criteria by adding the requirement for proof of actual paid-in capital equivalent to at least 1% of the total project cost.

For a typical 400MW greenfield offshore wind project in Korea, the ECL commitment and paid-in capital amounts to 300 billion KRW and 20 billion KRW, respectively, as calculated below:

i. Expected Total Investment Cost (TIC) for a 400MW project: approx. 2 trillion KRW (5 billion KRW/MW)

ii. 1% of the total project cost for paid-in capital: 20 billion KRW

iii. ECL commitment to 15% of the total project cost: 300 billion KRW (including the paid-in capital)

The two requirements serve as a dual barrier to screen disingenuous developers by raising the standards for the project owner's financial capabilities. While the paid-in capital serves as a sufficient barrier, given its significant amount, the ECL requirement poses a serious challenge to foreign investment in Korean offshore wind. The guidelines explicitly require a legally binding document and prohibit the inclusion of "reversible internal conditions," such as "availability of the necessary capital" and "board approval" in the ECL. In a standard international governance environment for corporates and financial institutions, such equity commitment letters are considered as "unconditional" obligations, and it is commercially incongruent to require them before making the final investment decision by the relevant governing body.

Contrary to its intended purpose, the new ECL guideline is now acting as a major obstacle for credible, financially qualified investors and developers – particularly foreign ones – and has generated considerable market uncertainty. As a direct consequence, the new ECL guideline has substantially slowed down the EBL application process, reduced the number of EBLs approved, and resulted in some EBL applications being rejected.

The new ECL guideline is widely considered to be misguided, especially as it requires unconditional equity commitment at the time of the EBL application, despite the fact

that greenfield offshore wind projects typically require 4 to 6 years of further development. Any form of equity commitment letter at such an early stage inevitably includes customary conditions, such as “board approval” and “equity and debt funding,” as essential risk management and governance measures designed to ensure responsible and transparent investment practices.

This guideline is significantly affecting and discouraging foreign participation in the development of and investment in the Korea’s offshore wind market – at a time when the country needs to engage with international developers and investors to accelerate the growth of its offshore wind industry. Numerous foreign players are finding it increasingly difficult to meet the new ECL guidelines.

AMCHAM urges the Korean government and its agencies to actively promote and encourage participation from foreign developers and investors and to provide a legal and regulatory framework that supports the creation of a large-scale renewable energy industry.

- **Issue**
  Equity Commitment Letter discouraging foreign investment and participation

- **Relevant Regulations**
  Standard Evaluation Form of Electricity Business License

- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE)

- **Recommendation**
  AMCHAM urges the Korean government to revise the requirements in the Equity Commitment Letter to prevent disproportionately discouraging foreign investment.

Fast-Track Approach to Delayed Interconnection Analysis

The Electricity Business License (EBL) is considered one of the initial steps in renewable energy project development, as it sets the site boundaries and the resultant project capacity. During the EBL deliberation, the Electricity Review Committee (ERC) requests technical grid review opinions (Interconnection Analysis) from the Korea Electric Power Corporation (KEPCO) and the Korea Power Exchange (KPX) to assess the earliest possible interconnection timeline. KEPCO is generally expected to respond within three weeks of receiving the request. However, in practice, its interconnection analysis tends to be delayed by four to five months. In some cases, even when projects have met all the requirements for EBL review, the ERC has been unable to deliberate on them for over a year due to KEPCO's delay in completing its technical grid review.

Considering that the EBL process marks the first step in the renewable energy project development, delays in interconnection analysis—ranging from several months to over a year—pose significant time and financial risks for genuine projects from U.S. developers. These delays also restrict opportunities for swift private investment in the sector. To minimize the impact on U.S. developers and facilitate renewable energy project development in South Korea, KEPCO and KPX should prioritize addressing delayed grid reviews for projects that have met all necessary requirements during the EBL review stage.

- **Issue**
  Delays in grid review have caused significant delays in the EBL deliberation process

- **Relevant Regulations**
  Electric Utility Act

- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE), Electricity Regulatory Committee (ERC)

- **Recommendation**
  AMCHAM urges that KEPCO and KPX prioritize delayed grid reviews for projects that have met key requirements—such as financial capability, technical capability, and community acceptance—during the EBL review stage.

Need for Strengthening the Hydrogen Sector

South Korea aspires to become a global leader in the targeted use of hydrogen to decarbonize power and other hard-to-abate sectors. To achieve this, it conducted the world's first auction for low-carbon hydrogen and ammonia-derived power generation at the end of last year. However, the auction's success fell short of expectations, primarily due to price uncertainties, the technology readiness level of certain areas of the supply chain (e.g., electrolyzers), and infrastructure availability.

Despite this, the National Assembly, recognizing hydrogen's potential as a key energy resource and a solution to climate change, enacted the Hydrogen Business Act. The government's pursuit of establishing a hydrogen economy ecosystem is commendable.

To maintain momentum in the hydrogen sector and prepare for the emerging international hydrogen economy, policy efforts should focus on sustaining and strengthening the industrial ecosystem, grounded in current realities.

For instance, the existing auction evaluation process could be restructured to better reflect the decarbonization value of the product. Allocating taxpayers' decarbonization budgets toward lower carbon intensity could result in more CO_2 abatement per dollar spent, compared to alternatives near the carbon intensity threshold set by MOTIE. Yet, at the same time, it is crucial to factor in price considerations in the evaluation criteria, with priority given to the profitability of power generation methods, as this market is being cultivated through future-oriented government budgets. A balanced and cautious approach would optimize taxpayer spending and foster positive public opinion.

Furthermore, in evaluating non-price factors, the focus should be expanded to consider the potential for export growth, as the industry will play a significant role in developing overseas markets. This would further enhance the competitiveness of domestic industries in the hydrogen economy, which is expected to grow substantially in the near future.

Moreover, key prerequisites for investment in low-carbon hydrogen and hydrogen carriers include government support to drive demand and infrastructure development. The CHPS (Clean Hydrogen Power System) can further facilitate the development of the hydrogen supply chain by addressing concerns from participants across the value chain. These include:

i. Adjustments to the price structure for bids into CHPS (fixed KRW/kWh): Due to the nature of CHPS as a power auction, and the requirement for fixed bids in KRW/kWh, not allowing for adjustments, including foreign exchange fluctuations, places commercial risks on auction participants. CHPS could mitigate these risks by leveraging standard terms used for other internationally traded commodities, such as LNG.

ii. Increase lead time for planning and development: To support the activation of low-carbon hydrogen and ammonia market, CHPS 2025 should account for the time needed to develop large-scale low-carbon hydrogen and ammonia production plants. A 48-month minimum timeline with additional 12-month grace period would be more feasible for supply projects nearing Final Investment Decision (FID).

- **Issue**
  Need for sustaining and strengthening the industrial ecosystem by restructuring current auction evaluation process

- **Relevant Regulations**
  Act on the Hydrogen Economy Promotion and Hydrogen Safety Management

- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE)

- **Recommendation**
  Korea should commit to strengthening the industrial ecosystem by restructuring the auction evaluation process.

Opportunities for Private Investment in Grid Infrastructure

In recent years, limitations in interconnection capacity have become a significant challenge for the development of renewable energy. Despite strong investor motivation to advance projects, the lack of an established timeline for interconnection continues to create uncertainty in overall project timelines. While this issue may also be present in other markets, some have started to involve private investors in grid improvements. Given the vertical structure of Korea's electricity system, it would be beneficial for the government to consider mobilizing private funds for electricity infrastructure, as it has done in other sectors such as ports and highways. This approach could help alleviate current challenges and accelerate the growth of renewable energy.

- **Issue**
  Opportunities for private investment in grid infrastructure
- **Relevant Regulations**
  Act on Public-Private Partnerships in Infrastructure
- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE), KEPCO
- **Recommendation**
  Korea should engage private investors to help enhance grid capacity, supporting the growth of renewable energy and alleviating KEPCO's financial burdens.

Policy Improvement for the Distributed Power Sector

The Special Act on the Promotion of Distributed Energy, which aims to overcome the limitations of the centralized power system and expand renewable energy infrastructure by enhancing the efficiency of energy production, transportation, and utilization through distributed power sources, came into effect on June 14, 2024. However, several key areas still need improvement to ensure the policy's success.

For instance, KEPCO maintains a monopoly over power transmission, distribution, and sales, which makes it difficult for microgrids to operate independently. Additionally, KEPCO's prioritization of its existing power resources can hinder the widespread adoption of distributed power sources, such as renewable energy. Notably, the concentration of data on power demand, supply, and distribution—critical for the efficient operation of distributed power grids—within a company representing the existing centralized system could impede the development of the broader industrial ecosystem.

Moreover, the economic incentive for adopting decentralized power remains unclear, as it lacks detailed regional pricing regulations. While the Special Act provides a legal framework for differentiated electricity rates, the absence of specific guidelines for applying these differential rates has stalled progress on related projects. To address this, it is essential to develop a clear and specific standard for calculating differential tariffs, taking into account factors such as the distance from power plants, the actual costs of transmission and distribution, and regional variations between electricity production and demand.

- **Issue**
  Grant greater independence to microgrids and implement clear regional pricing regulations for decentralized power

- **Relevant Regulations**
  The Special Act on Activation of Distributed Energy

- **Relevant Agencies**
  Ministry of Trade, Industry and Energy (MOTIE)

- **Recommendation**
  AMCHAM recommends that KEPCO & KPX protocols ensure greater independence for microgrids and establish clear regional pricing regulations for decentralized power. Additionally, specific guidelines should be created to implement differential tariffs based on transmission costs and regional demand.

FINANCIAL SERVICES

- Overview
- Adherence to Regulatory Transparency[UNRESOLVED]
- Differentiation of Information Handling for Corporate Clients vs. Consumer Clients[UNRESOLVED]
- Excessive Regulatory Control on Financial Products[NEW]
- Liberalization of Firewall Standards among Financial Entities within Korea[UNRESOLVED]
- Measured Liberalization of Korean Data Protection Standards for Financial Companies[UNRESOLVED]
- Relaxation of Korean Network Segregation and Cloud Computing Standards for Financial Companies[UNRESOLVED]
- Relaxation of Restrictions on the Short Sale of Korea Treasury Bonds (KTB)[UNRESOLVED]

FINANCIAL SERVICES

OVERVIEW

Given Korea's potential to become a financial hub in the region, AMCHAM commends the Korean government's efforts to align its regulations with global standards. In particular, we appreciate the Financial Services Commission (FSC)'s well-intended deregulatory reforms to expand service usage in the financial sector. We also applaud the government's efforts to enhance the efficiency and stability of securities settlement and FX trading for offshore investors, as well as the FSC's recent measures to improve the regulatory framework governing network separation and financial data security through the regulatory sandbox program.

However, Korea's regulatory environment still poses challenges to its competitiveness and reduces the flexibility of foreign financial services companies operating in the country. AMCHAM urges the Korean government to work closely with international businesses and the U.S. government to enhance investor confidence in the Korean market and provide the necessary infrastructure for multinational companies to thrive in Korea.

INDUSTRY ISSUES

Adherence to Regulatory Transparency

Financial industry participants continue to receive administrative guidance from regulators that is not aligned with existing regulations. This creates two sets of regulatory requirements: 1) a public set of written and promulgated regulations and 2) a grey area of unwritten guidance issued by regulators. This grey area is developed without input from the financial sector and often contradicts current regulations or the rights of financial companies. For instance, extensive unwritten product regulations, such as FX-dominated products, restrict innovation and limit customer choice. The existence of these two sets of rules makes it difficult for financial companies to operate and fully exercise their rights as outlined in the written regulations. This regulatory inconsistency undermines efforts to position South Korea as a regional and global financial hub, as it erodes confidence in the rule of law, uniformity, and predictability.

- **Issue**
  Challenges arising from regulatory inconsistencies between administrative guidance and current regulations undermine Korea's regulatory predictability and uniformity.

- **Relevant Agencies**
  Financial Services Commission (FSC), Financial Supervisory Service (FSS)

- **Relevant KORUS Provision**
  Chapter 13 (Financial Services) Annex13-B (Specific Commitments)

- **Recommendation**
  The development and implementation of regulations through a transparent process are critical for the growth of South Korea's financial sector. Off-the-book rules that are not aligned with written regulations erode confidence in the regulatory system. To avoid these issues, South Korea should uphold its commitments under KORUS, particularly Chapter 13 – Financial Services – Annex13-B (Specific Commitments), which underlines South Korea's commitment to "expand and enhance transparency" that "interested parties are provided an opportunity to comment on that guidance."

Differentiation of Information Handling for Corporate Clients vs. Consumer Clients

The Regulation on Entrustment of Information Processing by Financial Companies has permitted, in principle, financial companies to outsource their information processing work to overseas institutions. In reality, however, consultations did not go smoothly during the reporting process, serving as a barrier for overseas outsourcing.

Corporate client information that is largely disclosed to the public already requires a differentiated information processing guideline compared to those required for individual client information. With the introduction of differentiated guidelines for corporate clients, advanced global financial services can be provided to domestic corporate clients, and further revitalization of the digital financial economy is expected.

- **Issue**
  Need for global financial companies to consolidate information in overseas information processing systems in order to support corporate clients

- **Relevant Regulations**
  Regulation on Supervision of Electronic Finance, Article 11, paragraph 11, Regulation on Supervision of Electronic Finance, Article 14-2, Regulation on Entrustment of Information Processing of Financial Companies, Article 7, paragraph 3

- **Relevant Agencies**
  Financial Services Commission (FSC), Financial Supervisory Service (FSS)

- **Relevant KORUS Provision**
  Chapter 13 (Financial Services)

- **Recommendation**
  AMCHAM urges the Korean government to consider that corporate client information should be subject to a differentiated information processing guideline, distinct from that for individual client information.

Excessive Regulatory Control on Financial Products

While regulatory oversight on financial products is essential to ensure customer protection, particularly in light of recent incidents in Korea, the current level of regulation has made it increasingly difficult to differentiate products in certain categories. As a result, financial institutions are forced to offer nearly identical products, which limits consumer choice.

This regulatory environment poses a challenge for foreign financial institutions, as it significantly limits their ability to introduce diverse product designs developed through international experience into the Korean market. Moreover, financial products denominated in USD – a global currency and one of the most stable investment assets – face disproportionate regulatory treatment compared to KRW-denominated products. This excessive control hampers product innovation and reduces market competitiveness.

- **Issue**
  Excessive regulatory control on financial products
- **Relevant Agencies**
  Financial Services Commission (FSC), Financial Supervisory Service (FSS)
- **Relevant KORUS Provision**
  Chapter 13 (Financial Services)
- **Recommendation**
  To create a balanced regulatory environment that both protects consumers and encourages product innovation, financial regulatory authorities should adopt a more principles-based approach to product regulation. This would grant financial institutions greater flexibility in product design while ensuring essential consumer protection measures are maintained. Additionally, regulators must ensure that USD-denominated financial products, recognized globally for their stability, receive fair and balanced regulatory treatment comparable to KRW-denominated products. This approach would enhance customer choice and promote market efficiency.

Liberalization of Firewall Standards among Financial Entities within Korea

South Korea currently sticks to a specialized banking system that requires the separation of banks, securities companies, and asset management companies, making it impossible for foreign financial companies to share information with their affiliates. Under such circumstances, many foreign financial institutions that have adopted a universal banking system must divide their organization into several units/entities in Korea. Firewall regulations that restrict the exchange of information among financial companies specializing in different businesses serve as a strong practical disincentive for Korea's case as a regional hub in Asia.

- **Issue**
  Korea's specialized banking system restriction on information exchanges among financial companies
- **Relevant Agencies**
  Financial Supervisory Service (FSS).
- **Relevant KORUS Provision**
  Chapter 13 (Financial Services)
- **Recommendation**
  We urge Korea to liberalize firewall standards among financial entities within Korea to facilitate the exchange of information among financial entities within Korea.

Measured Liberalization of Korean Data Protection Standards for Financial Companies

The liberalization of Korean data protection standards for financial companies operating in Korea would enhance the attractiveness of Korea to U.S. and global companies as a regional financial hub. Targeted liberalization of the Personal Information Protection Act, the Use and Protection of Credit Information Act, and the Act on Promotion and Communication Network Utilization and Information Protection to a level comparable to their counterparts in the U.S. and other developed OECD nations is desirable.

- **Issue**
  The measured liberalization of Korean data protection standards for financial companies

- **Relevant Regulations**
  Personal Information Protection Act (PIPA), Protection of Credit Information Act (PCIA), Act on Promotion and Communication Network Utilization and Information Protection, etc. (“Network Act”).

- **Relevant Agencies**
  Ministry of the Interior and Safety (MOIS), Financial Services Commission (FSC), Financial Supervisory Service (FSS).

- **Relevant KORUS Provision**
  Chapter 13 (Financial Services)

- **Recommendation**
  We urge Korea to liberalize data protection standards to a level comparable to those of the U.S. and other developed OECD nations.

Relaxation of Korean Network Segregation and Cloud Computing Standards for Financial Companies

The relaxation of Korean network segregation and cloud computing standards for financial companies operating in Korea that want to leverage global cloud hubs located overseas would enhance the attractiveness of Korea to U.S. and global companies as a regional financial hub. The financial sector faces significant challenges in utilizing global IT capabilities in Korea, including cloud and AI services, given the rules that mandate the separation of internal and external networks. Introduced following a large-scale cyber-incident, the rules were codified in the Electronic Financial Supervisory Regulation. The regulation specifically introduced network separation rules that require separate internal networks for business purposes and external networks (with access to the internet). These factors not only drive up business expenses but also hinder the implementation of innovative technologies and systems, which could streamline operations, enhance customer care, and improve overall service quality. The inability of financial services companies' employees based in Korea to work across jurisdictions, with related parent company organizations, also slows down innovation as IT and related teams are only able to operate within the internal network. The rules also stifle innovative solutions that local and global financial technology firms can develop and provide for financial companies, as well as internal development of such solutions. Targeted relaxation of the Regulation on Supervision of Electronic Financial Transactions to a level comparable to the regulations of the U.S. and other developed OECD nations is desirable.

- **Issue**
  Relaxation of Korean network segregation and cloud computing standards for financial companies that want to leverage global cloud hubs located overseas
- **Relevant Regulations**
  Electronic Financial Transactions Act, Regulation on Supervision of Electronic Financial Transactions
- **Relevant Agencies**
  Financial Services Commission (FSC), Financial Supervisory Service (FSS)
- **Relevant KORUS Provision**
  Chapter 13 (Financial Services)

- **Recommendation**

  We urge Korea to liberalize its network segregation and cloud computing standards to a level comparable to standards of the U.S. and other developed OECD nations, and recommend that the government work with the financial sector to accelerate reforms to the Electronic Financial Supervisory Regulation (Financial Services Commission) that would remove network separation while protecting company systems and customer data.

Relaxation of Restrictions on the Short Sale of Korea Treasury Bonds (KTB)

Banks are required to cover KTB's position on the same day they trade with foreign investors to avoid breaching short sale regulations, even if the settlement with the foreign investor is due several days after the trade date.

This regulation limits banks' ability to offer competitive prices to clients, particularly for illiquid off-the-run bonds, especially when a client's Request for Quotation (RFQ) comes late in the day near market close. In such cases, sourcing the bond on the trading date becomes challenging. If KTB were included in the World Global Bond Index (WGBI), it is estimated that $60bn in inflows could be generated, and clients would demand more active market-making for off-the-runs bonds

- **Issue**
  Restriction on short sales of KTB
- **Relevant Regulations**
  Financial Investment Services and Capital Markets Act, Article 180
- **Relevant Agencies**
  Financial Services Commission (FSC), Financial Supervisory Service (FSS).
- **Recommendation**
  We recommend that Korea relax the short sale rule, allowing banks to cover KTB positions on the bond settlement date rather than the trade date.

LABOR

- Overview
- Expansion of Parental Leave Pay & Substitute Workforce Support
- Labor Flexibility
- Reform of Working Hours System

LABOR

OVERVIEW

South Korea's labor market continues to present challenges for businesses, particularly due to the rigid regulatory framework that governs hiring, firing practices, and working hours. These challenges have become more pronounced in recent years, as the country's labor flexibility has remained relatively low compared to its regional competitors. Although labor flexibility is a critical factor for attracting foreign direct investment (FDI) and enhancing business competitiveness, the current labor system in South Korea limits companies' ability to respond swiftly to market fluctuations, thus increasing operational costs and reducing overall workforce adaptability.

In response to these issues, the government has introduced discussions on reforming the working hours system and expanding parental leave pay to foster a better work-life balance for employees. However, businesses—particularly SMEs—continue to face difficulties in managing employee leave, especially in securing qualified substitute workers. This gap in workforce support has led to productivity losses, particularly in specialized industries where skilled labor is crucial.

By addressing these challenges with thoughtful and practical reforms, South Korea would be able to enhance its appeal to international investors and support long-term, sustainable economic growth.

INDUSTRY ISSUES

Expansion of Parental Leave Pay & Substitute Workforce Support

South Korea has made significant progress in enhancing parental leave policies to address low birth rates and promote a better work-life balance, including recent amendments that took effect on February 23, 2025. The government has shifted towards strengthening parental rights, by steadily increasing parental leave pay, introducing policies to encourage fathers' participation in childcare and providing better protection for workers taking leave.

However, the use of dispatch workers (temporary workers) as substitutes for parental leave remains a challenging issue, especially for SMEs due to the immediate difficulty of finding substitute workers. While the law permits dispatched workers to be used for non-designated tasks when there is a vacancy due to childbirth, illness, or injury, and the dispatch period may exceed two years in cases of paternity, many businesses still face difficulties due to limitations in how dispatch workers are utilized. Dispatch workers often cannot fully replace permanent employees because of restrictions on the types of tasks they can perform and the historically limited use of dispatch workers. This is particularly problematic in industries requiring highly skilled workers or specialized knowledge.

To alleviate this burden, the government has introduced financial support measures for companies hiring temporary replacements. However, the awareness and utilization rate of such programs remain low. According to the Ministry of Employment and Labor (MOEL), many SMEs struggle to find skilled temporary workers, leading to productivity gaps and additional costs.

The lack of skilled substitute workers is particularly evident in specialized industries where employee expertise is crucial. While government subsidies are available for hiring replacements, businesses often report difficulty in finding adequately trained personnel. Employers have called for additional support in workforce training programs to ensure that temporary replacements can seamlessly integrate into existing workflows.

- **Issue**
  Despite improvements in parental leave policies, businesses continue to face challenges in securing substitute workforce support, leading to potential productivity losses.

- **Relevant Regulations**
  Employment Insurance Act, Equal Employment Opportunity and Work-Family Balance Assistance Act, Act on the Protection, etc. of Temporary Agency Workers

- **Relevant Agencies**
  Ministry of Employment and Labor (MOEL)

- **Recommendation**
  AMCHAM supports further improvements in parental leave policies, including increased subsidies for substitute workforce programs and incentives for companies that actively promote parental leave. A robust parental leave system not only supports employees but also contributes to a more sustainable and inclusive labor market in Korea.

Labor Flexibility

South Korea’s labor market remains one of the most rigid among OECD countries, with strict employment protection laws and significant restrictions on dismissals. While labor flexibility is a key factor in attracting foreign direct investment (FDI) and ensuring business competitiveness, regulatory frameworks often create burdens for companies operating in Korea. The rigid labor system limits companies' ability to respond effectively to market fluctuations, increasing operational costs and reducing employment opportunities.

Compared to regional competitors, such as Japan, Hong Kong, and Singapore, Korea still lags in the area of labor flexibility, including hiring and firing practices and work hours. Particularly, the current overtime system is limited to a weekly basis and impacts the efficiency of work and individual flexibility. Creating an environment that enables companies to quickly adjust their workforce in response to evolving market demands will position Korea as an appealing destination for international businesses. Political leaders have also emphasized the need for labor market flexibility, with proposals to ease dismissal regulations and improve employment practices.

- **Issue**
  The lack of labor market flexibility poses challenges for businesses, making it difficult to adjust quickly to market changes. At the same time, employees face restrictions that limit their work-life balance and flexibility.

- **Relevant Regulations**
  Labor Standards Act

- **Relevant Agencies**
  Ministry of Employment and Labor (MOEL).

- **Recommendation**
  AMCHAM urges the Korean government to consider reforms that offer companies greater flexibility in adjusting their workforce in response to economic conditions, while safeguarding worker protections. It is essential that labor market reforms align with international best practices, fostering an environment that strengthens Korea’s global competitiveness.

Reform of Working Hours System

South Korea's working hours system has been a subject of continuous debate, particularly with recent discussions on revising the 52-hour workweek rule. Initially introduced to improve work-life balance, the policy has presented challenges for industries requiring greater flexibility, particularly in sectors with fluctuating workloads such as manufacturing, IT, and services.

The government has proposed various modifications, including allowing workers to manage their total working hours on a monthly, quarterly, or annual basis rather than adhering to rigid weekly caps. The recent change in the application of working hours has introduced more flexibility in the 52-hour workweek. Formerly, additional working hours on a daily basis were considered overtime, but now they are considered additional working hours exceeding the total weekly working hour limit. While these changes aim to provide businesses with operational flexibility, concerns persist regarding overtime compensation, worker fatigue, and enforcement mechanisms. In a recent survey conducted by the Korea Chamber of Commerce and Industry (KCCI), most companies expressed difficulties in complying with the rigid work-hour system, citing negative impacts on productivity and global competitiveness.

In addition to concerns raised by businesses, labor unions and employee rights groups have expressed apprehension regarding potential increases in workload and the risk of overwork. A study conducted by the Korea Labor Institute (KLI) highlights that prolonged flexible work arrangements without proper safeguards may result in adverse effects on employee health and well-being. The challenge lies in designing a system that balances operational efficiency for businesses while safeguarding workers' rights.

- **Issue**
  The current rigid work-hour system poses challenges for both businesses and employees, requiring reforms that balance economic needs with labor protections.

- **Relevant Regulations**
  Labor Standards Act

- **Relevant Agencies**
  Ministry of Employment and Labor (MOEL).

- **Recommendation**
  AMCHAM encourages ongoing dialogue between the government, businesses, and labor representatives to ensure that any reforms

align with international best practices, support business growth, and maintain employee well-being. A well-balanced working hours system will contribute to Korea’s global competitiveness and productivity.

MEDICAL DEVICES

- Overview
- Accelerating Patient Access to Innovative Medical Technologies UNRESOLVED
- Exclusion of Advanced Medical Equipment Companies from Relevant Policy Discussions UNRESOLVED
- Reimbursement Coverage for Innovative Medical Technologies UNRESOLVED
- Policy Support for Medical Devices Necessary for Cancer Diagnosis and Treatment NEW
- Activation of Home-based Treatment and Expansion of the Digital Health Industry NEW
- Global Harmonization in the Medical Device Approval System NEW

MEDICAL DEVICES

OVERVIEW

Korean society is facing challenges in healthcare due to an aging population, rising healthcare costs, and the need for more efficient systems to ensure equitable access to care. Given these challenges, the medical device industry plays a critical role in enhancing quality of life, lowering healthcare costs, driving innovation in medical technologies, and supporting economic growth.

South Korea's medical industry is rapidly growing, fueled by advanced technologies, strong R&D, and a solid healthcare infrastructure. The country has become a hub for medical devices, pharmaceuticals, and biotechnology, with a focus on innovation. Government initiatives, regulatory reforms, and support for research have further boosted the sector, positioning South Korea as a global leader in medical technology, especially in digital health and AI-driven solutions.

South Korea's medical industry also thrives through strong collaboration with the U.S., particularly in the areas of research and innovation, facilitating to drive advancements in medical technologies and expand access to cutting-edge treatments.

However, U.S. medical device companies face several challenges in South Korea. The approval process involves multiple steps, including regulatory reviews, health technology assessments, and reimbursement decisions, which can delay market entry. The stringent requirements for reimbursement, particularly for innovative technologies, create additional barriers. While recent efforts to streamline these processes have been made, there is still room for improvement in reducing delays and ensuring quicker access for advanced medical devices. Furthermore, enhancing communication between the government and industry stakeholders could help ensure that the perspectives of U.S. manufacturers are better considered in policy decisions.

In today's dynamic business landscape, collaboration across sectors has evolved from a mere option to a necessity. AMCHAM and its member companies remain committed to building a healthcare system that encourages innovation, ensures accessibility, and provides high-quality care to all, in alignment with South Korea’s demographic and healthcare goals.

INDUSTRY ISSUES

Accelerating Patient Access to Innovative Medical Technologies

Korea's healthcare system involves multiple patient access processes, including regulatory approval from the Ministry of Food and Drugs Safety (MFDS), New Health Technology Assessment (nHTA) approval from the Ministry of Health and Welfare (MOHW) and the National Evidence-based Healthcare Collaborating Agency (NECA), and reimbursement coverage and pricing approval from MOHW and the Health Insurance Review & Assessment Service (HIRA). To expedite these approval procedures, MOHW has implemented several initiatives:

1. **The Parallel Review (PR) process, inspired by the parallel review system of the U.S. Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS):** This PR process allows for concurrent reviews of regulatory approval and nHTA applications, aiming to reduce the overall lead time for market access.

2. **The Preliminary Market Entry and Post-evaluation System, which allows new medical devices to be used immediately after approval as non-reimbursed (or self-paid) item after product registration with clinical evaluation:** This is expected to reduce the market entry process from a maximum of 490 days to as little as 80 days. Currently, this system is limited to digital therapeutics, in vitro diagnostic devices, and AI-assisted diagnostic devices. However, there are proposals to expand the scope to include innovative medical device designated products and orphan medical device designated products from the pilot stage. While the government plans to gradually expand eligible product categories, it is suggested that these two categories be included from the outset to maximize the system's impact.

3. **A restructuring of the market entry process, evaluating various aspects such as the effectiveness of the technology, improvement in patients' quality of life, and cost-effectiveness based on real-world data from clinical settings:** This new approach aims to expand patient and consumer choice while stimulating industry growth.

While the Korean government has made significant strides in improving the market access process for new medical technologies, there is still room for improvement, particularly in the reimbursement coverage and pricing decision-making process. The implementation of the Parallel Review process, the Preliminary Market Entry and Post-evaluation System, and the restructuring of the market entry process are

positive steps towards reducing delays and improving patient access to innovative medical devices.

However, to maximize the impact of these initiatives, it is crucial to consider expanding the scope of the Preliminary Market Entry and Post-evaluation System. Specifically, the proposal to include innovative medical device designated products and orphan medical device designated products from the pilot stage deserves serious consideration. By incorporating these categories early on, the system could provide more comprehensive support for cutting-edge medical technologies and address unmet medical needs more effectively. This expansion would not only benefit patients by providing quicker access to innovative treatments but also support the growth and competitiveness of the medical device industry, including U.S. manufacturers.

Addressing the remaining challenges in the reimbursement and pricing process, along with the proposed expansion of the Preliminary Market Entry and Post-evaluation System, could significantly reduce the disadvantages currently faced by innovators due to delayed market access. These improvements would help align the Korean healthcare system more closely with the rapid pace of medical device innovation, ultimately benefiting patients, healthcare providers, and the medical technology industry.

- **Issue**
  Delays in the approval process that deny patient-access to innovative medicines and medical technologies

- **Relevant Regulations**
  National Health Insurance Act

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), Health Insurance Review & Assessment Service (HIRA), National Health Insurance Service (NHIS)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions), Article 2 (Access to Innovation)

- **Recommendation**
  AMCHAM urges that the reimbursement coverage and pricing approval process by the MOHW and the HIRA be accelerated to meet the legally mandated 100-day timeframe. Additionally,

reimbursement coverage and pricing approval should be integrated into the PR process.

Exclusion of Advanced Medical Equipment Companies from Relevant Policy Discussions

Medical technology is advancing rapidly in medical equipment, such as CT, MRI, and robotic surgery. Typically, enhanced medical devices, primarily consumable ones, aim for reimbursement through a value appraisal track. Conversely, medical equipment is usually procured directly by hospitals, leading to pricing discussions between the hospitals and providers. However, the pricing of the medical procedure associated with the medical equipment, known as the Resource-Based Relative Value Score (RBRVS), is already established, lacking a mechanism to capture additional value for the improved performance of the medical equipment.

The value of advanced medical equipment is insufficiently represented in the Resource-Based Relative Value Score. Particularly noteworthy is the ironic situation wherein enhanced medical equipment, designated to alleviate the workload of medical staff, may paradoxically decrease the score. In essence, the introduction of improved medical equipment can result in a reduction of the price of medical procedures.

Medical equipment has undergone remarkable advancements in recent years. Technologies embedded within this equipment, facilitating personalized solutions and treatments, have the potential to significantly enhance patients' quality of life and yield cost-effective outcomes. Consequently, a more comprehensive understanding of this equipment is anticipated to positively influence both patients and healthcare finances.

However, medical equipment companies have historically been excluded or sidelined from various government policy decisions. While pharmaceutical companies and medical device companies (primarily consumable medical devices) have been engaged in the decision-making process and consulted regarding policy changes, medical equipment companies have not been included in these communications. Therefore, there is an urgent need to establish a communication channel that enables medical equipment companies, as suppliers, to participate in discussions regarding policy improvements related to medical equipment.

- **Issue**
  Lack of communication channel between medical equipment companies and the government stakeholders

- **Relevant Regulations**
  National Health Insurance Act

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), Health Insurance Review & Assessment Service (HIRA)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions), Article 2 (Access to Innovation)

- **Recommendation**
  AMCHAM encourages the Korean government to open communication with medical equipment companies to discuss policies regarding medical equipment

Reimbursement Coverage for Innovative Medical Technologies

U.S. medical device manufacturers must follow the pricing and reimbursement policies set by the Korean government as the country focuses on cost containment within its national healthcare system.

The importation of medical devices necessitates appointing an importer or representative based in Korea to oversee medical device approvals and ensure regulatory compliance. As part of the pre-market approval process, the Ministry of Food and Drug Safety (MFDS) mandates the submission of testing reports on safety and efficacy. Moreover, companies are required to negotiate pricing terms with the Korean Health Insurance Review and Assessment Service (HIRA) in addition to obtaining medical device approvals.

Issues that the medical device industry in Korea currently faces include the reimbursement pricing regulated by the National Health Insurance (NHI), the implementation of a new healthcare technology assessment system for medical devices, and the forthcoming regulation mandating device registration every five years, set to take effect in 2025.

With the implementation of the KORUS FTA, U.S. medical device companies can request a review of government pricing and maximum reimbursement determinations for their products through an Independent Review Process. This review process, established to oversee medical devices and drug prices, operates independently from the Ministry of Health and Welfare (MOHW), the National Health Insurance Service (NHIS), and the Health Insurance Review and Assessment Service (HIRA).

However, innovative technologies often struggle to enter the market due to the stringent and high standards of the evidentiary requirements necessary to obtain specific reimbursement coverages. These requirements include: 1) prospective comparative study, 2) retrospective comparative study meta-analysis, 3) prospective comparative study meta-analysis, 4) randomized prospective comparative clinical study, and 5) cost-effectiveness research. Considering the evolving nature of innovative medical technology and its potential benefits to patients, there is a need for more practical and flexible approaches to determine reimbursement coverage. The current evidentiary requirements for innovative medical technologies are significantly stricter than those for traditional medical technologies. This places a disproportionate burden on relevant manufacturers and hinders the market entry of innovative medical technologies, which could otherwise enhance patient care, save lives, and reduce NHI spending and medical costs through effective and efficient healthcare resource utilization.

In order to facilitate the rapid market entry of new technologies, the current grace period system is only applicable for 2 years, and there is a policy need for its expansion. A faster policy decision regarding the recently discussed 2+2 approach is necessary. When evaluating new medical technologies, it is important to consider the characteristics of the target diseases (severity, number of patients, etc.) and adopt more flexible evaluation requirements.

Additionally, discussion regarding how to preserve the cost of medical materials needs to take place. For medical materials tied to policy prices, recent increases in raw material costs, transportation fees, and exchange rates have made it impossible to preserve the cost. Therefore, separate improvements for these products are necessary. In particular, products that are essential must be prioritized to ensure a stable supply.

Due to the inability to preserve costs, companies are facing significant challenges in maintaining stable supply, and in some cases, withdrawal from the market is being considered depending on the disease. Among medical materials tied to fixed fees, it is urgent to establish mechanisms to preserve costs, starting with those used for severe patients.

Lastly, Korea's Innovative Medical Device Company Certification System, implemented in 2020, supports small and medium-sized enterprises (SMEs) and startups with innovative technologies to enhance their market competitiveness. However, challenges include complex processes and a focus on domestic companies. The medical device industry, with its smaller clinical trials and rapid technological advancements, requires a certification system that better reflects these characteristics. To support industry growth, the system should evolve to provide a flexible and expedited approval process. Enhancing support qualifications, evaluation criteria, and reward structures will foster global enterprise participation and boost the competitiveness of the medical device sector.

- **Issue**
  Lack of reimbursement coverage and limited market access for innovative medical technologies due to nHTA and rigid reimbursement pricing system

- **Relevant Regulations**
  National Health Insurance Act, New Health Technology Assessment (nHTA)

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), Ministry of Food and Drug

Safety (MFDS), National Health Insurance Service (NHIS), Health Insurance Review and Assessment Service (HIRA), National Evidence-based Healthcare Collaborating Agency (NECA)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions), Article 2 (Access to Innovation)

- **Recommendation**
  In order to foster the development of innovative medical technologies in Korea, it is crucial to adopt a flexible and practical approach for determining reimbursement coverage. Coverage with Evidence Development (CED) is a globally recognized method for adopting innovative medical technologies. It ensures better patient benefits by providing reimbursement coverage, conditional on the development of robust clinical benefit evidence. This approach allows companies to enter the innovation market without interruption. A new pricing system such as the “New Conditional Reimbursement” (also known as the Reference Pricing System), introduced in 2021, should be activated to improve patient access to innovative medical technologies. For products that demonstrate better clinical outcomes or cost-effectiveness compared to existing products included in procedure fees, proactive consideration should be given to individual pricing to ensure smooth adoption of promising products. While discussions regarding improvements to the nHTA system are ongoing, there has been little substantial progress. Therefore, greater flexibility and openness in the system’s operation are necessary.

Policy Support for Medical Devices Necessary for Cancer Diagnosis and Treatment

As the proportion of the elderly population in Korea has exceeded 20.6% (1,059 people) of the total population, the country has entered a super-aged society. This percentage is expected to reach 30% by 2036 and surpass 40% by 2050. Cancer, the leading cause of death in Korea, generally increases in incidence with age. Therefore, early diagnosis and optimal treatment of cancer in a super-aged society are crucial issues, both for healthy living and from the perspective of rapidly increasing medical costs.

Lung cancer is reported to be the leading cause of cancer incidence and mortality among various types of cancer. In a super-aged society, lung, colorectal, prostate, and breast cancers are predicted to increase further. For lung cancer, the 5-year survival rate is about 80% when detected early (based on 2017-2021 data). However, if cancer cells metastasize to other organs, the survival rate drops dramatically to 12.1%. Thus, early detection is extremely important. For early-detected cancers, minimally invasive surgery and precise radiation therapy are crucial for patients' post-treatment health and quality of life.

While revolutionary medical technologies for cancer diagnosis and treatment are rapidly advancing, there are many constraints in introducing these technologies under the current fee determination system. Despite being improved technologies, they are often assigned the same fees as previously listed technologies. Even after being approved through the new medical technology evaluation process, they frequently end up using existing medical procedure fees instead of establishing new fee categories. Although the government has consistently announced and applied reimbursement policies for high-priced cancer drugs, the passive policy regarding high-cost medical devices is increasing the burden of cancer treatment on patients.

While the government has announced plans to phase out low-fee structures and prioritize increases in surgical, procedural, and anesthesia fields, including surgical departments, it is difficult to convey industry opinions during these discussions. Therefore, policy support that reflects industry opinions is necessary to ensure that rapidly developing medical devices and related medical technologies can be used effectively and in a timely manner for domestic patients. This will provide a wider range of treatment options for severe cancer patients, reduce their economic burden, and maximize treatment effectiveness.

- **Issue**
  Increased patient burden due to low reimbursement rates and non-

covered services for medical devices used in cancer diagnosis and treatment

- **Relevant Regulations**
  National Health Insurance Act

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), Health Insurance Review and Assessment Service (HIRA), National Health Insurance Service (NHIS)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions), Article 2 (Access to Innovation)

- **Recommendation**
  AMCHAM urges the realization of appropriate reimbursement rates for medical devices used in cancer diagnosis and treatment processes, as well as coverage of technologies that have demonstrated confirmed safety and clinical efficacy.

Activation of Home-based Treatment and Expansion of the Digital Health Industry

Due to the growing elderly population and increasing numbers of patients with chronic diseases, the demand for homecare treatment and the importance of policy support for home-based care have risen. To enhance productivity and reduce healthcare costs, various homecare treatment fees and government support are essential.

Continuous patient care through digital health monitoring or remote support can improve the productivity of both the elderly and the economically active population, fostering a positive overall cycle.

For devices that have demonstrated effectiveness in managing chronic diseases through digital tools, providing separate reimbursement is crucial to increase their utilization in clinical settings and improve patient management.

- **Issue**
  The Medical Service Act is not well-suited to support effective communication between patients and physicians.

- **Relevant Regulations**
  Medical Service Act

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), National Assembly

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions), Article 2 (Access to Innovation)

- **Recommendation**
  AMCHAM recommends that the Medical Service Act be updated to include provisions that promote and support treatment and communication through digital health technologies between patients and physicians.

Global Harmonization in the Medical Device Approval system

The approval process for imported medical devices in Korea consists of two key steps: registering the overseas manufacturing facility and obtaining product approval.

According to the 2024 Annual Report on Food and Drug Statistics, a total of 7,065 medical devices of all classes were approved in Korea in 2023. Among them, imported medical devices accounted for 3,525 cases (approximately 49.9%). Additionally, among the 3,625 companies designated for medical device Good Manufacturing Practice (GMP) certification, 1,255 were importers, representing about 34.6% of the total.

The continuous increase in product approvals and overseas manufacturing facility registrations has placed a growing burden on the regulatory authorities responsible for these approvals. Furthermore, the shortage of human resources for on-site audits of overseas facilities has impacted the timing of product market launches.

Efforts have been made to join the Medical Device Single Audit Program (MDSAP), but a clear timeline for membership has not yet been provided. In cases where overseas manufacturing facility inspections are conducted solely by the review agencies or jointly with the Ministry of Food and Drug Safety (MFDS), the significant financial burden and shortage of human resources have led to approval backlogs, causing delays in market entry for new products and disruptions in the stable supply of medical devices. Progress was made in 2024 to allow on-site audit exemptions when submitting an MDSAP audit report. However, even in this case, on-site audit is still required for renewals, so the exemption is allowed only to a very limited extent.

- **Issue**
  Delayed product launch and difficulties to ensure the supply continuity
- **Relevant Regulations**
  Enforcement regulation to medical device act, Regulations for Approval, Notification, and Review of Medical Devices, Good Manufacturing Practices for Medical Devices
- **Relevant Agencies**
  Ministry of Food and Drug Safety (MFDS)
- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions), Article 6 (Regulatory Cooperation)

- **Recommendation**
  AMCHAM urges the Korean government to harmonize the product and manufacturing site registration regulations with international standards.

PHARMACEUTICAL

- Overview
- Lack of Transparency and Predictability[UNRESOLVED]
- Pricing of Global Innovative Drugs[UNRESOLVED]
- Necessity of Dual Pricing for Access to Innovative Medicines and Sustainable Supply[NEW]
- Need for Implementation of Indication-Based Pricing for Pharmaceuticals[NEW]
- Establishing a National Immunization System and Improving the National Immunization Program (NIP) Policy[NEW]
- Intellectual Protection Challenged by the Amendment to the Patent Act[NEW]

PHARMACEUTICAL

OVERVIEW

South Korea’s entry into a super-aged society in 2025 marks a pivotal moment for its healthcare system. With the challenges of low birth rates and an aging population, strengthening healthcare coverage and ensuring the sustainability of national health insurance are critical. The biopharmaceutical industry is well-positioned to contribute by not only extending life expectancy but also improving quality of life, reducing healthcare costs, and driving economic growth.

To support this, the Korean government has recently launched the National Bio Committee, a high-level body to unite public and private sectors and advance the biotech industry. As part of its goal to become one of the world’s top five biotech powerhouses by 2035, the government has unveiled a Bio Transformation Strategy, which includes restructuring bio infrastructure, integrating data across institutions, and developing regulatory guidelines for emerging fields like AI-based medical devices. By 2032, Korea aims to expand biopharmaceutical production capacity by 2.5 times, positioning the country as a global leader in production and sales.

AMCHAM commends the government's efforts to foster communication and collaboration with the biopharmaceutical sector, such as through regular roundtables with AMCHAM, which is critical for ensuring that industry concerns are addressed. These efforts create a cooperative environment that benefits both the sector and public health. Strengthening the U.S.-Korea alliance is key, emphasizing cross-border cooperation to drive innovation and expand healthcare access.

AMCHAM strongly supports fostering global collaboration in the pharmaceutical sector, recognizing that "open innovation" and valuing innovation are essential to achieving these goals. By enhancing cross-border partnerships and leveraging global expertise, South Korea can accelerate its path to becoming a leader in the biopharmaceutical field, improving citizens' lives.

Despite significant progress in improving pricing and reimbursement policies to facilitate faster access to innovative medicines, U.S. companies continue to face obstacles that limit their ability to introduce innovations to Korean patients. These challenges include complex regulatory pathways, uncertainty in pricing and reimbursement, and limited recognition of advanced therapies – all of which can deter both domestic and foreign investment. Addressing these hurdles by establishing transparent and predictable regulatory frameworks, strengthening public-private

partnerships, and cultivating a more favorable business environment that encourages domestic investment will be essential to ensuring that innovation reaches those who need it the most.

INDUSTRY ISSUES

Lack of Transparency and Predictability

The Korean government has been operating the private-public consultative bodies with industry associations to improve drug pricing and reimbursement policies and to disclose the results of the reimbursement evaluation, demonstrating its commitment to fostering a pro-innovation policy environment. However, there remains room for improvement in terms of transparency and predictability.

Given the challenge in demonstrating the cost-effectiveness of high-priced innovative medicines, the industry has requested the Korean government to raise the Incremental Cost-Effectiveness Ratio (ICER) thresholds for evaluating the cost effectiveness of treatment for severe and rare diseases to at least two to three times the GDP per capita. As of 2015, Korea's ICER threshold was reported to be 23,124 USD, which is lower than the country's GDP per capita of 34,356 USD for that year. When compared to other countries such as Australia (63,096 USD) and the United Kingdom (65,871 USD), this figure is considerably low. The excessively low ICER threshold discourages the entry of innovative, investment-heavy drugs into the Korean market, potentially limiting patient access to new medicines.

In 2021, the Korean government removed the reference to GDP per capita from the ICER threshold guidelines, introducing greater uncertainty into the cost-effectiveness evaluation process. According to the data released by the Health Insurance Review and Assessment Service (HIRA) in December 2024, the median ICER thresholds for anticancer and general disease treatments over the past five years (2019~2023) were KRW 39,930,000 (approximately USD 29,275) and KRW 27,660,000 (approximately USD 20,279), respectively. Considering that Korea’s GDP per capita in 2024 was KRW 49,136,000 (approximately USD 36,024), the value of new and innovative medicines is significantly underestimated in Korea. The fact that only 19 drugs have passed the economic evaluation over the past five years is evidence of the system's limitations in adequately reflecting the value of innovative new drugs.

Furthermore, it was informally disclosed during the 2024 Parliamentary Audit that the first official application of a flexible ICER threshold for innovative pharmaceuticals—an initiative the Korean government announced to incentivize innovation—resulted in only a 10% adjustment above the existing threshold, amounting to 55 million KRW (approximately USD 37,840). Meanwhile, HIRA continues its efforts to establish a standard for assessing the appropriate value of new drugs. In August 2024, HIRA revised the “Detailed Evaluation Criteria for Negotiation Target Drugs, including New

Drugs" by specifying the evaluation criteria for innovation. It is strongly recommended that measures to better reflect innovation be further strengthened.

New medicines must undergo reimbursement appropriateness evaluation by HIRA and drug price negotiation with the National Health Insurance Service (NHIS) for reimbursement. However, various subcommittees and the Drug Reimbursement Evaluation Committee (DREC) of HIRA often scrutinize reimbursement appropriateness with a heavy emphasis on price and budget impact. This results in pharmaceutical companies facing duplicated price-cut pressures even before engaging in drug price negotiation with the NHIS. Consequently, it becomes challenging for pharmaceutical companies to anticipate the appropriate pricing of medicines in Korea and develop a reasonable pricing strategy. In fact, the list price of medicines in Korea is among the lowest among OECD countries.

It is crucial that the efforts to enhance transparency through the disclosure of drug pricing evaluation details continue. By providing more comprehensive and predictable information, the government can foster a more collaborative and innovation-friendly environment, ultimately benefiting both the industry and patients in the long term.

- **Issue**
  Lack of predictability to pricing & reimbursement review process, as well as lack of transparency and due process for companies to apply for reimbursement

- **Relevant Regulations**
  Pricing & Reimbursement (P&R) regulations

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), Ministry of Food and Drug Safety (MFDS), National Health Insurance Service (NHIS), Health Insurance Review and Assessment Service (HIRA)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 2(Access to Innovation) & Article 3 (Transparency)

- **Recommendation**
  AMCHAM urges the expansion of criteria for raising the ICER threshold and the establishment of a more systematic evaluation framework to determine whether innovative drugs qualify for flexible ICER threshold application. Furthermore, the number of actual cases applying the flexible threshold

should be increased. To enhance transparency, clear notification and public disclosure should be provided when an application does not qualify for the flexible ICER threshold.

Pricing of Global Innovative Drugs

Although Korea has introduced new pricing and reimbursement policies since the enactment of the KORUS FTA in 2012, the pricing and reimbursement evaluation process still takes considerably longer compared to other major countries. This prolonged process devalues innovation by global pharmaceutical companies, thereby negatively impacting Korean patients' access to new and innovative medicines.

Recent studies conducted by industry associations such as PhRMA and KRPIA between 2023 and 2024 also highlight the limited access environment in Korea, as follows:

- Only 22% of the 460 new drugs launched from 2012 to the end of 2021 were reimbursed in Korea, a figure lower than the OECD average (29%) and that of other reference countries such as the U.S. (85%), Japan (48%), the U.K. (48%), and France (43%).
- The time from the global launch to public reimbursement in Korea averaged 46 months, longer than other reference countries such as the U.S. (4 months), Japan (17 months), the U.K. (27 months), and France (34 months). This means Korean patients often have to wait almost four years to access new drugs.
- Over the past decade (2012~2021), expenditure on new drugs accounted for only 2.1% of total medical expenditure and 8.5% of the total pharmaceutical expenditure in Korea, figures significantly lower than those in major developed countries.

In 2022, spending on innovative new medicines (New Chemical Entities) accounted for 16% of Korea's total pharmaceutical expenditures, reflecting a modest increase. However, this remains significantly lower than the A8 countries' average of 55.7% -- a key reference point for the Korean government in Health Technology Assessment (HTA), including the United States. This disparity highlights the need for a more supportive environment to enhance access to innovative treatments.

In 2024, the Korean government unveiled the "Second National Health Insurance Comprehensive Plan" and its "2024 Implementation Plan," which include the enhancement of patient access by valuing innovative medicines. This includes initiatives such as shortening the reimbursement evaluation process for new medicines used in treating life-threatening diseases from 330 days to 150 days through the "Approval-Evaluation-Negotiation System"; implementing a flexible ICER threshold for innovative new medicines; and expanding the "RSA" to include

medicines that significantly deteriorate the quality of life. The plan aims to extend eligibility for premium pricing benefits to certain pharmaceutical companies as well.

In addition, the Korean government is also planning to implement multiple measures to exert pressure on drug prices for the sustainability of the national health insurance budget. These measures include the de facto abolition of the health economic assessment exemption system and the imposition of an obligation to generate Real-World Evidence (RWE), revision to the “Price-Volume Agreement (PVA),” re-evaluation of reimbursed drugs, and re-evaluation of international drug prices.

The Second National Health Insurance Comprehensive Plan includes measures to strengthen the sustainability of the health insurance system and promote public health. However, specific improvements to the drug pricing system for recognizing the value of innovative medicines have not been realized. The existing pricing and reimbursement methods remain unchanged, and there has been no substantial reform. While the drug pricing benefits in the plan reflect both government and pharmaceutical industry input, further refinement through public-private consultations is needed. Industry concerns suggest that the improvements may be superficial, emphasizing the need for a thorough evaluation of the policy's impact and clear alternatives.

Another area for improvement in terms of promoting innovation is the “Innovation Pharmaceutical Company (IPC)” designation system, which the Korean government has been implementing since 2012 to promote and recognize the innovation of pharmaceutical companies. If a company is designated as an IPC, it can receive tax benefits, R&D support, premium pricing, and so on. However, as of February 2025, only four out of the 49 IPCs are multinational companies, indicating that the evaluation criteria may be overly favorable to domestic companies, particularly in terms of recognizing innovativeness.

Fortunately, the Korean government has been in discussions with the industry to enhance the IPC designation system. It is expected to announce improvements to the system in the first half of 2025. The industry anticipates that these changes will lead to fair evaluation and recognition of innovativeness for both domestic and multinational companies. The industry welcomes the government’s efforts to improve the system and to accurately reflect the value of innovative drugs. Aside from the evaluation criteria of IPC designation, the benefits conferred after being designated as an IPC are quite limited for multinational companies. To establish and foster a virtuous cycle in the innovation ecosystem, tangible benefits that recognize innovation for IPCs, such as preferential pricing and expedited procedures in the pricing and reimbursement processes, must be made visible. The industry is

committed to collaborating closely with government agencies to ensure effective implementation and calls for a clear policy direction that fosters seamless collaboration across ministries.

- **Issue**
  Rigid drug pricing and reimbursement policies that do not reflect the characteristics of the pharmaceutical industry and the value of innovation

- **Relevant Regulations**
  Global Innovative New Drug Pricing Benefit System

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), Health Insurance Review and Assessment Service (HIRA), National Health Insurance Service (NHIS)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions) & Article 2 (Access to Innovation)

- **Recommendation**
  AMCHAM urges the Korean government to uphold its commitment under the KORUS FTA amendment by accelerating the appropriate recognition of new medicines' value. We encourage a shift in drug pricing policies from a budgetary constraint approach to one that prioritizes flexibility and innovation, ultimately enhancing patient access to cutting-edge treatments.

Necessity of Dual Pricing for Access to Innovative Medicines and Sustainable Supply

Introducing innovative American pharmaceuticals into the Korean market requires a strategic pricing approach to ensure both equitable access and a sustainable supply. A dual pricing system is essential to addressing existing challenges within Korea's healthcare framework.

A key development occurred in early 2025 when new dual pricing regulations officially took effect. While this represents progress, the eligibility criteria remain highly restrictive, limiting the number of innovative drugs that can benefit. Among the 49 innovative pharmaceutical companies recognized in Korea, only four are foreign, with two originating from the U.S. This limited representation makes it difficult for many innovative drugs to qualify for dual pricing, increasing the risk of "Korea passing" or market withdrawal.

Additionally, Korea continues to assess new drug prices based on GDP levels set in 2007, failing to reflect the country's significant economic growth. As a result, high-cost innovative drugs developed in the U.S. often enter the Korean market at significantly lower prices, undermining their perceived value. Further complicating matters, Korea's complex post-evaluation measures frequently lead to repeated price reductions, making it challenging for pharmaceutical companies to sustain operations. This raises concerns about potential market exits or delayed product launches due to unsustainable pricing expectations.

Dual pricing can help mitigate these risks by allowing pharmaceutical companies to differentiate between the actual price and the listed price of their products. This would prevent Korea's lower drug prices from influencing global pricing structures, reducing the likelihood of "Korea passing" or market withdrawal. While dual pricing is a step in the right direction, Korea's drug pricing system remains unsustainable from the perspective of the U.S. companies, underscoring the need for further improvements.

- **Issue**
  The low initial pricing set at the time of reimbursement launch in the Korean market, combined with repeated price reductions, has heightened the risk of "Korea passing" and market withdrawal. This underscores the urgent need for improvements through the effective implementation and application of dual pricing.

- **Relevant Regulations**
  Criteria for Decision and Adjustment of Drugs (MOHW)

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), National Health Insurance Service (NHIS), Health Insurance Review and Assessment Service (HIRA)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 2(Access to Innovation)

- **Recommendation**
  AMCHAM urges the Korean government to revise current dual pricing regulations to enhance their practical applicability and effectiveness.

Need for Implementation of Indication-Based Pricing for Pharmaceuticals

Traditionally, many pharmaceuticals have been approved based on a single indication for their efficacy. However, there has been a surge in the development and release of new drugs that are approved for multiple indications. For example, in 2018, approximately 75% of oncology drugs sold in the United States were found to have multiple indications. This trend includes the continuous release of products, such as immuno-oncology agents, that can treat various diseases. As a result, while the pricing of a drug with a single indication often correlates directly with the value of that indication, the increasing prevalence of drugs with multiple indications necessitates a reasonable reflection of the value associated with each indication in their pricing.

In light of this shift, the existing single pricing system in South Korea is inadequate as it fails to reflect the diverse value of multiple indications. Consequently, only a few initially listed indications receive insurance coverage, while later indications face significant hurdles in obtaining insurance applicability. This situation leads to serious accessibility issues for patients requiring multi-indication drugs.

To address these issues, several major countries have implemented indication-based pricing schemes that differentiate the value of pharmaceuticals based on their clinical usefulness and cost-effectiveness for each indication. For instance, countries like Italy and Switzerland have established differential refund rates based on indications, while France and Japan employ a weighted average price approach for indications.

- **Issue**
  The existing single pricing system in South Korea does not adequately reflect the diverse value of multiple indications for pharmaceuticals, leading to limited insurance coverage for new indications and decreased accessibility for patients.

- **Relevant Regulations**
  Pricing & Reimbursement (P&R) regulations

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), National Health Insurance Service (NHIS), Health Insurance Review and Assessment Service (HIRA)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 2(Access to Innovation)

- **Recommendation**
  AMCHAM urges the Korean government to implement a P&R system that acknowledges the value of multiple indications, starting with a pilot program for indication-based pricing and progressing to full-scale adoption.

Establishing a National Immunization System and Improving the National Immunization Program (NIP) Policy

Given Korea’s demographic shifts and the rise of emerging infectious diseases, the KDCA's decision-making process for including new, innovative vaccines in the NIP must be predictable and expedited. Establishing a comprehensive National Immunization System (NIS) would ensure efficient and equitable vaccine distribution, improve coverage, streamline logistics, and provide timely access, particularly in underserved or remote areas. A well-structured system will also enhance immunization tracking, optimize supply management, and enable faster responses to public health threats.

Additionally, the agenda calls for a comprehensive review and enhancement of the National Immunization Program (NIP) policies. This includes updating vaccination schedules, expanding the list of vaccines based on emerging medical evidence, and strengthening public awareness initiatives to increase vaccination rates. Enhancing NIP policies will require improved training for healthcare providers, more effective communication strategies, and better coordination between national and local health systems.

To achieve these goals, three key recommendations are proposed:

1. Establishing a clearer process, timeline, and guidelines for the NIP system and vaccine tender standards.
2. Accelerating the inclusion of new innovative vaccines by allowing pharmaceutical companies, medical societies, and other stakeholders to officially apply for NIP listing of MFDS-approved vaccines.
3. Holding regular consultative advisory meetings and involving the pharmaceutical industry in the NIP process, particularly in the decision-making regarding the introduction of new vaccines.

These improvements will help build a more robust and responsive immunization framework, ensuring Korea is well-prepared to address current and future public health challenges.

- **Issue**
  Unpredictable NIP expansion and review timeline, delaying NIP inclusion of new innovative vaccines

- **Relevant Regulations**
  Infectious Disease Control and Prevention Act and Enforcement Regulation of the Act

- **Relevant Agencies**
  Korea Disease Control and Prevention Agency (KDCA)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 2(Access to Innovation) & Article 3 (Transparency)

- **Recommendation**
  AMCHAM urges the Korean government to clarify processes, accelerate new vaccine inclusion through official applications, and involve the pharmaceutical industry in decision-making for a more effective public health response.

Intellectual Protection Challenged by the Amendment to the Patent Act

The recent amendment to the Patent Act in December 2024 introduces a cap on the extension of patent terms and limits the number of patents that can be extended per approval to a single patent, which has a significant impact on pharmaceutical companies holding patented drugs.

- Patent Term Extension (PTE): The additional restriction of limiting the extension period to a maximum of 14 years from the approval date and restricting the number of extendable patents to one per approval is expected to create a more unfavorable environment for new drug patent holders.

- Insufficient Compensation for Patent Infringement: Recent rulings by the Korean Supreme Court have resulted in inadequate compensation for global pharmaceutical companies' innovative new drugs when patents are infringed. The forced price reduction of innovative products due to the market entry of generic products reduces incentives for R&D investment and weakens patent rights.

Prior to the announcement, the U.S. pharmaceutical companies operating in Korea have expressed deep concerns about the unilateral legislative process, where the opinions of various stakeholders had not been sufficiently considered, despite the substantial impact the bill may have.

In addition, the Democratic Party of Korea has recently proposed a bill to partially amend the Patent Act. This amendment aims to provide clear grounds for the government to exercise compulsory licensing in cases of national emergencies, specifically to prevent the spread of Class 1 infectious diseases such as COVID-19.

Drugs can only enter the market after undergoing a strict and lengthy review and approval process by health authorities, even after filing a patent application. Due to this characteristic, the patent term extension system is a critical component for pharmaceutical innovation. Thus, the system should be designed to appropriately compensate for the time spent on the approval process and provide incentives to continually encourage the research and development of new innovative medicines.

AMCHAM encourages the Korean government to collaborate with key stakeholders to either halt the enactment of the Patent Act Amendment Bill or amend the bill to align with U.S. practices. Specifically, the amendment should ensure that the Patent Term Extension (PTE) granted to the first and only patient covers all future indications approved before the expiration of the already-granted PTE. Additionally, a

comprehensive review of the IP compulsory licensing issue is essential for effective pandemic preparedness.

- **Issue**
  IP Challenges with the Patent Act Amendment Bill & Proposed Amendment to Patent Act on Compulsory Licensing

- **Relevant Regulations**
  The Patent Act, Patent Regulations, Pricing & Post-Management System

- **Relevant Agencies**
  Ministry of Health and Welfare (MOHW), Korean Intellectual Property Office (KIPO)

- **Relevant KORUS Provisions**
  Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions) & Article 2 (Access to Innovation)

- **Recommendation**
  AMCHAM urges the Korean government to collaborate with key stakeholders to either halt or amend the Patent Act Amendment Bill to align with U.S. practices, ensuring that PTE granted to the first patent covers all future indications approved before PTE expiration. Additionally, a comprehensive review of the IP compulsory issue is needed for effective pandemic preparedness.

TAXATION

- Overview
- Predictability in Tax Enforcement

TAXATION

OVERVIEW

South Korea's tax system is often perceived as unpredictable, which can present challenges for businesses, particularly foreign investors. Frequent revisions in tax laws and varying enforcement practices can create an environment of uncertainty that disrupts business planning and complicates the development of long-term investment strategies. For foreign investors who rely on clear and stable frameworks to navigate complex markets, these shifts in the tax landscape can make it more difficult to evaluate investment opportunities, whether for new ventures or expanding existing operations. While the government has made efforts to improve transparency in tax administration, the complexity and uncertainty surrounding tax regulations and compliance enforcement remain a concern for both local and international businesses. This unpredictability can complicate risk assessments, making decision-making processes around expansion, resource allocation, and long-term planning more challenging.

To better attract and retain global investors, it would be beneficial to enhance clarity and predictability in tax regulations. Measures such as expanded tax ruling requests and expedited advance pricing agreements could provide businesses with practical tools to obtain the certainty needed to make well-informed decisions and support cross-border transactions.

INDUSTRY ISSUES

Predictability in Tax Enforcement

To attract and retain global investors, it is crucial for Korea to enhance clarity and predictability in its regulatory environment, facilitating effective business planning.

To improve the predictability of the tax environment, the National Tax Service (NTS) could consider expanding the circumstances under which taxpayers can request tax rulings. By offering the possibility of advance rulings during the planning phase, even before an actual transaction occurs, the NTS could help businesses gain the certainty they need to make well-informed decisions. Additionally, it would be greatly appreciated if the NTS could explore ways to make the advance pricing agreement program more accessible and user-friendly for taxpayers. Simplifying these procedures and/or encouraging and expediting requests would improve predictability and help companies feel more confident in engaging in cross-border transactions.

- **Issue**
  The unpredictability of tax enforcement can create operational challenges for businesses and could potentially deter investment, especially for foreign enterprises.

- **Relevant Regulations**
  Corporate Tax Act, International Tax Coordination Law

- **Relevant Agencies**
  National Tax Service (NTS)

- **Recommendation**
  AMCHAM recommends that the National Tax Service (NTS) consider expanding opportunities for tax rulings and streamlining the advance pricing agreement process. These adjustments would offer businesses the certainty they need to plan, invest, and engage in cross-border transactions with confidence.

Table of Abbreviations

ABBR.	EXPANDED
AMCHAM	American Chamber of Commerce in Korea
CAFE	Corporate Average Fuel Economy
CBI	Confidential Business Information
CC	Common Criteria
CCA	Chemical Control Act
CED	Coverage with Evidence Development
CMS	Center for Medicare and Medicaid Services
COVID	Coronavirus Disease-19
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CSAP	Cloud Security Assurance Program
DAPA	Defense Acquisition Program Administration
ECHA	European Chemicals Agency
ELV	End-of-life Vehicle
EMA	European Medicines Agency
EPR	Extended Producers' Responsibility
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FSC	Financial Services Commission
FSS	Financial Supervisory Service
FTA	Free Trade Agreement
GHG	Greenhouse Gas
HIRA	Health Insurance Review and Assessment Service
HVAC	Heating, Ventilation & Air Conditioning
IaaS	Infrastructure-as-a-Service
ICT	Information Communication Technology
IPC	Innovative Pharmaceutical Company
JECFA	Joint FAO/WHO Expert Committee on Food Additives
K-BPR	Safety Control Act of Household Chemical Products and Biocidal Products
KCC	Korea Communications Commission

KDCPA	Korea Disease Control and Prevention Agency
KEA	Korea Energy Agency
KFTC	Korea Fair Trade Commission
KISA	Korea Internet Security Agency
KORUS	Free Trade Agreement between the United States of America and the Republic of Korea
K-REACH	Act on the Registration and Evaluation of Chemicals
KTB	Korea Treasury Bond
LMO	Living Modified Organism
MAFRA	Ministry of Agriculture, Food and Rural Affairs
ME	Ministry of Environment
MFDS	Ministry of Food and Drug Safety
MOA	Memorandum of Agreement
MOEL	Ministry of Employment and Labor
MOHW	Ministry of Health and Welfare
MOLIT	Ministry of Land, Infrastructure and Transportation
MOTIE	Ministry of Trade, Industry and Energy
MRFTA	Monopoly Regulation and Fair Trade Act
MSDS	Material Safety Data Sheet
MSIT	Ministry of Science and ICT
MVCA	Motor Vehicle Control Act
NDC	Nationally Determined Contribution
NECA	National Evidence-based Healthcare Collaborating Agency
NHIS	National Health Insurance Service
NHPA	National Health Promotion Act
nHTA	New Health Technology Assessment
NIE	National Institute of Ecology
NTS	National Tax Service
OECD	Organization for Economic Cooperation and Development
OEM	Original Equipment Manufacturer
OR	Only Representative
OSHA	Occupational Safety and Health Act
PIPA	Personal Information Protection Act
PIPC	Personal Information Protection Committee

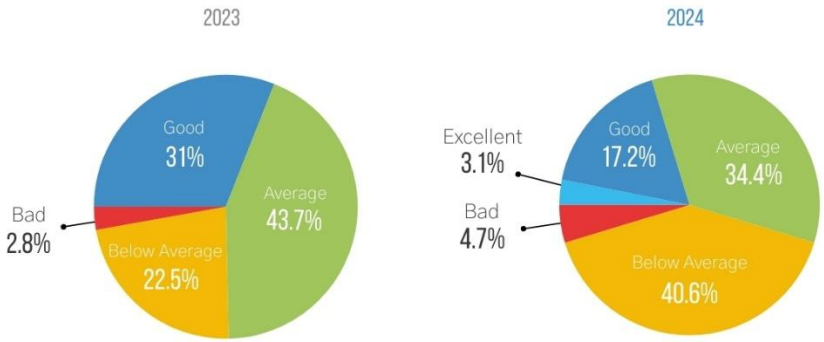
PR	Parallel Review
P&R	Pricing & Reimbursement
RDA	Rural Development Agency
R&D	Research & Development
REC	Renewable Energy Certificate
RFP	Request for Proposals
RFQ	Request for Quotation
RIFM	Research Institute for Fragrance Materials
SMEs	Small and Medium-Sized Enterprises
TAA	Technical Assistance Agreement
TBA	Telecommunication Business Act
WHO	World Health Organization
WTO	World Trade Organization

AMCHAM Business Survey 2025

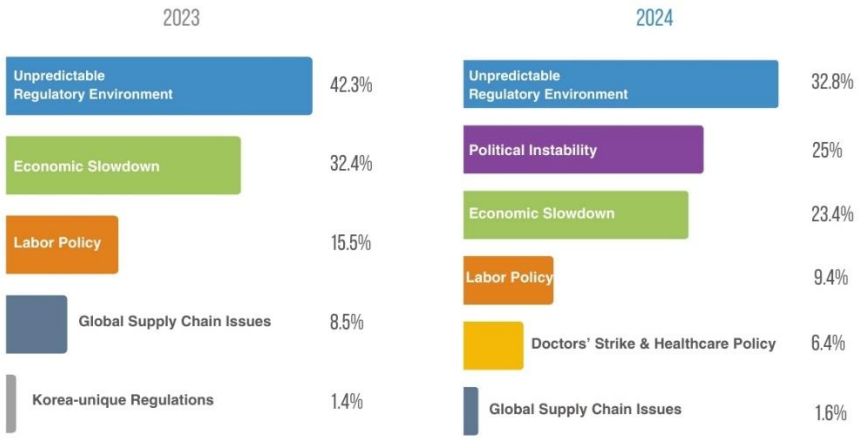
AMCHAM Since 1953 American Chamber of Commerce in Korea

Business Climate of Korea 2024

▸ *Current Business Environment in Korea*



▸ *Biggest Risks to Business Environment*



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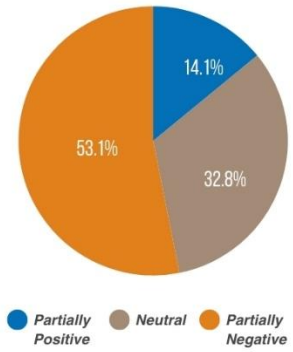
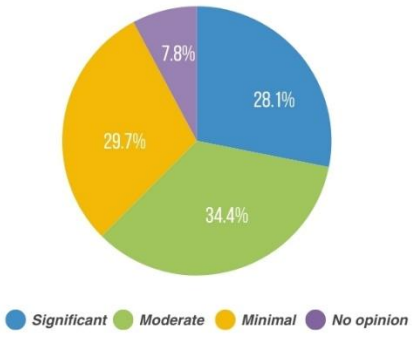
Business Growth Performance

Economic & Political Affairs

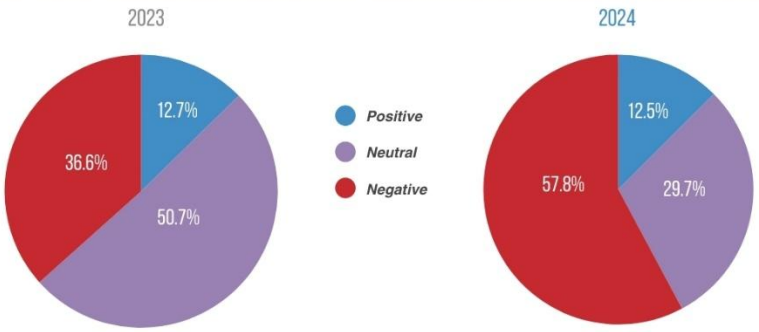
Impact of Global Economic Landscape



Impact of Recent Political Developments



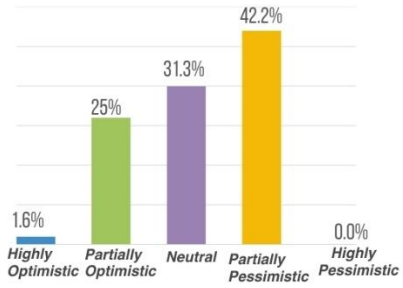
2024 Impact of Government Policies and Reforms



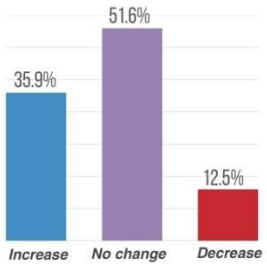
AMCHAM Business Survey 2025

Outlook for Korea

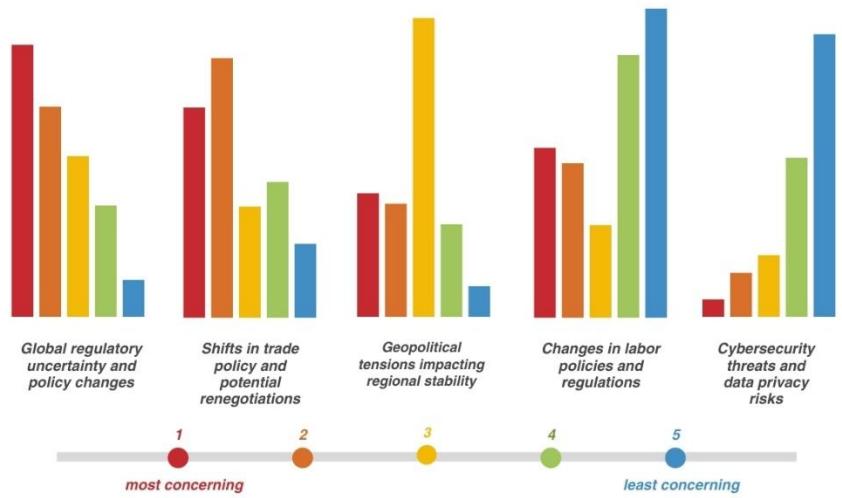
2025 - 2027 Business Outlook



2025 - 2027 Investment Outlook



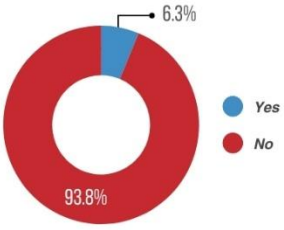
Potential Risk Factors



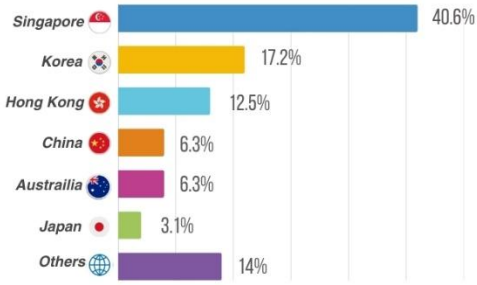
AMCHAM Business Survey 2025

Korea as a Regional Business Hub & APEC 2025

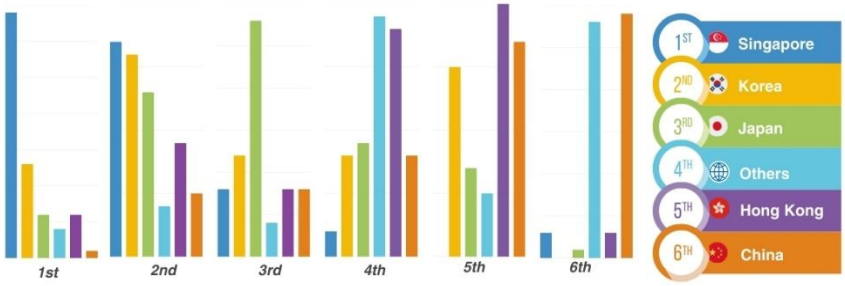
Is your company considering the possibility of relocating its Asian regional headquarters?



Location of Current Regional HQ

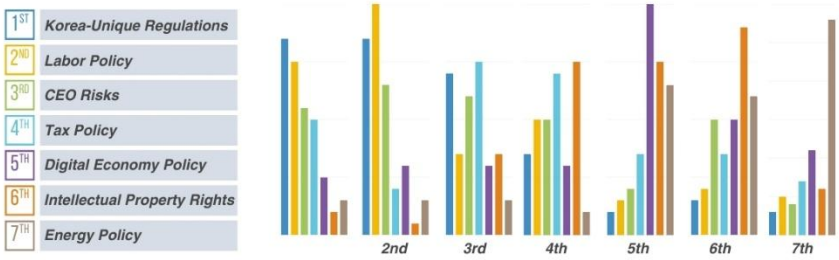


Countries Most Preferred as Regional HQ



1st = most attractive / 6th = least attractive

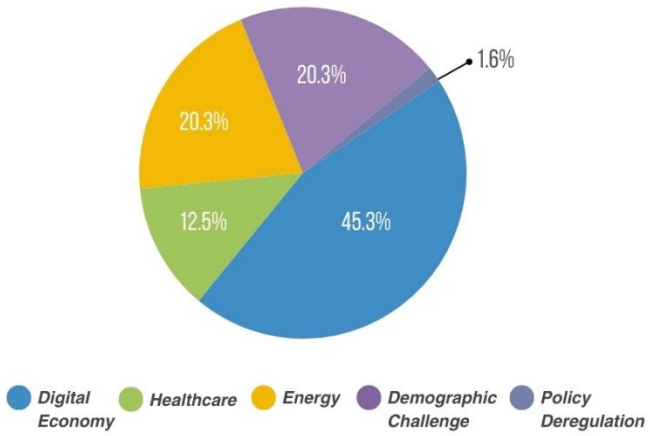
Reform Areas to Make Korea Regional HQ



1st = most attractive / 6th = least attractive

Korea as a Regional Business Hub & APEC 2025

Critical Area for Effective Private Sector Engagement at APEC 2025



Important Factor for Korea's Successful Hosting of APEC 2025