

70th anniversary of U.S.-Korea Alliance & AMCHAM Korea

2023

Expanded Edition

Business Environment Scorecard:

KORUS FTA & Indo-Pacific Economic Framework





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Business Environment Scorecard

Rating	Industry	Key Issues	Recommendations
Good Progress	Customs	 Origin Verification Lack of Transparency and Predictability	Utilize newly established Rules of Origin Working Group to address customs issues in transparent process that includes international companies.
Needs Improvement	Aerospace & Defense	 Onerous and Excessive Penalty Terms in Offset Guidelines Unclear Guidelines and Late Determination on Domestic Industrial Cooperation Quota The Increase in the Offset Quota for Sole-source Contracts 	 Incorporate additional provision in the Offset Guidelines so DAPA could consider replacement projects by the contractor that has greater offset value than the shortfall. Determine the exact extent of the Consortium requirement at an early stage so that overseas contractors could develop and propose high-quality industrial packages. Consider reductions in offset obligation for the sole-source program for effective and timely deployment of the end user services
Needs Improvement	Automobiles	 Emissions Standards Extended Producer Responsibility Damage Disclosure Requirements Warranty/ Recall Requirements Sale of Pre-certified Vehicles 	 Align environmental and safety standards with the U.S. Refrain from implementing new regulations that would act as technical barriers to U.S. automobiles. Review automotive laws and regulations in cooperation with automakers and eliminate those deemed outdated and unnecessary.
Needs Improvement	Chemicals	 Disclosure of Confidential Business Information Expanded Scope of Consumer Chemical Product Regulations Test Methods for Consumer Chemical Products Redundant Regulation under the Chemical Control Act (CCA) 	 Eliminate registration requirements for changes that have no relevance to human health. Allow sufficient grace period for new registrations. Harmonize testing methods for safety standards of consumer chemical products with global standards. Eliminate duplicate regulatory requirements.

Needs Improvement	Competition & Fair Trade	 Due Process and Transparency Protections Inadequate Protective Measurements in terms of Patent Infringement 	 Ensure consistent enforcement of KFTC guidelines. Establish rules in which evidence obtained in violation of the rules of procedure established by the KFTC cannot be used in KFTC investigation. Introduce appropriate patent policy measures to protect legitimate patent rights of innovators.
Needs Improvement	Energy & Environment	 Need for RE100 Policy Changes Localization Policy for Offshore Wind Turbines Domestic Certification Requirements for Large-and Medium-Sized Wind Turbines Need for Roadmap and Conversion Plan to Reduce HFC Usage 	 Commit to supporting the use of renewable energy and recognize the need to accelerate the progress of RE100 in Korea. Commit to the Most Favored Nation Treatment Principle and eliminated localization policy. Mutual recognition of safety certification should be allowed. Needs to develop a roadmap and conversion plan to reduce the usage of HFCs
Needs Improvement	Financial Services	 Differentiation of Information Handling for Corporate vs. Consumer Clients Measured liberalization of Korean data protection standards for financial companies Liberalization of firewall standards among financial entities within Korea Relaxation of Korean Network Segregation for Financial Companies Relaxation of Restriction on the Short Sale of KTB 	 Corporate client information requires an independent guideline. Liberalize data protection standards to a level comparable to the U.S. and other developed OCED nation standards. Liberalize firewall standards between financial entities within Korea to facilitate the exchange of information between financial entities within Korea. Liberalize network segregation and cloud computing standards for financial companies. Relax the short sale rule so that banks can cover KTB position on the bond settlement.
Needs Improvement	Food & Beverage	 Complicated risk review of living organisms and lack of transparency and predictability Unfair Restrictions on TV advertisement Prohibition on e-commerce sales of beverage alcohol 	 Streamline the approval process for the safety review for genetically modified crops by eliminating redundant and unnecessary procedures, and increase transparency and predictability. Lift ban on the broadcast advertising of alcoholic beverages containing 17% ABV or above. Allow advertising for alcohol products above 17% ABV to ensure a level playing field.

Needs Improvement	Government Procurement	Exclusion of U.S. companies through the designation of industries and products as appropriate for SMEs	Refrain from further closing the government procurement market to U.S. companies.
Needs Improvement	Pharma, Medical Devices	 Pricing of Global Innovative Drugs Reimbursement Coverage for Innovative Medical Technologies Lack of Transparency and Predictability Delayed Patient Access to New Medical Technologies 	 Revise innovative drug pricing to remove conditions that are discriminatory against global companies. Adopt flexible and practical approaches for reimbursement coverage determinations. Provide opportunities for the industry to comment on measures related to the regulations of pharmaceutical products and medical devices. Accelerate reimbursement coverage and pricing approval processes and include both in parallel review.
High Concern	Digital Economy	Fair Treatment toward U.S. companies Application of the Cloud Security Assurance Program (CSAP) Personal Information Protection Act (PIPA) Designation of a Local Representative Data Center Legislation	 Ensure U.S. companies are able to operate and compete with Korean and other foreign competitors on a level playing field. Allow logical network separation of non-sensitive information of the public sector and alleviate restrictions on entering the public sector cloud services market. Align personal information protection regulations to global standards. Reconsider the requirement for foreign telecommunications service providers to designate a local agent in Korea. Encourage Korea to partner with global companies to share best practices and lessons in service reliability.

INTRODUCTION

In commemoration of the 70th anniversary of the U.S.-Korea alliance and that of the American Chamber of Commerce (AMCHAM), AMCHAM is pleased to publish an expanded version of the annual KORUS FTA Scorecard report. This year's report covers broader industries and issue areas that are not traditionally covered under the KORUS FTA but constitute key aspects of doing business in Korea.

As the oldest and largest foreign chamber of commerce operating in the Republic of Korea today, AMCHAM is the premier business organization promoting the bilateral U.S.-Korea economic relationship. As a strong advocate for the KORUS FTA and the Indo-Pacific Economic Framework for Prosperity (IPEF), AMCHAM firmly supports the goal of advancing resilience, sustainability, inclusiveness, economic growth, fairness, and competitiveness between trading partners. We have been a close partner and resource to the U.S. government in this mission, working as a bridge between the two governments and business communities to secure a level playing field for U.S. companies in Korea.

Mission of AMCHAM Korea

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

- 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

- 70 years in history
- 800+ corporate members and affiliates
- 1.500+ individual members
- 30 industry committees
- Board of Governors



This report will outline the major areas of regulatory issues and recommendations of the U.S. business community regarding the implementation of the amended KORUS FTA, the four pillars of the IPEF (1. Fair & Resilient Trade; 2. Supply Chain Resiliency; 3. Clean Energy, Decarbonization, and Infrastructure; and 4. Taxation and Anti-Corruption), and the broader business environment for American companies in Korea. By supporting the full and faithful implementation of the amended KORUS FTA and principles of the IPEF, we hope that this report will contribute to strengthening the U.S.-Korea economic partnership to the benefit of businesses and consumers of both countries.

ECONOMIC IMPACT OF KORUS FTA

In 2022, the United States and South Korea marked the 10th anniversary of the KORUS FTA. At the time of its implementation a decade ago, the KORUS FTA represented the most advanced FTA in terms of the coverage of its comprising factors and legal binding force. It remains so today after the renegotiation of the agreement in 2018.

Over the last decade, Korea and the United States both benefited from the KORUS FTA with the total trade in goods rising 71% from \$100.1 billion in 2011 to \$171.2 billion in 2022. Both countries have seen a relatively equal amount of growth in goods exports. U.S. goods exports to Korea grew by 51% while Korea's exports to the United States grew by 86%.

There have been changes in the patterns of trade. Prior to the KORUS FTA's implementation, machinery and electrical parts were the two biggest categories of exports from the U.S. to Korea. Energy exports, specifically exports of crude oil and LNG, have since surpassed machinery and electrical parts as the leading U.S. exports to Korea.

Despite the disruption from the pandemic, trade between the U.S. and South Korea has continued to expand. U.S. exports to South Korea were at a high of \$56.5 billion in 2019 but grew to \$65.7 billion in 2022. Korea has seen a similar growth, with its exports to the U.S. increasing from \$77.5 billion in 2019 to \$105.5 billion in 2022.

Foreign Direct Investment has also grown under the KORUS FTA. U.S. investment in South Korea has grown modestly from \$28.2 billion in 2011 to \$38.1 billion in 2021, while South Korean investment in the U.S. has grown by 264% since 2011. South Korean investment in the U.S. grew from \$19.9 billion in 2011 to \$72.5 billion in 2021.

INDO-PACIFIC ECONOMIC FRAMEWORK (IPEF)

As part of the broader strategy to address the growing challenges in the Indo-Pacific region, the Biden administration has shown a continued commitment to the policy of securing a free and open Indo-Pacific as a top priority of U.S. foreign policy.

During the East Asian Summit in October 2021, President Biden announced the Indo-Pacific Economic Framework (IPEF) whereby the U.S. would secure a free and open Indo-Pacific region by promoting digital economy, technology, resilient supply chains, decarbonization and clean energy, infrastructure, and worker standards. 14 countries in the region, representing 40% of the global economy, have joined the initiative, and Korea has confirmed its participation in all four pillars of the IPEF.

AMCHAM will be establishing an IPEF Working Group in 2023 to provide industryspecific policy suggestions on the IPEF agenda between the U.S. and Korea.

BUSINESS ENVIRONMENT IN KOREA AS OF 2023

American businesses operating in Korea are major stakeholders for both U.S. and Korean economies. AMCHAM and its member companies stand ready to assist the efforts of both governments to create a stronger, more vibrant, innovative, and globally competitive bilateral economic and commercial partnership.

President Yoon Suk Yeol, since his inauguration on May 10, 2022, has championed economic policies to stimulate private sector-led growth and promote advanced industries post-COVID. Some of the recent examples include: taxation reform which includes corporate tax cuts; promotion of the semiconductor, green tech, and bio industries; expansion of nuclear power industry; and other deregulatory measures including labor market reform.

AMCHAM fully supports the Korean government's policy goal to create more sustainable jobs through greater integration of the global economy. In this context, AMCHAM encourages the Korean government to consult both domestic and international business communities prior to the roll-out of regulatory reforms to ensure that due consideration is given to the unique conditions affecting each sector.

transparency and predictability in regulatory changes is crucial to the overall health of the business environment and for the AMCHAM business community to commit future investments in and exports to Korea. We are particularly concerned about rapid and dramatic changes made to laws and regulations in response to domestic political pressures.

AMCHAM acknowledges and commends the significant progress the Korean Government has made in giving prior notice regarding new rules and regulations that impact businesses.

AMCHAM is committed to working closely with the U.S. and Korean governments to make further progress in the areas of improvement outlined in this report. We believe that these policy suggestions, once implemented, will go a long way towards creating a level playing field for foreign and domestic businesses in Korea and deepening the vital bilateral trade and investment ties between Korea and the United States.



AEROSPACE & DEFENSE

- Overview
- Onerous and Excessive Penalty Terms in Offset Guidelines
- Unclear Guidelines and Late Determination on Domestic Industrial Cooperation Quota
- Increase in the Offset Quota for Sole-source Contract

AEROSPACE & DEFENSE

OVERVIEW

South Korea is the United States' 18th largest market for aerospace exports as of May 2022. In 2021, the U.S.' aerospace exports to South Korea recorded a total of \$1.285 billion. Nearly 95 % of South Korea's total volume of aerospace imports from the world were made up of aircraft and their parts and components with more than 80 % of it imported from the United States.

AMCHAM strongly believes that the efficient reform of Korea's defense acquisition policy will serve to attract robust, high-value business opportunities to Korea. We are committed to supporting the Republic of Korea's national security interests and industrial objectives since its founding as well as the ROK-U.S. Alliance. AMCHAM hopes that both governments will cooperate with the industry to refine its acquisition policies to strengthen Korea's long-term ability to expand its defense industry ambitions on the global stage and bolster the strategic deterrence capability of the Republic of Korea.

INDUSTRY ISSUES

Onerous and Excessive Penalty Terms in Offset Guidelines

Articles 23.3. and 23.4. (see below) of the current Offset Guidelines (first introduced in Dec 2021) provide 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.

We recognize and appreciate that this change has incorporated the AMCHAM's request to reconsider the previously non-liquidating nature of the offset penalty provision. However, the newly introduced elements in this article create the following issues:

First, 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, an additional \$10m will be confiscated, making the total confiscated amount \$12m. 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, which is a very burdensome outcome.

This raises another issue: the performance bond is not sufficient to cover the total amount of confiscation, but there is nothing in the Guidelines that could compensate for this potential occurrence. We also need to bear in mind that performance bonds cost money and will have the effect of impacting the overall procurement cost.

A bigger picture issue here is the fact that the restrictive penalty provision in the Offset Guidelines binds the Defense Acquisition Program Administration (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 downturns in market conditions that 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. Therefore, it is highly recommended that an additional provision be included so that DAPA would have an option (but not necessarily an obligation) to consider replacement projects by the contractor that has a greater offset value than the shortfall.

Article 23.3. and 23.4 of DAPA Offset Guidelines, June 2022

"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

June 2022 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 by the contractor that has a greater offset value than the shortfall.

Unclear Guidelines and Late Determination on Domestic Industrial Cooperation Quota

In Article 15.6 of the current Offset Guidelines (see below), the contractor may include direct industrial content as part of the proposal, which would then be eligible to be decremented from the overall offset obligation. However, this direct offset offering was made an essential requirement under the name of "Consortium" in the recent Request for Proposals (RFPs) for HUH-2 and Large Transporter Secondary Project (LTAP-2) programs, and the extent of the Consortium requirement was a significant percentage of the main contract value. While it is true that the DAPA OD had conducted a number of explanatory sessions to explain their plans for Consortium to overseas contractors in the run-up to these two programs, the exact details of the scope and criteria for Consortium were not formally notified until the release of the RFP itself.

The lack of clarity and the late timing of Consortium determination present significant difficulties for overseas contractors in bidding for applicable DAPA programs. A potential bidder does not know, for example, how big the Consortium commitment needs to be until the RFP is released. When the RFP is released, the bidder has only around 45 – 90 days to prepare and submit a compliant proposal.

In many instances – particularly small-quantity procurements – a large-scale Consortium requirement may prove to be not only difficult but impractical, for the following reasons:

One, since a greater proportion of the subject system will need to be built in Korea, much higher levels of investment must be made to set up the local industry, which drives up the procurement costs. Two, it takes time to set up the local industry to be ready to produce and ship parts. Any company that is not already producing the parts for the bidder will require the necessary tooling, equipment, and technical data/assistance to be ready to manufacture, and additional time to actually produce the parts and deliver them. This is potentially a multi-year process and may not align with the delivery schedule of the subject system. A timely delivery is an important requirement to fulfill for the ROK services.

U.S. contractors are supportive of DAPA's plans to provide more opportunities for the ROK industry and create higher levels of involvement for ROK companies in major procurements. However, we believe it is important that efforts to require more direct industrial content be a multi-party process, rather than a unilateral determination. For example:

- There should be more occasions for meaningful dialogue between DAPA and overseas contractors, beyond a simple Q&A at DAPA-hosted sessions.
- The Korean government should engage overseas contractors through direct and regular discussions, rather than one-way survey and questionnaires (often outsourced to 3rd party research institutes).

Also, determining the exact extent of the Consortium requirements at an early stage would greatly help overseas contractors to develop and propose high-quality industrial packages. It would give them sufficient time to identify the right local companies, work through the U.S. government license issues, review quotes and proposals, and more. Unilaterally notifying bidders what the Consortium requirement is at the time of RFP release simply does not provide sufficient time to develop meaningful Consortium projects, which ultimately means the ROK industry does not receive the intended benefit of the DAPA policy.

Article 15.6 of DAPA Offset Guidelines, June 2022

"Where the IPT launches a foreign acquisition program via main program proposals under Article 119(3) of Regulations, if a Foreign Contractor signs the Main Contract by allocating a certain portion of its weapon systems (weapon systems, equipment, components, parts, etc.) to a KIP(s), the Director General may valuate the portion of the KIP(s)' participation under subparagraph 2. of Article 16(4), and deduct the value of the portion from Offset value, in which case, none of paragraphs from (1) to (5) shall be applied."

Issue

The requirement for industrial cooperation quota and offset coexist adding confusion to the policy without clear guidelines

Relevant Regulations

Article 15.6 of DAPA Offset Guidelines, June 2022

Relevant Agencies

Defense Acquisition Program Administration (DAPA)

Recommendation

AMCHAM urges the Korean Government to determine the exact extent of the Consortium requirement at an early stage to identify the right local companies, work through U.S. government license issues, and review guotes and proposals.

Increase in the Offset Quota for Sole-source Contract

Article 10.1.2. (see below) of the current Offset Guidelines (first introduced in Dec 2021) provides for 30% or greater offset obligation for sole source programs. This is a significant increase from the previous obligation threshold of 10%. We understand that DAPA's offset policy is intended to provide and expand opportunities for the ROK industry to become more involved in global supply chains, export their products to overseas markets, and enhance their capabilities. To this end, AMCHAM members have long been committed to providing such opportunities to our Korean industrial partners, and the ROK defense industry continues to benefit from the valuable purchase orders and know-how provided by U.S. contractors. At the same time, we must acknowledge the unavoidable fact that offset projects require investment and that the more offset obligation a procurement program has, the higher the cost of that program will be. A threefold increase in offset obligation for sole-source programs means that sole-source procurements will ultimately cost more for DAPA than before. This often impedes the end user services' ability to deploy the necessary systems effectively and on time.

Article 10.1.2. of DAPA Offset Guidelines, June 2022

- "(1) For the programs notified pursuant to Article 9(1) and (2), the Director General shall determine the Offset ratio as in the following subparagraphs in consideration of competing sources, attainability of the Offset negotiation target, etc. However, in the event that the amount for a unit program pursuant to Article 4(1) is not less than one hundred (100) million U.S. dollars, the IPT Director shall include it in the Basic Strategy of Acquisition Program, etc. and the Offset ratio shall be determined through the deliberation and coordination of the Defense Acquisition Program Promotion Committee (hereinafter referred to as the "Committee").
 - 1. For program with competing sources: fifty (50) percent or above of Estimated Main Contract Amount
 - 2. For programs without competing sources: thirty (30) percent or more of the Estimated Main Contract Amount

Issue

Significant increase in the offset quota for sole-source contract

Relevant Regulations

Article 10.1.2. of DAPA Offset Guidelines, June 2022

Relevant Agencies

Defense Acquisition Program Administration (DAPA)

Recommendation

AMCHAM recommends that the Korean government reconsider a threefold increase in offset obligation for sole-source program.



AGRICULTURE, FOOD & BEVERAGE

- Overview
- Agricultural Biotechnology
- Packaging Materials and Methods
- On-site Inspection of the OEM Manufacturers
- Unfair Restriction on TV Advertisement
- Alcohol E-Commerce

AGRICULTURE, FOOD AND BEVERAGE

OVERVIEW

Agricultural trade is a prime example of how expanded U.S.-Korea economic and commercial ties have benefitted both countries. While Korea imposes high tariffs averaging 57 % on agricultural goods from non-FTA partners, a majority of U.S. agricultural products are exempt from import duties under the KORUS FTA. U.S. agricultural exports to Korea have increased over 30% since the KORUS FTA entered into force in 2012. In 2021, Korea imported \$9.4 billion in agricultural products from the U.S., accounting for 28% of its total agricultural import market. South Korea was the sixth-largest export market by value for U.S. agricultural products in 2021.

Although the recent amendment negotiations of the KORUS FTA did not deal with agricultural trade, U.S. agricultural exports are expected to benefit from improvements made to customs and origin verification procedures that were agreed as part of the amendment package. AMCHAM hopes that the U.S. and Korean governments will continue to work together to promote mutually beneficial trade in agricultural goods.

ONGOING ISSUES

Agricultural Biotechnology

Agricultural biotechnology contributes to higher crop yields, health and environment, and conservation of energy, soil, and water resources. Unfortunately, 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 a challenging regulatory environment for U.S. agricultural biotechnology exports.

The Ministry of Food and Drug Safety (MFDS) and the Rural Development Agency (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, per the LMO Act, three additional agencies, i.e. 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 mandated to be a part of the consultation process, making as many as five agencies conducting safety reviews for each of the new biotech crops. The Risk Review Consultations (RRC) by these three additional agencies have created unnecessary problems as each agency issues specific data requirements that cannot be justified by risk assessment principles. These additional requirements add no value to the assessment and have created issues of nontransparency and unpredictability in Korea's biotech crop safety assessment process. As the LMO Act mandates participation by all five agencies, it limits the potential for streamlining the system without legislative changes. The U.S. had multiple discussions with the Ministry of Trade, Industry and Energy (MOTIE) and other relevant agencies regarding this issue and will continue to engage with Korea on improving its approval process for agricultural biotechnology.

Since 2008, major grain exporting countries and their value chain stakeholders have repeatedly requested improvement in these regulations by amending the LMO Act to remove the requirement for the consultation of the three additional agencies in the RRC. However, there have been no meaningful improvements thus far.

Issue

The overly complicated process for risk review of living modified organisms, 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 process for genetically modified crops by eliminating redundant and unnecessary procedures and increasing transparency and predictability. To prevent non-tariff barriers in Korea's biotech grain trade which amounts up to \$2.5 billion a year, MOTIE, the responsible national authority for the LMO act, should be the appropriate ministry to take the initiative. It will also be important for the Korean government to clarify its position on how to deregulate agricultural products that are increasingly being developed through new breeding techniques such as gene editing (e.g. CRISPR). Such a policy should be based on science, as well as the terms stipulated in the KORUS FTA, so that its implementation would promote innovation and trade.

Packaging Materials and Methods

Currently, Korea targets 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 shall comply with the standards for packaging methods, covering

the rate of packaging space and layers. As per the Standards of Product Packaging Materials and Packaging Methods, the detailed standards for food and beverage products are as follows:

Products	Standards		
Froducts	Rate of packaging space	Number of package layer	
Processed food	Less than 15%	Less than 2	
Beverages	Less than 10%	Less than 2	
Alcohol	Less than 10%	Less than 2	
Confectioneries	Less than 20% (For decoration cake: less than 35%)	Less than 2	
Health functional food	Less than 15%	Less than 2	

However, due to various sizes and heights of products, it is difficult to apply a uniform method to each 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. Moreover, partial amendments to the Recycling Act proposed in 2020 mandate pre-inspection on packaging materials to ensure compliance with specified packaging requirements. Such regulations place an onerous financial burden on industry stakeholders and would delay product releases, weakening companies' competitiveness in the market.

Issue

Excessive regulations on packaging materials and methods

Relevant Agencies

Ministry of Environment (ME)

Relevant Regulations

Special Act on Imported Food Safety Control

Recommendation

We urge the Korean government to reconsider excessive regulations on packaging methods and materials.

On-site Inspections of the OEM Manufacturers

Per the Special Act on Imported Food Safety Control, the Ministry of Food and Drug Safety (MFDS) mandates that any business entity who imports and sells food, etc., and has entrusted manufacturing or processing to an exporting country by original equipment manufacturing (OEM) requires an imported food sanitation audit institution to conduct on-site inspections on an enterprise manufacturing or processing imported food, etc., by OEM. In pursuant of Article 10 of the Special Act, the MFDS may designate an institution that can professionally conduct on-site inspections. In particular, unless otherwise registered as a "good importer" pursuant to Article 7 (Registration of Good Importers) of the Special Act, it is required for a business entity to conduct an on-site inspection every two years regardless of its good track records of audit results, bearing all the expenses incurred by the inspection, including travel expenses, the interpretation fee, and etc. This imposes a severe burden on U.S. companies in importing OEM foods and health functional foods to Korea due to increased import costs and complicated administrative processes.

Issue

Burdensome requirements mandating OEM manufacturers to have an on-site inspection every two years

Relevant Agencies Ministry of Food and Drug Safety

Relevant Regulations Special Act on Imported Food Safety Control

Recommendation

We urge the Korean government to ease the mandatory on-site inspection requirements.

Unfair Restrictions on TV Advertisement

Citing health concerns, the Korean government bans TV commercials for high-calorie and low-nutrient foods, such as hamburger and pizza between the 5-7 pm timeframe, which could now be extended to 5-8 pm. There is a concern about reverse discrimination against certain food franchise industries including U.S. companies. Moreover, broadcast advertising of alcoholic beverages that contain 17% or more of alcohol is also prohibited in South Korea, while products below this threshold are permitted, albeit with restrictions. The general rules are as follows:

Medium Type	Alcohol below 17% ABV	Alcohol with 17% ABV and above
Terrestrial & Cable TV, SKY Life, Terrestrial & Satellite DMB, Real-time IPTV	Allowed from 22:00 to 7:00 of the following day	Completely banned
Radio	Allowed from 17:00 to 8:00 of the following day	Completely banned
IPTV VOD Advertisements	Allowed from 22:00 to 7:00 of the following day	Completely banned

The largest spirits category in Korea is Soju. It contains alcohol content just below 17% ABV and is thus able to advertise consistently within the rules above. Conversely, the majority of international spirits, especially whiskies that have a minimum 40% ABV requirement, are prohibited from any form of broadcast advertising. As is in the case of e-commerce, Korea is an outlier among leading and developed economies around the world in relation to TV and broadcast advertising. In Asia, specifically, developed markets like Japan, China, Taiwan, Singapore, and Australia all allow TV and radio advertising for alcohol products above 17% ABV. Unlocking advertising for alcohol products above 17% ABV in Korea (and other international spirits) will ensure a level playing field with local products.

Issue

Broadcast advertising prohibition of alcoholic beverages with 17% ABV or above

Relevant Regulations

National Health Promotion Act (NHPA), The Broadcasting Advertising Review Regulations

Relevant Agencies

Ministry of Health and Welfare (MOHW), Korea Communications Standards Commission (KCSC)

Recommendation

We urge the Korean government to reconsider extending the timeframe of TV advertisement of high-calorie and low-nutrient food and lift the ban on broadcast advertising of alcoholic beverages with 17% ABV or more.

Alcohol E-Commerce

As a general rule, e-commerce is not allowed for the liquor industry in Korea, contrary to the global best practices in leading economies like the UK, Australia, China, Japan, and the U.S. However, with the passing of the Act on Promotion of Korean Traditional Liquor in 2017 by the Ministry of Agriculture, Food and Rural Affairs, alcohol beverages locally produced using local ingredients receive a 50% tax reduction and are permitted to be sold to consumers via e-commerce. To be designated as "Korean traditional liquor", a product is required to be 1) manufactured by a holder of a national intangible cultural heritage, 2) manufactured by a Korean food master in the area of alcoholic beverages, designated under Article 14 of the Food Industry Promotion Act, and 3) produced directly by agricultural business entities.

E-commerce has accelerated the growth of the traditional liquor category during the COVID-19 pandemic leading to greater discrimination against non-traditional brands, especially imported products like Scotch whisky. Industry analysis suggests that e-commerce has helped the significant growth of the traditional liquor category, while the wider industry has experienced stagnant growth or decline.

More broadly, e-commerce sales of beverage alcohol – especially premium categories like whiskies – in key markets such as the UK, Australia, China, Japan, and the U.S. have grown significantly in recent years. It is unfortunate that South Korea – one of the world's leading economies and a global pioneer in setting cultural and lifestyle trends – lags behind in this policy area, adversely impacting consumer choice, government revenue, and the growth of exports like whiskies.

Issue

E-commerce sales prohibition of alcohol

Relevant Regulations

National Health Promotion Act

Relevant Agencies

National Tax Service (NTS), Ministry of Agriculture, Food and Rural Affairs (MAFRA)

Recommendation

We urge the Korean government to lift the ban on online liquor sales.



AUTOMOBILES

- Overview
- GHG/CAFE rules for 2026-2030
- End-of-Life Vehicle & Extended Producer Responsibility
- Damage Disclosure Requirements
- Warranty/Recall Requirements
- Sale of Pre-certified Vehicles

AUTOMOBILES

OVERVIEW

U.S. automakers have seen significant benefits under the KORUS FTA thanks in large part 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. As a result, U.S. exports of passenger cars to Korea have grown 627% since 2011, while Korean exports of passenger cars to the U.S. grew 83% in the same period. The U.S. share of Korea's imported automobile market has risen to the second highest, overtaking Japan.

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 will provide significant protection for the U.S. industry and potentially encourage further investment by Korean automakers in the U.S.

While technical measures imposed in the name of the environment or safety continue to create an unlevel playing field for U.S. automobiles in Korea, AMCHAM expects that U.S. automobile exports will grow as outstanding non-tariff barriers are addressed. In this context, any protective measures, such as new tariffs on imports of automobiles and automotive parts, taken in the interest of protecting the U.S. automotive industry, would be counterproductive and would risk undoing the significant gains that U.S. automakers have made in Korea under the KORUS FTA. AMCHAM hopes that both governments will cooperate with the industry to remove remaining barriers and refrain from imposing new barriers to the bilateral automotive trade.

INDUSTRY ISSUES

GHG/CAFE rules for 2026-2030

As part of the KORUS FTA amendment, Korea committed itself to taking U.S. regulations into account when setting future fuel economy targets and to include more lenient targets for small manufacturers. In early 2021, however, Korea finalized its regulation for the Korean Corporate Average Fuel Economy (CAFE) for 2021-2030, which adopted the most stringent overall greenhouse gas (GHG) target in the world, posing a significant barrier for U.S. automakers.

Recently, the Korean government has decided to improve its commitment to the climate change framework and push for a 37% reduction in emissions. In lieu of the Korean CAFE mid-term review, the Korean government plans to develop new GHG/CAFE rules for 2026-2030.

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 needs to adopt transparent procedures and communication with the industry in creating new GHG/CAFE rules for 2026-2030.

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 producers' 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.

Damage Disclosure Requirements

Korea requires automakers to notify a purchaser (1) of any "defect" (e.g., a scratch in the paint) occurring between the time the vehicle was released from the factory and its delivery to the purchaser and (2) whether the "defect" was repaired. The requirement imposes a much higher burden on imported automobiles, given the fact that the supply chain between manufacturer and consumer is longer, resulting in a higher chance that the vehicle might be scratched, etc., in transit. The burden is especially significant for low-volume importers.

Issue

Requirement to report repair history that is unfairly burdensome on imported vehicles

Relevant Regulations

Motor Vehicle Control Act / Damage Disclosure Regulation

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

AMCHAM recommends that Korea align with many U.S. states by excluding damages to glass, tires, bumpers and other interior components if replaced with original equipment manufacturer (OEM) parts and setting a de minimis reporting threshold at 4.5% of manufacturer's suggested retail price (MSRP). Additionally, repair costs should be calculated using automakers' Pre-Delivery Inspection Center repair costs, not using the rates assessed by independent repair shops for domestic as well as imported vehicles.

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 to notify 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 2%. 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.

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.

Issue

Vehicles imported into Korea for marketing and developmentrelated purposes that are not eligible for sale due to the strict interpretation of the regulation

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

We encourage the Korean government to permit 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.



CHEMICALS

- Overview
- Disclosure of Confidential Business Information
- Expanded Scope of Consumer Chemical Product Regulations
- Test Methods for Consumer Chemical Products
- Redundant Regulations under the Chemical Control Act (CCA)

CHEMICALS

OVERVIEW

Although U.S. chemical exports to Korea have benefitted from duty-free treatment under the KORUS FTA, Korea's regulatory environment, with a growing number of non-tariff technical burdens, remains challenging. Following highly publicized accidents involving toxic humidifier disinfectants in 2011, "chemophobia" has been widespread in Korean society. On multiple occasions, concerns about the safety of chemical substances in various household products have been inflated by sensationalist media reporting. In response, the Ministry of Environment (ME) and the Ministry of Employment and Labor (MOEL) have introduced a series of tightened regulations on chemical products. Korea's Act on Registration and Evaluation of Chemicals (K-REACH), Chemical Control Act (CCA), Consumer Chemical Products and Biocides Safety Act (K-BPR) and Industrial Health and Safety Act (ISHA) are examples of Korean standards that are overly strict, compared with regulations of the U.S. and the EU. Such regulations create an unlevel playing field by imposing regulatory barriers that inhibit U.S. companies' access to the Korean market.

ONGOING ISSUES

Disclosure of Confidential Business Information

K-REACH, CCA, and ISHA require the disclosure of the full composition information of chemical mixtures to the authorities. These are duplicate regulations but entail slightly different requirements and government systems, further complicating Korea's chemical regulatory system. Such disclosure requirement is especially burdensome for U.S. exporters of chemicals to Korea. U.S. exporters often cannot reveal such information either due to concerns over confidential information leakage, or because they may not have the full composition information when raw materials are supplied by a third party, such as "mixture in mixture" products. If a U.S. exporter cannot fulfill the disclosure requirement, its export to Korea will be restricted.

Under the amended K-REACH, ME provides the Only Representative ("OR," designated person in charge of registration and notification) method to comply with the registration and notification process for third-party importers. OR is the only way to register/notify chemical substances imported by third parties. However, the Korean market volume is too small compared to the global market volume to justify the cost and burden of complying with this process for global companies. Under the newly amended K-REACH, the penalty for the manufacture, importation, or sale of chemicals without registration has been heightened up to 5% of the average annual sales of the company for the three years prior to the year of violation.

The amended ISHA puts an additional burden on chemical companies. To import a chemical product, a company is required to register its data on the products' substance under the amended K-REACH, declare and obtain approval under K-CCA, receive approval on the Material Safety Data Sheet (MSDS), and receive the Confidential Business Information (CBI) approval for any substance registered as hazardous on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) that the company otherwise would not disclose for confidentiality reasons.

Issue

Korean regulations that require the disclosure of confidential business information

Relevant Regulations

Korea's Act on Registration and Evaluation of Chemicals (K-

REACH), Chemical Control Act (CCA), Industrial Health and Safety Act (ISHA)

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

While AMCHAM appreciates the importance of transparency to protect consumers from potentially dangerous chemical substances, this goal can be met by requiring companies to submit information only on hazardous substances so as to protect confidential business information. In addition, penalties for non-registration of substances should be adjusted to a level that is less severely punitive.

Expanded Scope of Consumer Chemical Product Regulations

K-BPR significantly expands the scope of consumer chemical products subject to registration and/or safety confirmation. The definition of "Consumer Products" is broadened to cover not only household products but also industrial/professional products. As a result, U.S. companies that import or produce consumer chemical products must fulfill the safety and labeling standards that entail significant costs and take on severe regulatory responsibilities, such as biennial reporting, testing at designated labs every three years, etc. Frequent and redundant registrations are required even for minor formula changes, creating particular difficulties for imported products.

Some products that were previously not subject to these requirements may fail to pass the newly required tests. In such cases, there will be a risk that the import and sale of such products will be discontinued. This will impact both U.S. exporters and Korean end users, especially where alternative products that fulfill the new safety and labeling standards are not available.

Issue

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

Relevant Regulations

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 relevance to human health. Percent changes, changes in minor ingredients like perfume, and inert chemical changes in formulas are examples of irrelevant chemical changes that should be exempted. Redundant registration requirements, e.g., between CCA and K-BPR, should be eliminated. A sufficient grace period for registration of such changes should be granted to minimize difficulties for businesses.

Test Methods for Consumer Chemical Products

Under K-BPR, ME maintains its own safety testing methods for safety and labeling standards of consumer chemical products, which are different from globally standardized testing methods. ME only recognizes certified testing agencies in Korea, which are mostly semi-governmental organizations, and does not recognize globally certified agencies. These conditions put an extra burden on global companies in Korea, which are required to conduct additional sets of testing for certification and to modify products to meet ME's safety standards when they import consumer chemical products from the U.S. This can function as a barrier for global companies to enter the Korean consumer chemical product market.

Issue

Korea's lack of recognition on globally standardized testing methods.

Relevant Regulations

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 harmonize its testing methods for safety and labeling standards for consumer chemical products with globally standardized testing methods. Testing results from globally certified testing agencies should be recognized in Korea.

Redundant Regulations under the Chemical Control Act (CCA)

CCA is a law created for the purpose of managing chemical substances and preventing chemical accidents. According to Article 3 (Scope of Application) of the law, products regulated under other laws are excluded from the control of CCA. However, household chemical products controlled by the 'Chemical Control Act on Consumer Chemical Products and Biocides Safety Control' and hygiene products controlled by the 'Hygiene Control Act' are still in the scope of CCA's regulation.

Issue

Redundant regulations under the 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 try to eliminate duplicate regulatory requirements.



COMPETITION & FAIR TRADE

- Overview
- Due Process and Transparency Protections
- Inadequate protective measurements in terms of patent infringement

COMPETITION AND FAIR TRADE

OVERVIEW

The importance of protecting fair competition is enshrined as a core pillar of the KORUS FTA. In Chapter 16 on Competition-related Matters, both parties committed themselves to ensuring strengthened due process protections for subjects of competition law enforcement actions. The role of the Korea Fair Trade Commission (KFTC) in enforcing competition law is vital to allowing fair competition and redressing unfair practices so as to create a market environment in which both Korean and U.S. companies can succeed and thrive. AMCHAM fully recognizes the need and authority of the KFTC to audit companies' compliance with the various matters that fall within the jurisdiction of the KFTC to include fair and free competition, consumer protection, avoidance of cartels and fair standard terms and conditions.

Over the last few years, there has been a renewed passion for the enforcement of the Fair Trade Law, and this has resulted in a significant increase in the number of audits. As part of the Korean government's goal of creating a fair society, the KFTC announced its intention to restructure and improve Korea's competition law enforcement system so as to maximize efficiency. AMCHAM welcomes the KFTC's determination to reform and improve the competition law and enforcement in Korea and we hope to work closely with the KFTC towards that end.

ONGOING ISSUES

Due Process and Transparency Protections

Given the renewed passion for enforcement, some of the working-level officials of the KFTC have been extremely passionate in the quest for information. Multinational companies operating in Korea have voiced concerns that the KFTC targets multinational companies with more aggressive enforcement efforts. Some multinational companies have felt that they have been targeted by the KFTC with unnecessarily coercive investigations, including aggressive raids of company facilities without prior notice and without the presence of an attorney, even when such practices contradict the KFTC's own investigative guidelines. In addition, international companies have received excessive and repetitive requests for document submissions by the KFTC, which is seen as an abuse of its investigative authority.

When obtaining information and data, it is important to follow proper procedures and due process in the conduct of investigations and the rules applicable to such investigations established by the KFTC. AMCHAM welcomes commitments by the KFTC to due process in their investigations and the publishing of such rules.

Issue

International companies feel that they have been unfairly targeted with relatively aggressive enforcement efforts, including practices in violation of the KFTC's own guidelines.

Relevant Regulations

Fair Trade Law

Relevant Agencies

Korea Fair Trade Commission (KFTC)

Relevant KORUS Provision

Chapter 16 (Competition-related Matters)

Recommendation

In the spirit of the KORUS FTA, the KFTC should review its investigative practices with a view to ensuring full and transparent enforcement of its investigative guidelines guaranteeing fair process and equal treatment for domestic and international companies. While we do not believe the investigators are

intentionally avoiding or evading the rules established by the KFTC, we believe it would be appropriate for the KFTC to engage in regular training programs to ensure consistent adherence to such rules.

We believe it would be beneficial for the KFTC to adhere to rules similar to those required to be followed by the prosecutors, whereby evidence obtained in violation of the rules of procedure established by the KFTC cannot be used by the KFTC in its investigations. This would contribute to transparency and predictability by ensuring that procedural rules are followed.

Inadequate protective measurements in terms of patent infringement

A recent decision by the Korean Supreme Court has undermined patent enforcement in Korea and the ability of innovators to be awarded appropriate damage when a patent-infringing generic launches in the market. When a generic product enters the Korean market, the price of the innovator product is automatically reduced. In November 2020, the Korean Supreme Court held that generic companies were not liable for damages caused by a mandatory price reduction to a patented product even if the patent was upheld and the generic company entered the market illegally, forcing the price cut in question.

The Supreme Court decision essentially eliminates any deterrent for a generic company to launch its product during ongoing patent litigation. This jurisprudence contravenes Korea's commitment in Article 18.10(5)(b) of KORUS that "in determining damages for infringement of intellectual property rights, its judicial authorities shall consider...the value of the infringed good or service measured by the market price..." That market value cannot reasonably be the reduced price triggered by the launch of a patent-infringing generic.

Issue

The Supreme Court's decision allowing companies to launch generic products during ongoing patent litigation

Relevant Regulations Supreme Decision 2018Da221676

Relevant Agencies

Supreme Court

Relevant KORUS Provision

Chapter 18 (Intellectual Property Rights) Article10 (Enforcement of Intellectual Property Rights)

Recommendation

Strong patent protection, which includes the protection of patent rights during the entire patent term, is necessary for innovative companies to continue to invest in R&D for new innovative products. AMCHAM urges Korea to introduce appropriate patent policy measures to protect the legitimate patent rights of innovators.



CUSTOMS

- Overview
- Origin of Verification

CUSTOMS

OVERVIEW

The KORUS FTA reduces, and in most cases, eliminates tariff and non-tariff barriers between the two parties for most industrial and consumer goods by January 2026. For this tariff elimination to yield meaningful benefits for exporters and consumers of both the U.S. and Korea, it is essential that the customs authorities of both countries fully and faithfully implement the agreement.

Under the revised KORUS FTA, Korea committed itself to addressing long-standing concerns with onerous and costly verification procedures through an agreed Customs Principles for conducting verification of origin on imported products under KORUS FTA and establish the Rules of Origin Working Group (under the Committee on Trade in Goods) to monitor and address future issues that arise. AMCHAM hopes that the operation of this working group, alongside regular meetings between the U.S. Customs and Border Protection (CBP) and the Korea Customs Service (KCS) will generate meaningful improvements on the customs origin verification issues outlined below and allow full opportunities for input from international companies.

ONGOING ISSUES

Origin Verification

We fully understand that the agreement provides enforcement provisions through verifications as preferential tariff treatment provides duty savings and may pose the risk of abuse in the form of false or undocumented preferential claims. It has been our concern that the KCS has conducted unduly onerous verifications of claims for preferential tariff treatment for low-risk imports under the KORUS FTA and levied unreasonable penalties on U.S. companies. Demands for excessive and unnecessary documentation have cost U.S. exporters considerable time and money and jeopardized preferential treatment for eligible U.S. exports. KORUS claims have been rejected by the KCS for minor errors on certification of origin and supporting documentations and the KCS has limited the ability of companies to correct minor errors for legitimately eligible/originating goods, preventing companies from taking advantage of KORUS FTA claims for originating U.S. products.

Recently, we have seen some positive changes in the FTA implementation regulations/KCS guidelines regarding the KORUS FTA verification procedures. For instance, the KCS has published certain verification guidelines for its customs officers who are responsible for conducting origin verifications (effective November 14, 2018). This is to satisfy and implement the negotiated modifications which produced a list of eight principles designed to reduce these onerous verifications practice and calls for the creation of a working group to monitor these issues. The KCS has also amended its FTA Implementing Regulations by allowing importers to correct/supplement previously issued certificates of origin (effective August 30, 2019).

It appears that many KCS verification issues have been resolved by bilateral talks between the two parties over the past several years. However, there are still concerns that the customs offices within the KCS have a considerable level of discretion regarding origin verification. For instance, some KCS origin verification officers tend to prefer communicating with Korean importers rather than U.S. manufacturers' or sellers' appointed representatives in Korea, which may increase the risk of leakage of confidential business information. AMCHAM will continue monitoring the progress of the implementation of the new verification guidelines, the amendment to the FTA Implementing Regulations, as well as the other remaining issues.

Issue

Origin verification procedures that are unduly onerous and lack predictability

Relevant Agencies

Korea Customs Service (KCS)

Relevant KORUS Provisions

Chapter 6 (Rules of Origin and Origin Procedure), Chapter 7 (Customs Administration and Trade Facilitation)

Recommendation

The KCS should conduct origin verifications in a manner that facilitates trade in goods between the U.S. and Korea in line with the purpose of the KORUS FTA. The KCS should verify the accuracy of information for imports identified as high risk for noncompliance and implement the verification guidelines to maximize consistency and transparency as agreed as part of the recent KORUS renegotiations. In addition, KCS officers should display consistent willingness to communicate with the appointed representatives of U.S. manufacturers or sellers regarding the KORUS FTA origin verification. When Korean importers find it difficult to provide origin information during the early origin verification phase due to business confidentiality of the inquired information, the KCS should not prematurely deny KORUS FTA preferential treatment and impose penalties. In such cases, the KCS should ascertain whether the U.S. manufacturers, sellers, or their appointed representatives have the intent to provide supplementary origin information to the KCS at a later phase (via direct international origin verification).



DIGITAL ECONOMY

- Overview
- Fair Treatment towards U.S. Companies
- The Application of the Cloud Security Assurance Program (CSAP)
- Personal Information Protection Act (PIPA)
- Designation of a Local Representative
- Data Center Legislation

DIGITAL ECONOMY

OVERVIEW

Free movement of data across borders is essential to 21st-century commerce and the Fourth Industrial Revolution. Unfortunately, Korea's regulations impose highly stringent and globally unique requirements on cloud and internet service providers which veer from international standards. Such regulations restrict market access opportunities for the U.S. and other global service providers who have difficulty complying due to the global nature of their business operations, thereby having the effect of favoring local providers to the detriment of global providers. They also isolate Korean businesses and consumers from access to globally innovative technologies and services, which could spur greater economic productivity and innovation within Korea.

AMCHAM supports digital trade regulations that enable and facilitate the cross-border flow of data and avoid data localization requirements. 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 around the world 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 recent actions by the Korean government to better align Korea's regulations on cloud and internet services with global standards and usher in the Fourth Industrial Revolution. In particular, we welcome the establishment of the Presidential Committee on Digital Platform Government with an initiative to create a data-based digital platform where the government could join hands 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. It is our hope that the Korean government will work closely with international businesses and the U.S. government in order to address these concerns and create a truly level playing field for domestic and multinational companies in the digital economy sector.

INDUSTRY ISSUES

Fair Treatment towards U.S. Companies

While AMCHAM understands that the Korean government has its own authority. there is a concerning trend that U.S. companies have been singled out for discriminatory treatment, as well as additional requirements and restrictions that apply neither to their Korean competitors nor to other foreign competitors. U.S. companies have also received far greater scrutiny from Korean authorities than their counterparts, such as duplicate and excessive investigations by multiple agencies including the Korea Communications Commission (KCC), the Korea Fair Trade Commission (KFTC), and the police. Although AMCHAM understands that the National Assembly has the authority to audit government agencies, it is concerning that U.S. company representatives are frequently called to testify. The National Assembly has also taken an extremely heavy-handed approach against executives from U.S. companies to the extent of arbitrarily pursuing legal action, while not taking any action against Korean company representatives and Korean government agencies. Such actions will have chilling effects on U.S. investments in Korea and the confidence of U.S. and other foreign investors in being able to do business without fear of discrimination or unfair treatment in Korea.

Issue

The tendency of the local market to target and restrict business operations of U.S. IT companies in a discriminatory manner

Relevant Regulations

Telecommunication Business Act ("TBA"), Monopoly Regulation and Fair Trade Act (MRFTA)

Relevant Agencies

Korea Communications Commission (KCC), Korea Fair Trade Commission (KFTC)

Relevant KORUS Provisions

Chapter 12 (Cross-Border Trade in Services), Chapter 15 (Electronic Commerce), Chapter 17 (Government Procurement)

Recommendation

Ensure that U.S. companies are able to operate and compete with Korean and other foreign competitors on a level-playing field

The Application of the Cloud Security Assurance Program (CSAP)

Korea-unique data protection standards for public cloud computing services continue to be a factor that deters foreign cloud service providers from entering the public cloud market. Guidelines of the Ministry of the Interior and Safety (MOIS) and the Korea Internet Security Agency (KISA) require public agencies to use "Software-as-a-Service" (SaaS) and "Infrastructure-as-a-service" (IaaS) only from cloud service providers that have obtained the Cloud Security Assurance Program (CSAP) certification by KISA. The certificate requires: 1) physical network separation; 2) discriminatory local and global Common Criteria (CC) Certification; and 3) use of Korea-specific or Korea-unique encryption modules. Such Korean standards impose excessive security requirements and veer significantly from global standards, making it overly burdensome for U.S. companies to comply with just to serve a single market.

The three criteria mentioned above serve as barriers to foreign cloud service providers. This makes it more difficult for U.S.-based ICT companies to enter the SaaS market as well as the laaS market for public institutions, including local governments, public corporations, public schools, and public research institutes.

The Ministry of Science and ICT (MSIT) proclaimed the Amendment to the Notification on the Security Certification of Cloud Computing Service on January 31, 2023. The amendment regulates the classification of the CSAP certification along with the three-tier impact level categories of "High", "Moderate", and "Low" and the inclusion of logical separation of the network for cloud service providers certified with the "Low"-tier CSAP. Given that the previous requirement of physical separation has long acted as a critical technical barrier for many CSPs in providing services to the public sector over the last several years, AMCHAM welcomes the MSIT's decision and hopes to see a breakthrough that supports a full-scale regulatory reform in the cloud computing industry.

Issue

Korea-unique data protection standards for public cloud computing that deter U.S. companies from entering the Korean market

• Relevant Regulations

Cloud Security Assurance Program (CSAP) certification

Relevant Agencies

Ministry of the Interior and Safety (MOIS), Korea Internet & Security Agency (KISA)

Relevant KORUS Provisions

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

Recommendation

AMCHAM encourages the Korean government to allow logical rather than physical network separation of non-sensitive information of the public sector (i.e. excluding information deemed relevant to national security).

Personal Information Protection Act (PIPA)

The 2011 Personal Information Protection Act (PIPA) imposed stringent requirements on service providers seeking to transfer customers' personal data outside Korea. The law requires data exporters to provide customers with extensive information about the data transfer, including the destination of the data, any third party's planned use for the data, the time and method of the data transfer, and the duration of retention. Less stringent requirements apply to data transfers to third parties within Korea. These restrictions pose barriers to the cross-border provision of Internet-based services that depend on data storage and processing services, provided by a company directly or through third parties, and effectively privilege Korean over foreign suppliers in any data-intensive sector without materially contributing to privacy protection.

In September 2021, the Personal Information Protection Commission (PIPC) submitted a proposed amendment to the PIPA to the National Assembly to increase a penalty to three percent of the total global revenue. The proposed amendment would also grant the PIPC the authority to suspend a company's cross-border data transfers in case of a significant violation of the cross-border data transfer related provisions or failure to sufficiently protect the transferred personal data, about which U.S. stakeholders have raised concerns.

In December 2022, The National Policy Committee of the National Assembly passed a bill to amend the PIPA. The Proposed Amendment will go to the Legislation and Judiciary Committee of the National Assembly for review of the structure and language and then will be submitted to the plenary session of the National Assembly for final voting. The Proposed Amendment, which combines and consolidates most of the PIPA amendment bills submitted to the National Assembly so far, includes 1) expansion of data subject's rights, such as data portability and the right to refuse or request explanation on automated decision-making, 2) integration of separate PIPA

provisions applicable to online service providers into the general PIPA with economic sanctions in the form of administrative penalties and fines, but with an upward adjustment in the penalty and fine base (from "relevant revenue" to "total revenue"). The Proposed Amendment is also more restrictive with respect to the overseas transfer of personal information for the purpose of outsourcing, as it requires that the outsourcing is "necessary for entering into or performing the contract with the data subject," in addition to the data controller's disclosure of certain information about the overseas transfer in its privacy policy, in order for the data controller to forgo obtaining each individual's consent.

These regulations tilt the playing field against U.S. data storage and processing service providers and are inconsistent with the most favored nation treatment principle under the KORUS FTA, as well as the World Trade Organization (WTO) General Agreement on Trade in Services (GATS). Requiring global content providers to install servers in Korea and to provide services only through these servers in effect mandates data localization.

Moreover, such a requirement is not an effective way to advance the purported goal of ensuring the stability of network services, as the quality of internet connections is managed and controlled by internet service providers and online service providers have no capability to guarantee the quality or speed of internet connections.

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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 Korea to align the personal information protection regulations with global standards and to seek more effective ways to facilitate cross-border transfer of data in line with global standards.

Designation of a Local Representative

In May 2020, South Korea's National Assembly passed an amendment to the Telecommunications Business Act, which requires large content providers to ensure network stability and to appoint local representatives. The industry expressed concerns that this stability provision obligates content providers to guarantee the quality of service on networks that they cannot and do not control.

AMCHAM understands the intent of this Act 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 to provide services in Korea for certain U.S. service providers that cannot designate an agent in Korea, especially those U.S. internet companies whose operations are relatively small

The regulation runs counter to 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 produce results that are similar to requiring the designation 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)

Relevant Agencies

Ministry of Science and ICT (MSIT), Korea Communications Commission (KCC)

Relevant KORUS Provisions

Chapter 12 (Cross-Border Trade in Services)

Recommendation

We encourage the Korean government to end the requirement for foreign telecommunications service providers to designate a foreign agent in Korea, which is likely to impose significant hardships on U.S. service providers and ultimately have adverse consequences for the domestic value-added telecommunications service market.

Data Center Legislation

In the aftermath of a recent fire and service outage at the Pangyo data center in late 2022, the National Assembly passed the data center bills into law which will come into force in 2023. While AMCHAM appreciates the need for strengthening data center resilience and redundancy, the new legislation is not aligned with global norms and best practices around disaster recovery and management. Such a regulation imposes an excessive burden on data center business operators and potentially hinders the development of various technologies that enable the stable provision of the services. In addition, the data center legislation has potential extraterritorial implications and sets a concerning precedent. Most data centers owned and operated by global technology companies already have robust redundancy and disaster recovery measures; other countries do not have mandatory redundancy requirements.

Issue

Recent legislation that imposes disaster recovery-related obligations on major CPs and data centers

Relevant Regulations

Broadcasting Communications Development Act (BCDA), Act on Promotion of Information and Communications Network Utilization and Information Protection, Etc. ("Network Act") Telecommunication Business Act ("TBA")

Relevant Agencies

Ministry of Science and ICT (MSIT)

Relevant KORUS Provisions

Chapter 12 (Cross-border trade in services)

Recommendation

We encourage the government to partner with global companies to share the best practices and lessons in service reliability.



ENERGY & ENVIRONMENT

- Overview
- Need for RE100 Policy Changes
- Localization Policy for Offshore Wind Turbines
- Domestic Certification Requirements on Large- and Medium- Sized Wind Turbines
- Need for Road Map and Conversion Plan to Reduce HFC Usage

ENERGY & ENVIRONMENT

OVERVIEW

The Korean government announced its plan to achieve "Zero Carbon Emissions" by 2050. In order to achieve the target, Korea will reduce its reliance on coal during the transitional "energy mix" period and direct its focus on nuclear, LNG, and renewable energy.

The energy industry, including the renewable energy sector and nuclear power plants, is expected to gain momentum following Korea's participation in the Indo-Pacific Economic Framework (IPEF). In line with one of IPEF's key agendas, decarbonization and the expansion of clean energy, it is highly likely that Korea will amend its energy policies to align with the U.S.' expansion of the green industry.

The Korea-U.S. solar alliance is expected to accelerate as a result of the Inflation Reduction Act (IRA), which includes tax deductions for solar modules and batteries produced in the U.S. by 2030. With Korea's participation in the IPEF, the hydrogen industry is also expected to gain momentum.

A great limitation to Korea's energy industry, however, lies in the renewable energy sector. While solar power generation has increased significantly, wind power is still dependent on offshore wind power generation which is in its early stages. Meanwhile, onshore wind power faces various difficulties, such as local opposition, complicated licensing procedures, and paralysis in energy transportation and networks. Whether Korea will be able to achieve its goal of "Zero Carbon Emissions" heavily depends on the speed of its coal phase-out and renewable energy expansion.

INDUSTRY ISSUES

Need for RE100 Policy Changes

RE100 is a global inter-enterprise agreement project that aims to replace 100% of the electricity usage of companies with renewable energy by 2050. In order to achieve this goal, companies should fully commit to using electricity generated from renewable energy or purchase Renewable Energy Certificates (RECs) in proportion to the electricity used.

Currently, RE100 member companies doing business in Korea consume around 180 TWh of energy per year. These businesses are advocating for greater policy changes to remove the barriers to renewable electricity in Korea. These policy suggestions include 1) creating a power market structure that enables renewables to compete fairly with fossil fuels, 2) increasing the national renewable energy usage goal to accelerate corporate use of renewable energy, 3) improving accessibility to Power Purchase Agreements, 4) enhancing the transparency of renewable electricity certificates and tracking systems.

Issue

Need for legislation and policy changes to incentivize corporates to use renewable energy

Relevant Regulations

Act on the Promotion of the Development, Use and Diffusion of New and Renewable Energy

Relevant Agencies

Ministry of Trade, Investment and Energy (MOTIE), Korea Energy Agency (KEA)

Recommendation

Korea should commit to supporting the use of renewable energy and recognize the need to accelerate the progress of RE100 in Korea.

Localization Policy for the Offshore Wind Turbines

Offshore wind has the potential to supply substantial amounts of clean energy to meet power needs while creating jobs and addressing the climate crisis. Further, offshore wind power plants can provide reliable and increasingly affordable renewable power. For these reasons, Korea has aggressively adopted proactive offshore wind energy policies to capture the benefits of economic growth, energy independence, and reduced greenhouse gas emissions.

Much like onshore wind power, wind turbines account for a high proportion of project development costs in offshore wind power generation. According to the Global Wind Energy Council (GWEC), wind turbines constitute the largest portion, 35%, of offshore wind facility investment costs.

On December 17, 2021, the New and Renewable Energy Center of the Korea Energy Agency (KEA) announced the amendment to the Rules on Issuance of Supply Certificates and Operation of Trading Market (the "REC Rules"). The amendment includes a Local Contents Requirement (LCR) to be applied to the bidding of wind turbines for offshore wind energy projects by allocating additional Renewable Energy Certificates (RECs) to products in proportion to the local content ratio.

The LCR effectively puts foreign companies at a disadvantage in the competition. The requirement does not comply with Korea's national treatment obligations under the General Agreement on Tariffs and Trade (GATT) and the KORUS FTA which specifies that imported products of a WTO member country should receive treatment that is no less favorable than those granted to the equivalent products of domestic origin.

Issue

Localization policy for offshore wind turbines that is disadvantageous to foreign companies

Relevant Regulations

Rules of Issuance of Supply Certificates and Operation of Trading Market

Relevant Agencies

Korea Energy Agency (KEA)

Relevant KORUS Provisions

Chapter 9 (Technical Barriers to Trade)

Recommendation

Korea should commit to the Most Favored Nation Treatment Principle stated in the KOREA FTA and General Agreement on Tariffs and Trade (GATT).

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

The Korea Energy Agency (KEA)'s KS Certification system, which came into effect in 2014, inhibits the smooth entry of foreign suppliers into the market. Companies are obliged to hold KS Certification in order to receive government subsidies, as products without the certification are excluded from Renewable Energy Certificate (REC) issuance. As Korea's regulatory environment does not recognize international safety certification standards, the KS Certification requirement serves as an obstacle for foreign companies who try 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

Mutual recognition of safety certification should be allowed to enhance the partnership and synergy between the two industries.

Need for Road Map and Conversion Plan to Reduce HFC Usage

On January 19th, 2023, Korea ratified the Kigali Amendment to the Montreal Protocol, becoming the 147th country to sign the Amendment. The Kigali Amendment calls for a gradual reduction in the consumption and production of hydrofluorocarbons (HFCs), which are potent greenhouse gases that are being used in heating, ventilation & air conditioning (HVAC) and refrigeration segment such as air-conditioning, chiller and refrigeration units. All HFCs have their unique global warming potential (GWP) figure depending on the level of CO2 emission.

As a response to the ratification of the Kigali Amendment, the U.S. implements the American Innovation and Manufacturing (AIM) Act, a framework from the U.S. Environmental Protection Agency (EPA) on the sales and use of the HFC. The AIM Act directs EPA to address HFCs by phasing down production and consumption, maximizing reclamation and minimizing releases from equipment and facilitating the transition to next-generation technologies through sector-based restrictions.

As such, Korea needs to prepare a national-level transition roadmap to reduce the usage of HFC. It needs to develop sector-specific GWP-based restrictions. Also, the development of a conversion plan to low GWP materials is needed in order to motivate MNCs' investments to localize production facilities in Korea and alleviate the level of supply chain independency.

Issue

Need for Road Map and Conversion Plan to Reduce HFC Usage

Relevant Regulations

Ozone Protection Law

Relevant Agencies

Ministry of Trade, Industry and Energy (MOTIE), Ministry of Environment (ME), Korea Petroleum Industry Association

Recommendation

Korea needs to develop a roadmap and conversion plan to reduce the usage of HFCs



FINANCIAL SERVICES

- Overview
- Differentiation of information handling for corporate clients vs. consumer clients
- Measured liberalization of Korean data protection standards for financial companies
- Liberalization of firewall standards among financial entities within Korea
- Relaxation of Korean network segregation and cloud computing standards for financial companies
- Relaxation of restriction on the short sale of Korea Treasury Bond (KTB)

FINANCIAL SERVICES

OVERVIEW

With the Korean government nurturing ambitions to become a financial hub in the region, it is important to AMCHAM that Korea continues to be viewed as a safe and predictable place to do business. Amid the growing geopolitical tensions in the region, there is a compelling case to be made for Korea to become a regional financial hub and we want to help the Korean economy succeed.

AMCHAM applauds recent actions by the Korean government to better align Korea's regulations with global standards. In particular, we welcome the Financial Services Commission (FSC)'s well-intended deregulatory efforts to expand the usage of cloud services in the financial sector. However, Korea's regulatory environment still serves as a factor undermining its competitiveness and reducing the flexibility of foreign financial services companies operating in Korea. AMCHAM truly hopes that the Korean government will work closely with international businesses and the U.S. government to strengthen investor confidence in the Korean market and provide the right infrastructure for multinational companies to do more business in Korea.

ONGOING ISSUES

Differentiation of Information Handling for Corporate Clients vs. Consumer Clients

The Regulation on Entrustment of Information Processing of 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 from that 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 Services (FSS).

Relevant KORUS Provision

Chapter 13 (Financial Services)

Recommendation

Corporate client information requires a differentiated information processing guideline from that for individual client information.

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 Internal Safety (MOIS), Financial Services Commission (FSC), Financial Supervisory Services (FSS).

Relevant KORUS Provision

Chapter 13 (Financial Services)

Recommendation

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

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 Services (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.

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. 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 Services (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.

Relaxation of Restriction on the Short Sale of Korea Treasury Bond (KTB)

Banks must cover KTB's position in the market on the same day they trade with foreign investors to avoid short sale regulation breaches, despite a settlement with the foreigner being due several days after the trade date.

This regulation hinders showing competitive offers to clients especially for illiquid offthe-run bonds, particularly when client RFQ (Request For Quotation) comes late in the day near market close, since it will be tough to source the bond from the market on the trading date.

Around \$60bn inflow is estimated if KTB were to be included in the World Global Bond Index (WGBI) and clients will demand active market making for off-the-runs.

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 Services (FSS).

Recommendation

We recommend Korea to relax the short sale rule so that banks can cover KTB position on the bond settlement date instead of the trade date.



GOVERNMENT PROCUREMENT

- Overview
- Designation of Products and Industries as Appropriate for SMEs

GOVERNMENT PROCUREMENT

OVERVIEW

The KORUS FTA contains government procurement provisions, in which both countries commit themselves to opening their procurement markets to the other party. Although both the U.S. and Korea were members of the WTO Government Procurement Agreement (GPA) before the enactment of the KORUS FTA, U.S. companies' access to the Korean market was severely limited in practice. The KORUS FTA reflects and builds on the WTO GPA commitments by substantially lowering the threshold amount for coverage and expanding the scope of government agencies subject to the agreement.

ONGOING ISSUES

Designation of Products and Industries as Appropriate for SMEs

The Ministry of SMEs and Startups (MSS) has the authority to designate certain industries and products as "appropriate for SMEs." If an industry or product is so designated, central government agencies are required to procure the relevant products from domestic SMEs, excluding U.S. companies from the market.

In recent years, MSS has expanded the scope of products and industries subject to such definition, especially in newly emerging industries such as information technology. Rather than supporting the growth of domestic SMEs, such policies have had the unintended effect of more products from low-cost producer countries being sold in the Korean procurement market, due to those who import their products from these countries and sell these products as their own, to the detriment of U.S. products. Additionally, while expanding the scope, there were not enough statistical data and opinions considered from the relevant authorities.

As U.S. companies are leaders in technology and innovation and bring business to numerous Korean SMEs as channel partners in sales and service delivery, further restricting the scope of U.S. companies' participation in Korea's government procurement market would have negative consequences for innovation, employment, industrial development, and the quality of public service in Korea.

Although the KORUS FTA allows preference for domestic SMEs in government procurement, the expanded designation of industries and products as appropriate for SMEs seems designed to exclude multinational vendors from the market, going against the principle of national treatment set forth in the KORUS FTA.

Issue

The designation of products and companies as appropriate for SMEs unfairly excluding U.S. vendors from the public procurement market

Relevant Agencies

The Ministry of SMEs and Startups (MSS)

Relevant KORUS Provisions

Chapter 12 (Cross-Border Trade in Services) Article 2 (National Treatment), Chapter 17 (Government Procurement)

Recommendation

We urge Korea to refrain from actions that would further limit the participation of U.S. companies in Korean government procurement market, such as expanding the scope of industries and products designated as appropriate for SMEs.



PHARMACEUTICAL & MEDICAL DEVICES

- Overview
- Pricing of Global Innovative Drugs
- Reimbursement Coverage for Innovative Medical Technologies
- Lack of Transparency and Predictability
- Delayed Patient Access to New Medical Technologies

Pharmaceuticals & Medical Devices

OVERVIEW

New medicines and devices not only extend life spans but also improve quality of life, reduce medical expenses, and can become a future growth engine for the economy. Transparency, predictability, and a fair system that rewards the value of innovation are vital for supporting the research and development of innovative drugs and medical devices, which can require many years and billions of dollars to develop. The cost of rewarding such innovation more than pays for itself, as the policy would then lead to fewer hospital visits and a reduced need for long-term care and hospital stays.

As U.S. companies continue to lead the world in research and development in the pharmaceutical and medical devices sectors, they have made great contributions to enhancing the quality of care for patients in Korea. However, Korea's pricing and reimbursement policies for pharmaceutical and medical devices have not always recognized the value of such contributions made by global innovative companies in a fair, transparent, and nondiscriminatory manner.

The renegotiated KORUS FTA stipulates that the value of medical innovation by international companies be duly recognized and rewarded. AMCHAM and its member companies in the pharmaceutical, medical devices and life sciences industries are appreciative of the opportunity to join in on the effort to build a healthcare system in Korea that promotes and incentivizes innovation while providing affordable and accessible care for all.

INDUSTRY ISSUES

Pricing of Global Innovative Drugs

Korea's pharmaceutical pricing and reimbursement policies significantly depress the price of new and innovative medicines, devaluing the innovative contributions of global pharmaceutical companies. Although Korea has introduced new pathways for reimbursement listing since the enactment of the KORUS FTA, new drug prices remain low at around 42% of the OECD average according to Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) as of November 2021. U.S. companies have expressed concerns regarding the lack of transparency and predictability of these policies.

As agreed during the KORUS FTA amendment negotiations, Korea's Health Insurance Review and Assessment Service (HIRA) published a revision of the Global Innovative New Drug Pricing Benefit System on December 31, 2018, revising the program to remove discriminatory criteria and ensure compliance with Korea's obligations under the KORUS FTA. Although the amendments made in December 2018 removed discriminatory elements of the Korean premium pricing system, the revisions to the program's criteria made by the Ministry of Health and Welfare (MOHW) also substantially narrowed the program's scope such that it may dramatically limit the ability of any company, foreign or domestic, to qualify for premium pricing.

The new policy sets forth five conditions new drugs must satisfy in order to qualify for premium pricing: (1) it should have a new mechanism or be a new substance; (2) there should be no alternative treatment; (3) it should have clinically meaningful data such as an extension of survival time for a significant period; (4) it should have the U.S. Food and Drug Administration (FDA)'s designation of Breakthrough Drug (BTD) or the European Medicines Agency (EMA)'s accelerated assessment of Priority Medicines (PRIME); and (5) it should be an orphan drug or an anticancer treatment. The pharmaceutical industry has expressed disappointment that despite requests for improvement made during the public comment period, these are unrealistic requirements that almost no new drugs will be able to satisfy. The industry is concerned that without further improvement, the new policy will have little to no benefit in terms of improving reimbursement for the value of global innovative drugs.

In addition, the Ministry of Health and Welfare (MOHW) designates certain companies as Innovative Pharmaceutical Companies (IPC), which receive tax credits, R&D support, and favorable drug pricing. However, the current accreditation criteria lack transparency and discriminate against the U.S. and other foreign innovators by requiring domestic investments to prove "innovativeness." As of September 2022, only 3 out of 43 designated IPCs were non-Korean biopharmaceutical companies.

- Issue: Unfair pricing for medicine that does not reflect 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: To fulfill the commitment made during the KORUS FTA amendment negotiations to provide meaningful consultation and transparency during the revision of its pharmaceutical pricing policy, AMCHAM urges the Korean government to organize a consultation body that includes the government, domestic and foreign pharmaceutical industries, as well as other relevant associations for an active discussion on improving Korea's premium pricing policy to appropriately recognize the value of global innovative drugs.

Reimbursement Coverage for Innovative Medical Technologies

U.S. medical device manufacturers must follow the Korean government's pricing and reimbursement policies as the country grapples with cost containment under its national healthcare system.

The importation of medical devices requires the assignment of an importer or representative based in Korea to manage medical device approvals and to ensure regulatory compliance. As part of pre-market approval requirements, the Ministry of Food and Drug Safety (MFDS) requires testing reports on safety and efficacy. In addition to medical device approvals, companies need to negotiate pricing terms with the Korean Health Insurance Review and Assessment Service (HIRA).

Current issues facing the medical device industry in Korea include reimbursement pricing governed by the National Health Insurance (NHI), the new healthcare technology assessment system for medical devices, and the new regulation requiring devices to be registered every 5 years, which takes effect in 2025.

With the implementation of the KORUS FTA, U.S. medical device companies can now request a review of government pricing and maximum reimbursement determinations for their products through an Independent Review Process. Established to regulate medical devices and drug prices, this review process is independent of 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 fail to enter the market due to the strict and high standards of the evidentiary requirements to obtain specific reimbursement coverages such as 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 stage of innovative medical technology advancement and the potential benefit to patients, more practical and flexible approaches for reimbursement coverage determination are required. The current evidentiary requirements for innovative medical technologies are also much stricter than the ones required in medical technologies in the traditional medical technology arena. They pose a discriminative burden to the relevant manufacturers and hinders the market entry of innovative medical technologies, which can contribute to providing better patient care, saving patient lives, and also saving NHI spending and medical costs with effective and efficient healthcare resource utilization.

- Issue: Lack of reimbursement coverage for innovative medical technologies
- 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: To foster the development of innovative medical technologies in Korea, flexible and practical approaches for the determination of reimbursement coverage are required. The Coverage with Evidence Development (CED) is a globally recognized method to adopt innovative medical technologies bringing better patient benefits while providing reimbursement coverage under the condition of developing necessary and robust clinical benefit evidence without interrupting companies' entry to the innovation market. A new pricing system such as the "New Conditional reimbursement" notified in 2021 should be activated for better patient access to innovative medical technologies.

Lack of Transparency and Predictability

The Ministry of Health and Welfare (MOHW) and the Health Insurance Policy Deliberation Committee under the MOHW review the measurements of managing reimbursement for expensive medicines for serious diseases in order to increase patient access and secure the sustainability of health insurance. The discussion and enforcement of regulations proceed without any procedure of hearing the opinions of the industry even though the committee's decisions greatly affect the businesses of global healthcare companies in Korea.

In addition, Korea's Health Insurance Review and Assessment Service (HIRA) often disregards evidence of clinical benefit and evaluates innovative medicines using an unreasonably low and outdated cost-effectiveness threshold that has declined in real terms over time. For medicines not subject to the cost-effectiveness threshold, HIRA proposed expanding the number of countries it could use to recommend the lowest international price from seven to nine. Following HIRA's review and recommendations, the National Health Insurance Service (NHIS) can also require additional concessions as a condition of NHIS reimbursement and impose excessive and repeated price cuts even if HIRA has already deemed these medicines to be cost-effective. As a result, Korea's government-set prices are among the lowest in the OECD.

Moreover, various subcommittees review and make decisions during the Pricing & Reimbursement (P&R) process. However, these subcommittees do not share the output of their deliberation, and applicants are often not sufficiently provided with information or reasonable opportunities for appeal regarding the evaluation and decisions of the process.

The KORUS FTA expressly provides that with respect to laws, regulations, and procedures of general application respecting any matter related to the pricing, reimbursement, or regulation of pharmaceutical products or medical devices, each Party shall provide interested parties an opportunity to comment on such proposed measures at an appropriate time that may enable such comments to be reflected in the measures.

- Issue: Lack of predictability to pricing & reimbursement review process, 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 encourages the Korean government to provide opportunities for the industry to comment on measures related to the regulations of pharmaceutical products and medical devices.

Delayed Patient Access to New Medical Technologies

Korea requires multiple patient access processes, such as 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 Health Insurance Review & Assessment Service (HIRA). To shorten the lead time of these approval processes, MOHW, benchmarking the U.S. Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS) parallel review process, introduced the Parallel Review (PR) process that allows for the regulatory approval and nHTA application reviews to proceed concurrently.

While the PR process contributes to shortening the patient access lead-time, the reimbursement coverage and pricing decision-making process is not included in the PR process. In most cases, the reimbursement coverage and pricing decision-making process, particularly for new and innovative medical devices that have gone through the nHTA process, takes significantly longer than other processes (often takes two to three years), exceeding the legally mandated timeframe of 100 days.

Various factors contribute to this significant delay, including 1) a lack of coordination between relevant departments within HIRA; 2) inefficient administrative operation; 3) a lack of communication with stakeholders (e.g., advisory healthcare professionals and specialty societies); 4) organization understaffing; and 5) a lack of commitment to complying with a legally required review timeframe.

Delayed patient access caused by the lengthy review time is disadvantageous to innovators, especially U.S. medical device manufacturers, because the product life cycles of medical devices are as short as 18 months. The delayed adoption of innovative medical devices, therefore, reduces the period of market exclusivity for innovators.

- Issue: Delays in the approval process that deny patient-access to new 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: The process for reimbursement coverage and pricing approval from the MOHW and the HIRA should be accelerated to be within the legally mandated timeframe of 100 days. Reimbursement coverage and pricing approval should also be included in the PR process.

Table of Abbreviations

ABBR.	EXPANDED
AMCHAM	American Chamber of Commerce in Korea
AIM	American Innovation and Manufacturing
ABV	Alcohol by Volume
BCDA	Broadcasting Communications Development Act
BTD	Breakthrough Drug
CAFE	Corporate Average Fuel Economy
CBI	Confidential Business Information
CBP	U.S. Customs and Border Protection
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
ELV	End-of-life Vehicle
EMA	European Medicines Agency
EPA	Environmental Protection Agency
EPR	Extended Producers' Responsibility
FDA	Food and Drug Administration
FSC	Financial Services Commission
FSS	Financial Supervisory Services
FTA	Free Trade Agreement
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GHG	Greenhouse Gas
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GPA	Government Procurement Agreement
GWEC	Global Wind Energy Council

GWP Global Warming Potential

HFC Hydrofluorocarbons

HIRA Health Insurance Review and Assessment Service

HVAC Heating, Ventilation & Air Conditioning

laaS Infrastructure-as-a-Service

ICT Information Communication Technology
IPC Innovative Pharmaceutical Company

IPEF Indo-Pacific Economic Framework

ISHA Industrial Safety and Health Act

K-BPR Safety Control Act of Household Chemical Products and Biocidal Products

KCC Korea Communications Commission

KCS Korea Customs Service

KCSC Korea Communications Standards 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

KPBMA Korea Pharmaceutical and Bio-Pharma Manufacturers Association

K-REACH Act on the Registration and Evaluation of Chemicals

KTB Korea Treasury Bond

LCR Local Contents Requirement
LMO Living Modified Organism

LTAP2 Large Transporter Secondary Project

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

MOF Ministry of Fisheries

MOHW Ministry of Health and Welfare MOIS Ministry of Interior and Safety

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

MSRP Manufacturer's Suggested Retail Price

MSS Ministry of Startups and SMEs

MVCA Motor Vehicle Control Act

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

NIFS National Fisheries Research and Development Institute

NTS National Tax Service

OD Offset Division

OECD Organization for Economic Cooperation and Development

OEM Original Equipment Manufacturer

OR Only Representative

PCIA Protection of Credit Information Act
PIPA Personal Information Protection Act

PIPC Personal Information Protection Committee

PoP Proof of Performance

PR Parallel Review
PRIME Priority Medicines

P&R Pricing & Reimbursement

RDA Rural Development Agency

R&D Research & Development

REC Renewable Energy Certificate

RFP Request for Proposals

RFQ Request for Quotation

RRC Risk Review Consultations

SaaS Software-as-a-Service

SMEs Small and Medium-Sized Enterprises

TAA Technical Assistance Agreement

TBA Telecommunication Business Act

TSN Trade Secret Names

TWh Terawatt hour

WGBI World Global Bond Index WTO World Trade Organization