(16.5.2015-31.12.2015) for the first time since 2007.[76] Korea's latest SSG measures were notified to the WTO Committee on Agriculture in July 2016.[77]

3.2.9 Standards and other technical requirements

3.2.9.1 Standards, testing, and certification

3.70. During the review period, the institutional setting in this area remained relatively unchanged.[78] The Korean Agency for Technology and Standards (KATS), an affiliate of MOTIE, sets, administers, and disseminates Korean Industrial Standards (KSs) on the basis of the National Standardization Act and the Industrial Standardization Act. In December 2013, KATS was reorganized to strengthen the role of industrial standards and to augment their economic added value. KATS, the official enquiry point on industrial products under the WTO Agreement on Technical Barriers to Trade, is in charge of planning and coordinating national standards policy. The Korea Standards Association (KSA), a KATS affiliate with public and private sector membership, provides comprehensive knowledge services (standardization, standards, certification and training), and several private bodies perform standardization-related tasks.[79] Other bodies performing standards-related work include the Korea Research Institute of Standards and Science (responsible for metrology standards and measurement) (KRISS), and the Telecommunications Technology Association (TTA), an agency affiliated with the Korea Communications Commission, which is responsible for group standards for telecommunications, information technology, radio communications, and broadcasting.[80] The National Standards Council reviews general plans for the introduction of national standards and coordinates the standards-related activities of the different ministries.

3.71. Standard development remains government-led, and is a significant element of Korea's industrial policy. The KATS implemented its fourth National Standards Plan (2016-20) with key policy goals including the development of standards for new growth engine activities, for improving people's daily life, and the eradication of redundant certification systems. Its third National Standards Plan (2011-15) had the same key policy goals. At present, it aims to advance the national standards system, strengthen the standard technology infrastructure, actively participate in international standardization activities, and assist the private sector in increasing its capacity to develop standards.[81]

3.72. Under the Framework Act on Administrative Regulations (last amended by Act No. 9965, 25 January 2010), a regulatory impact analysis (RIA), including cost-benefit analysis, has been required since 1997, prior to introducing a new regulation or reinforcing existing regulations.[82] The

[76] WTO documents G/AG/N/KOR/47, 25 January 2013; and G/AG/N/KOR/49, 8 January 2015.

[77] WTO document G/AG/N/KOR/55, 18 July 2016.

[78] Korea faces huge testing and certification demand, and according to the authorities it provides speedy and inexpensive services, and has a high level of digitalization and the ability to respond quickly to market changes. Nevertheless, its testing and certification agencies appear to lag behind their counterparts overseas (e.g. BV of France, SGS of Switzerland, and Intertek of the UK), *inter alia*, in terms of brand power, and service diversity. As of 2014, their overall capabilities were considered to be around 65.4% of those of global leading agencies; more specifically, their service expansion capabilities and the testing and certification standardization capabilities were just 46.9% and 53.6% of those of the global leading institutes respectively. Interview with Seong Si-heon, administrator of KATS, published in the online *Business Korea* article titled "Korean Agency for Technology and Standards – Augmenting Added Value by Strengthening Industrial Standards", 31 January 2014. Viewed at: http://www.businesskorea.co.kr/english/features/special-reports/3370-korean-agency-technology-and-standards-augmenting-added-value#sthash.cbQ06lXW.dpuf.

[79] In 2013, the KSA opened a KS Certification Support Centre and a Global Standardization Support Centre. Online MOTIE and KSA information. Viewed at: http://english.motie.go.kr/?cat=58&paged=4 and http://www.ksa.or.kr/eng/index.jsp.

[80] The TTA sets industry standards and has been instrumental in creating the current Korean Information and Communication Standards. The TTA also collaborates with international and national standards organizations, such as the ITU. KRISS is a public institute registered in the Ministry of Education, Science and Technology (MEST), and it mainly serves as the national metrology institute (NMI). KRISS also manages National Centre for Standard Reference Data (NCSRD).

[81] Between 2010 and 2013, Korea made 236 proposals for new international standards at ISO (168) and IEC (68). KATS online information. Viewed at: http://www.kats.go.kr/en/content.do?cmsid=404 and http://www.kats.go.kr/en/content.do?cmsid=407.

[82] The authorities indicated that KATS continues to prepare, adopt and apply standards in line with the provisions of Annex 3 of the WTO TBT Agreement (Code of Good Practice). SPS measures are taken mainly against diseases that are new to Korea and that are subject to strict domestic preventive measures.

RIA has been carried out by three Ministry of Food and Drug Safety (MFDS) divisions in different fields. KATS is implementing a technical regulatory impact assessment (TRIA) aiming to comprehensively review costs, advantages, impacts and compatibility of regulations for technical regulation issues. In 2015, out of 602 cases suggested for adjustment 52% were adjusted.

3.2.9.1.1 Voluntary, compulsory, national, and aligned standards

3.73. The Korean standardization system consists of technical regulations (mandatory standards) developed by ministries and government agencies, as well as standards (voluntary) set by KATS (KSs) and the Radio Research Agency (Korea Communications Standards, KCSs). As of 2015, the KCSs, set on the basis of the Framework Act on Broadcasting and Communications Development and operated by the Ministry of Science, ICT and Future Planning, were "consolidated" into KSs (Korean Standards). As from 2015, KATS has re-organized the KSs to better reflect current market demand and technological development, and moved ahead with a new standards development system.[83] The KSs with lower utilization are being repealed, and those affecting consumer safety and requiring compliance with international standards are to be updated. As from 2015, seven ministries and one agency (Ministry of Science, ICT and Future Planning; Ministry of Environment; Ministry of Agriculture, Food and Rural Affairs; Ministry of Employment and Labour; Ministry of Oceans and Fisheries; Ministry of Food and Drug Safety; and Korea Forest Service) have participated in developing KSs. On the basis of the expertise of each ministry, Korea is to develop KSs and improve efficiency in adopting standards and technical regulations. The standards enactment and revision procedure will be improved so that the relevant agencies can independently work on and manage their standardization plans; so far the KS processes have been handled by KATS only.

3.74. KATS prepares the roadmap for standardization and carries forward standard development in connection with government policies and R&D. In 2011, eight sectors were subject to national standards coordination projects: smart grid, 3D businesses, electric cars, cloud computing, nuclear power, smart media, smart logistics, and smart medical information; as of 2016, KATS was to proceed with the same type of projects in the fields of smart factory, smart health, next generation steel, next generation material and wearable smart-equipment.

3.75. As of April 2016, about 3,072 (about 15% of all standards) KSs (5,000, or 24.6%, in 2010) were contained in 5,470 (15,375 in 2010) technical regulations issued by 19 government ministries. At the end of April 2016, 20,495 KSs had been adopted (23,622 in 2010). The allocation of all KSs by sector was: chemicals, textiles, and ceramics (4,518, 22%); machinery (3,120, 15%); electricity (3,469, 17%); metal, mining, and construction (2,368, 11.5%); transportation machines, shipbuilding, and the aerospace industry (1,522, 7.4%); information technology (1,636, 8%); and food, environment, etc. (3,862, 19%). At April 2016, 19,880 (97%) of KSs had been harmonized with corresponding international standards, compared to 14,157 (59.9%) in 2010. Non-harmonized standards, i.e. those that are either unique to Korea, with no corresponding international norm (e.g. for kimchi), or cannot be harmonized because of their link to other domestic regulations, remain in place; no information on developments on "Korea-specific" standards since 2012 was available from the authorities.[84] Roughly 3% (2.5% in 2010) of KSs have been established without any reference to international standards. In April 2016, approximately 66% (60% in 2010) of KSs were subject to international ISO/IEC harmonization.

3.76. At March 2016, Korea maintained bilateral MoUs with 42 agencies (46 in 2011) from 31 (33 in 2011) countries for mutual cooperation in global standardization activities, exchange of

[83] Interview with the administrator of KATS published in the online *Business Korea* article titled "Korean Agency for Technology and Standards – Augmenting Added Value by Strengthening Industrial Standards", 31 January 2014. Viewed at: http://www.businesskorea.co.kr/english/features/special-reports/3370-korean-agency-technology-and-standards-augmenting-added-value#sthash.cbQ06lXW.dpuf.

[84] At the time of the previous Review, according to the authorities, there were very few "Korea-specific" standards, and these were maintained only where there were no equivalent international standards and when there was sufficient justification. Moreover, "Korea-specific" standards were not aimed at creating unnecessary obstacles to international trade; they involved Korean traditional food products and related items, such as *gwamegi* (dried Pacific saury or mackerel pike), *doenjang* (fermented soybean paste), *gochujang* (thick soy and red pepper paste), and kimchi refrigerators.

technical information related to standards and conformity assessment, organization of standardization meetings, operation of joint education programmes, and exchange of experts.[85]

3.2.9.1.2 Food, health-related and other measures

3.77. Legislative responsibility for regulating food safety and quality remains divided between several ministries. The Ministry of Food and Drug Safety (MFDS) regulates food safety (including foods of plant, animal and aquatic origin), whereas the Ministry of Agriculture, Food and Rural Affairs (MAFRA) deals with animal and plant health (including import quarantine measures for animal, livestock products and plants). The Ministry of Oceans and Fisheries deals with aquatic health including import quarantine measures for fishery products and safety for exporting fishery products. Safety of foods, pharmaceuticals, medical devices and cosmetics is governed by the Ministry of Food and Drug Safety (MFDS), formerly the Korea Food and Drug Administration (KFDA) – a government body upgraded to ministerial level in March 2013.[86] MFDS's main role is to protect public health and safety, including the safety of food and livestock products. MFDS, with its six regional offices, and the National Institute of Food and Drug Safety Evaluation, a think-tank, are responsible for establishing and enforcing basic legislation and its implementing regulations, as well as setting standards and specifications for domestic and imported foods, including livestock products, functional foods, food additives, food packaging, containers and equipment (Section 3.2.9.2).[87] As from March 2013, standards and specifications for meat, dairy, and egg products have been handled by the MFDS, whereas quarantine standards for animals and animal products have been handled by MAFRA. The MFDS regulates domestic and imported salts for domestic consumption, with the exception of industrial salt and solar salt, which are inspected by the Animal and Plant Quarantine Agency (QIA).

3.78. Imports of pharmaceuticals continue to require a free sale certificate, issued by an authority of the exporting country. Any person intending to import medical devices or pharmaceuticals must obtain an item-specific approval from, or file a notification with, the MFDS in accordance with the relevant law. Item-specific pre-approval involves the submission of extensive clinical trial data and other safety and efficacy-related data as prescribed by the Pharmaceutical Affairs Act Enforcement Decree.[88] Manufacturers must submit detailed data on certain active pharmaceutical ingredients under the MFDS's Drug Master File.

3.79. Each batch of imported pharmaceutical products remains subject to batch release testing by the healthcare authorities, even if they have already been tested and released by the manufacturer and the health authority of the country of origin. The authorities indicated that the same rules and regulations are applied in accordance with the Pharmaceutical Affairs Act to domestically distributed biological drugs (locally and foreign produced), and results of tests conducted by foreign manufacturers or health authorities of the exporting country must not substitute results of batch or lot release tests conducted by the MFDS. For some medical devices used for medical practice, the Government needs to determine whether they are eligible for reimbursement before they are used at healthcare institutions including hospitals, since all healthcare institutions in Korea are reimbursed by the Government for medical services provided to patients. With regard to medical devices subject to health technology assessment, under the relevant laws, it takes up to about 17 months (or 510 days) from the date of application for MFDS approval by a device manufacturer to the date when the MFDS approval is granted and the product is launched onto the market: approval takes 80 days; health technology assessment 280 days; and listing the product for reimbursement 150 days.

[85] Online KATS information. Viewed at: http://www.kats.go.kr/en/content.do?cmsid=408.

[86] Following the March 2013 revision of the National Government Organization Act, the policy-making function of the Ministry of Health and Welfare (MOHW) regarding food and drug safety, and the duties of the former Ministry for Food, Agriculture, Forestry and Fisheries regarding sanitation and safety of agro-livestock fishery products were transferred to the MFDS. Online MFDS information. Viewed at: http://mfds.go.kr/eng/index.do?nMenuCode=9.

[87] USDA Foreign Agricultural Service (2015d).

[88] Most regulations in this area are harmonized with the International Conference on Harmonization (ICH) guidelines. Since March 2016, the MFDS has participated in ICH as an observer and it is considering becoming a regular member.

3.80. Cosmetics are regulated by the MFDS and fall under two categories: "functional" cosmetics and regular cosmetics.[89] "Functional" cosmetics include whitening, anti-wrinkle, and sunscreen and tanning products. The MFDS reviews only "functional" cosmetics for pre-market approval. For all other regular cosmetics, the Korea Pharmaceutical Traders Association (KPTA) has been authorized by the MFDS to review and certify import permission requests submitted by the Korean importer. The MFDS administers registration requirements on imported and domestically produced "functional" cosmetics. Importers must conduct "self-regulated" quality inspection for each product type to ensure conformity with the cosmetic standards and test methods.[90] Cosmetics importers are required to file a customs report to, and obtain prior approval from, the Korea Pharmaceutical Traders Association (KPTA) on all products. Test results submitted by overseas manufacturers using quality standards that are internationally accepted or certified, or that are more stringent than the Korea Cosmetic Good Manufacturing Practice (KCGMP) standards, are accepted without any additional quality testing in Korea. Quality inspection by the importer of cosmetics is required, according to manufacturing serial/batch number. Certain products classified as cosmetics (e.g. depilatory, hair dye products) overseas are not considered as such in Korea; reportedly, this makes it hard to harmonize regulations with other countries. The MFDS is revising the Cosmetics Act; depilatories and hair dye products are to be classified as cosmetics by the end of 2017.

3.2.9.1.3 Conformity assessment

3.81. KATS is responsible for conformity assessment, certification, registration and testing of industrial products for voluntary (KS) standards. It runs the Korea Laboratory Accreditation Scheme (KOLAS), which accredits testing and calibration laboratories and inspection bodies, as well as the Korea Accreditation System (KAS), which accredits product certification bodies. Accreditation accords with internationally recognized standards. In 2015, there were 487 (403 in 2011) accredited testing laboratories, 209 (193 in 2011) calibration laboratories, 55 (46 in 2011) inspection bodies, 8 proficiency testing providers in KOLAS and 20 (16 in 2011) product certification bodies in KAS.[91]

3.82. Korea maintains a single national integrated certification mark, the Korea Certification (KC) mark, fully implemented as from January 2011.

3.83. In 2011, KATS set a five-year comprehensive plan on quality management to identify quality-related issues that could be addressed to enhance sustainable growth and Korea's international competitiveness. The plan laid out 15 major actions and strategies in order to rank 10th in terms of global quality competitiveness by the year 2015; its results have been generally satisfactory and at present KATS is working on a basic plan of quality management for 2016 to 2020.

3.84. Certification authorities are encouraged to negotiate mutual recognition arrangements (MRAs) with foreign counterparts. KOLAS is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Multilateral Recognition Arrangement (MLA) for testing and for calibration; as of May 2016, 89 accreditation bodies from 74 countries participated in the MLA. KATS is a signatory to the International Accreditation Forum (IAF) MLA for bodies operating product certification systems. Korea also maintains an extensive network of MRAs, especially with APEC economies. The Korean Accreditation Board (KAB) and KAS form part of the Pacific Accreditation System (PAC). KAB is a signatory of the IAF MLA for Quality Management Systems, and participates in the IAF MLA for Environmental Management Systems. Korea is also a member of the APEC MRA on Conformity Assessment of Telecommunications Equipment (Phase I and II) and of Part I of the APEC Electrical MRA; it does not intend to participate in Part II and III of the latter. It joined the MRA on Conformity Assessment of Electrical and Electronic Equipment in 2015.[92]

[89] Korea is the world's 10th largest cosmetics market, representing nearly 2.8% of the global market and worth US$7.8 billion (2014). Viewed at: http://www.export.gov/southkorea/doingbusinessinskorea/leadingsectorsforusexportsinvestment/cosmetics/index.asp.

[90] WTO document WT/TPR/S/268/Rev.1, 8 November 2012.

[91] Online KOLAS information. Viewed at: https://www.kolas.go.kr/english/.

[92] Online APEC information. Viewed at: http://www.apec.org/Groups/Committee-on-Trade-and-Investment/~/media/7F1C151806EE44D48FC04FA3D4BFDD49.ashx.

3.85. Korea maintains: an APEC-TEL MRA with Canada (1997), the United States (2005), Viet Nam (2006), and Chile (2007) on recognition of test results for telecommunications equipment; an FTA with the EU with provisions on recognition of conformity assessment for telecommunications equipment; and an MRA with Singapore (2006) on electrical and electronic appliances under the Korea–Singapore FTA. Under the Industrial Technology Innovation Promotion Act, the NEP (New Excellent Product) certification system continues to cover products manufactured with new technologies developed first in Korea or improved with innovative technologies. The certificate is valid for three years. NEP-certified products receive government support to expand sales channels and accelerate technology development. Products certified as NEP receive an additional qualification point in procurement by government and public organizations. At the time of the previous Review, the authorities indicated that the NEP system does not affect international trade. No data on the specific product coverage of and financial support under the NEP system was available from the authorities.

3.86. The MFDS facilitates food imports through the "authorization of foreign official laboratories" system and the "pre-confirmed registration system of imported foods". The former covers inspection agencies authorized by the Government of the exporting countries and the MFDS; it includes 59 agencies in 9 countries. Test results issued by these agencies are recognized by the MFDS and therefore relevant imports are exempt from laboratory inspection. Under the "pre-confirmed registration system of imported foods", foodstuffs pre-approved and registered based on site inspection at the exporter's premises and advanced test certification of an officially authorized agency are exempt from laboratory inspection. Korea has not joined the APEC MRA on Conformity Assessment of Foods and Food Products.

3.87. Following the revision of the Act on the Management and Support for the Promotion of Eco-Friendly Agriculture/Fisheries and Organic Foods (New Organic Act) in 2012, as from 1 June 2013 a mandatory organic certification programme requires all domestic and imported organic fresh (unprocessed) and processed produce and livestock products to be certified by a MAFRA accredited certifying body.[93] As of December 2015, 15 Korean certifying agencies and four foreign certifying agencies were accredited by MAFRA's National Agricultural Products Quality Management Service (NAQS) for certification of organic processed food products. Korea maintains a zero-tolerance policy for the inadvertent presence of biotech content in processed organic products (Sections 3.2.9.2.1 and 3.2.9.3); any organic products tested positive for genetically modified organisms (GMOs) importers/producers can be instructed to remove an organic claim from the product label and NAQS may investigate the case to see if there is any intentional violation.[94] In response to consumer demand for a higher standard of environment-friendly agricultural products, Korea stopped issuing new certification for low pesticide organic agricultural produce in 2010 in view of the discontinuation of this category in 2016.[95] In lieu of certification by accredited certifying agents, the 2012 Act allowed MAFRA to have an equivalency agreement on processed organic products with foreign trade partners. On 1 July 2014, the United States and Korea adopted an equivalency arrangement allowing processed food products certified as organic in the United States or Korea to be sold as organic in either country without having to go through a costly certification process again under the importing country's standards.

3.88. During the review period, action was also taken in the areas of reporting, declaration of conformity, testing and environmental impact review. In 2013, an Act on the Registration and Evaluation of Chemicals requiring manufacturers and importers of chemical substances to register and comply with annual reporting requirements was enacted and notified to the WTO TBT Committee; on 18 February 2014, the Ministry of Environment (MOE) released implementing regulations in force as of 1 January 2015.[96] A new regulation requiring companies to make

[93] The certification for organic produce is classified into two categories: organic and no-pesticide. For livestock products, two categories of certification are available: organic livestock and no-antibiotic livestock. USDA Foreign Agricultural Service (2015d); USDA Foreign Agricultural Service (2015b).

[94] USDA Foreign Agricultural Service (2015c).

[95] Sustainable agricultural produce has been classified into three categories: organic produce, no-pesticide produce, and low-pesticide produce (until 2015), and can be labelled accordingly. For livestock products, two categories of certification are available: organic livestock and no-antibiotic livestock (WTO document WT/TPR/S/268/Rev.1, 8 November 2012).

[96] Concerns remain with these registration and reporting requirements, in particular the high costs and potential release of sensitive business information, as well as the 20 days for interested parties to submit comments prior to implementation. USTR (2015). WTO documents G/TBT/N/KOR/305, 9 March 2011;

information on chemical products, such as the name and quantity of chemical products in production facilities, publicly available was implemented as of 1 January 2016.[97] KATS released its final Safety Regulations rule for information technology equipment, effective 1 July 2013; these regulations expanded the scope of products subject to a supplier's declaration of conformity, and adopted the most current International Electrotechnical Commission (IEC) standard.[98] In March 2014, an environmental impact review on the use of cadmium in solar panels determined that a hazard existed for using Cadmium Telluride (CdTe).[99] Pursuant to an amendment of the Motor Vehicle Management Act, Korea requires, as of 8 January 2015, that all auto manufacturers or dealers report vehicle repair histories to vehicle purchasers in order to account for any damages taking place between the manufacturing site and customer delivery.[100]

3.2.9.1.4 Transparency

3.89. New and/or revised legislation and the implementing guidelines are published in the government gazette for public comments; these changes are also notified regularly to the WTO for Members' comments. Between 2012 and 2015, Korea made 281 new notifications under the WTO Agreement on Technical Barriers to Trade (the TBT Agreement); the majority remained under Article 2.9 of the Agreement, and in 91.1% of the notified cases the timeliness of the submission allowed for a comment period of 60 days or more, while in only 11 cases the period was less than 45 days.[101] To help Korean companies respond to technical barriers to trade, KATS maintains a TBT division, which is exclusively responsible for WTO/TBT-related affairs. KATS maintains an online information service on technical regulations of respective countries, which are notified to the WTO.[102] KATS runs a TBT Notifications Alert Service, which transmits TBT notifications to stakeholders by email and encourages them to submit their comments.

3.90. During the review period, Members raised specific trade concerns (STCs) at the Committee on Technical Barriers to Trade regarding several measures under consideration or taken by Korea (e.g. relating to chemical material; thin-film solar panels; PCV flooring material, wallpaper and paper linoleum, and toys; wood products; automobile standards; tyres for motor vehicles; cell phone electromagnetic values/exposure; cosmetics; radio-frequency identification tags for imported whiskeys; and energy efficiency of windows).[103]

G/TBT/N/KOR/305/Add.1, 30 August 2013; G/TB/N/KOR/478, 28 February 2014; and, G/TBT/N/KOR/592, 5 August 2015.

[97] USTR (2016).

[98] Nevertheless, concerns remain as the regulation requires separate safety certification with respect to each factory's products, even for identical products produced by the same company but in a different factory, and does not establish a certificate renewal process. Furthermore, despite being a member of the IEC System for Conformity Testing and Certification of Electrical and Electronic Components, Equipment and Products Certification Bodies' Scheme (CB), KATS is not currently accepting CB reports without additional testing. Finally, the final rule imposes burdensome labelling requirements for information that could be disclosed instead in an insert or manual. USTR (2015); USTR (2016).

[99] Korea requires solar panels to be certified by the Korea Management Energy Corporation (KEMCO) before they can be sold for projects receiving government support provided to the vast majority of solar projects in the country. KEMCO maintains a standard for thin-film solar panels that can only be satisfied by panels manufactured from amorphous silicon and copper indium gallium selenide. Over recent years Korea was urged at WTO TBT Committee meetings to adopt in full the relevant international standard, IEC 61646, without limiting its application solely to the type of thin-film solar panel its industry produces. USTR (2015).

[100] This new reporting requirement seems to discriminate against auto importers because local auto manufacturing sites are co-located with the Pre-Delivery Inspection (PDI) facility, thus vehicles are unlikely to require any reportable reconditioning; since imported vehicles routinely undergo some kind of reconditioning that would require reporting under this law, consumers perception of imported vehicles could be harmed. USTR (2015); USTR (2016).

[101] In 2014 and 2015, Korea made 35 and 71 online notification submissions (TBT NSS), respectively. WTO documents G/TBT/33, 27 February 2013; G/TBT/34, 7 March 2014; G/TBT/36, 23 February 2015; and G/TBT/38/Rev.1, 24 March 2016.

[102] Viewed at: http://www.knowtbt.kr/eng/index.aspx/.

[103] Historically, Korean measures are frequently subject to TBT STCs. Overall, from 1995 to 2015, 30 new STCs have been raised against Korean measures before the TBT Committee. This makes Korea the 4th WTO Member with most measures discussed in the Committee, only behind the EU, China and the United States. However, in 2015, Korea was not among even the top 8 Members in terms of measures subject to STCs. WTO documents G/TBT/33, 27 February 2013; G/TBT/34, 7 March 2014; G/TBT/36, 23 February 2015; and, G/TBT/38/Rev.1, 24 March 2016.

3.2.9.2 Sanitary and phytosanitary measures

3.2.9.2.1 Food standards-setting framework

3.91. Korea's regulatory system takes into account the opinions of consumers and industry, and reflects them in the decision-making process.[104] The main laws affecting food standards and specification are the Food Sanitation Act (last amended in 2016), the Food Code and the Food Additive Code. Since 2008, a Food Safety Policy Committee comprehensively revises and coordinates food safety management tasks dispersed across the various ministries and agencies; so far each relevant agency has developed comprehensive three-year food safety plans (2008-11, 2012-14, 2015-16) to carry out food safety control schemes to prevent hazardous food at all stages of the food chain from production to distribution. Following efforts to consolidate all imported food regulations, which were scattered among various acts, into a single act, a Special Act on Imported Food Safety Management, effective as of 4 February 2016, requires all foreign food facilities and establishments to be registered by the MFDS. Reportedly, this act is to facilitate sound transactions and enhance public health by guaranteeing the safety of imported foods in the domestic market and food exported overseas, to promote quality, and to provide correct information, as well as to provide the legal grounds to take measures if foreign manufacturers decline audits.[105] A six-month grace period for foreign facility registration, until 3 August 2016, was granted to allow a smooth transition.

3.92. As from March 2013, the responsibility of implementing the Hazard Analysis of Critical Control Point (HACCP) programme (see below) and the recall systems for food, livestock, and dairy products were transferred from MAFRA to the MFDS. The MFDS expanded the application of the Hazard Analysis Critical Control Point system to 13,991 firms by December 2015 compared to 2,500 firms in 2012. In addition, the MFDS sets and implements regulations governing safety evaluations of agricultural products that have been enhanced through biotechnology and labelling requirements for both agricultural products and processed food products manufactured using GMO ingredients (Section 3.2.9.3).[106]

Maximum residue levels

3.93. The MFDS remains responsible for regulating pesticide residues in foodstuffs, in accordance with the maximum residue levels (MRLs) set in the Food Code and applied for both domestic and foreign products.[107] The authorities indicated that MRLs are established based on the scientific residue data, and the MFDS tries to harmonize them with the CODEX tolerance whenever possible until full enforcement of the "positive list" (see below); if the standard is different to that of the CODEX, it is reassessed to promote standards harmonization.[108] As of December 2015, the MFDS had set MRLs for 449 pesticides in agricultural products and 79 pesticides in ginseng products. The Food Code also lists MRLs for 82 pesticides and 147 veterinary drugs in meat, fish, eggs and milk products that remain virtually unchanged since the previous Review. In addition to the Food Code, the MFDS maintains an MRLs database (Pesticide Residue Database) for agricultural products, in Korean with English translations.[109] Food importers have to provide lists of all food ingredients and additives to the MFDS and the QIA for customs clearance; the ingredient content ratio (mixture ratio of materials) is not required.

[104] WTO document WT/TPR/S/268/Rev.1, 8 November 2012.

[105] As for establishments of livestock products, including dairy products, the MFDS will recognize establishments that have a record of export to Korea prior to the implementation of the Special Act. Those establishments with a record will not require any additional registration. For any new establishment that wishes to export products to Korea, registration shall be made through the exporting Government. USDA Foreign Agricultural Service (2015c).

[106] USDA Foreign Agricultural Service (2015d).

[107] In addition to MFDS, MAFRA and the Ministry of Environment (MOE) handle pesticide-related matters. MAFRA is responsible for pesticide registration and the MOE is responsible for testing pesticide levels in water, soil and agricultural products. USDA Foreign Agricultural Service (2015d).

[108] If an MRL is established in the Food Code for a pesticide in a particular agricultural product, other tolerance levels, such as CODEX, are not accepted. However, for pesticides where tolerance levels have not been established in the Korean Food Code, the following rules apply: the CODEX standards set for a particular agricultural product (excluding crop groupings) in question shall apply; if the previous provision is not applicable, the lowest residue limit for the pesticide in question for a similar agricultural product shall apply; and if both previous provisions are not applicable, the lowest of the residue limits of the pesticide for any agricultural crop applies. USDA Foreign Agricultural Service (2015d).

[109] See 2009 KFDA online information. Viewed at: http://eng.kfda.go.kr/policy/pesticides.php.

3.94. Since 2015, Korea has been in the process of shifting to a new positive list system (PLS) for agrochemical residues which would inhibit the use of non-registered pesticides which are not evaluated by scientific assessment and would no longer allow imports of food containing agrochemical residues unless the substance has been listed, or approved, for the commodity in question and an MRL has been established. The MFDS plans to first complete the transition to the PLS for tropical fruit and nuts/seeds by the end of 2016; it then plans to complete the transition for all other crops by the end of 2018 and veterinary drugs by 2020. In the process of making this shift, Korea is requiring new import tolerances for agrochemicals not already registered for use in the country.[110] This process may prove a significant challenge to exporters of fruit and grain if import tolerances are not set at an appropriate level and in a timely manner; sufficient time for a smooth transition to the PLS may be required.[111] After a single MRL violation by an export shipment to either Korea or another country, Korea may impose restrictive import requirements on that product's grower, shipper, and importer, and may require a number of compliant shipments to Korea before the requirement is removed.

Food additives

3.95. All food additives require prior approval. As of December 2015, Korea had a positive list of 605 (601 in 2011) approved food additives.[112] Food additives and related items are grouped into three categories: (a) chemical synthetics (408 items), (b) natural additives (197 items), and (c) mixed substances (7 categories of mixture of approved additives). Reportedly, even though there may be an established CODEX standard for a given food additive, domestic or imported foods with "reasonable" levels of a food additive may not be marketed, either because their food additive is not registered in the Korean Food Additives Standards Code, or because it failed to comply with item-specific standards specified in the Code or its usage in a certain food product is not specified in the existing Food Additive Code.[113] Getting a new additive added to the approved list usually takes a year or more. In 2015, food additives were to be reclassified based on the Codex Alimentarius Commission; a revised plan for the classification system for food additives was to bring them in line with that of advanced countries.[114] The authorities indicated that, since 2012, eight new food additives were authorized, and the relevant standards and specifications have been consistently revised for their harmonization with global standards.[115]

3.96. A 2009 system of managing safety of OEM (original equipment manufacturing) food imports mandates OEM food importers to perform on-the-spot inspection and self-quality control for OEM food products (food and food additive imports other than agricultural items, forestry items and alcoholic beverages manufactured by overseas contractors and labelled with the contractor's brand). The MFDS and city/province authorities conduct regular on-site inspections for domestically produced food products. If imported OEM food products prove to be safe, their imports are to increase once consumer confidence is restored.

Genetically modified products and living modified organisms

3.97. Korea's legislation on the marketing of genetically modified agricultural products (GMAPs), , continues to apply equally to domestic and imported GMAPs. Since 1 January 2008, Korea has implemented the Act on Transboundary Movement of Living Modified Organisms (LMO Act), the law implementing the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Imports of biotech grains, as well as genetically engineered animals, are regulated under the Food Sanitation Act and the LMO Act, which was last revised in December 2012 and became effective on 12 December 2013, to, *inter alia*, provide a definition of stacked events[116]; its Enforcement Decree, the Enforcement Regulations, and the Consolidated Notice were revised in 2014.

[110] If no domestic MRL has been established, then an import tolerance will be required in order to import foods containing substances not approved for use in Korea. If no import tolerance is set, 0.01 ppm will be applied as the default tolerance. USDA Foreign Agricultural Service (2015d); USTR (2016).

[111] USTR (2015).

[112] USDA Foreign Agricultural Service (2015d).

[113] WTO document WT/TPR/S/268/Rev.1, 8 November 2012.

[114] Ministry of Food and Drug Safety (2013).

[115] These items are polyvinyl alcohol, urease, sodium fluoride, potassium iodate, butane, ammonium phosphatides, polyethylene glycol, and calcium caseinate.

[116] Despite the revisions, it appears that the regulations still do not distinguish between biotech for food, feed and processing (FFP) and biotech seed, do not eliminate the redundant risk assessment process, and do

3.98. Food safety and environmental risk assessments (ERAs) are mandatory on biotechnology crops and LMOs. The authorities indicated that, in accordance with CODEX guidelines and OECD Biosafety Consensus Documents, safety of LMOs for food is evaluated under the principle of substantial equivalence based on scientifically valid and justified data such as comparison of toxicity, allergenicity and the nutrients of the GM food in question and its non-GM counterpart; they consider that the approval procedure is legitimate and does not lead to unnecessary delays.[117] The MFDS remains responsible for risk assessment for human health of food-related GMAPs and maintains a policy of zero tolerance for the presence of biotechnology products in processed food that is labelled as organic (Section 3.2.9.1.3). It has authority to conduct mandatory safety assessments to evaluate genetically modified organisms (GMOs) in products used for human consumption. The Rural Development Administration (crop cultivation environment), the National Institute of Ecology overseen by MOE (as from end-2013, replacing the National Institute of Environmental Research) (natural ecosystem), and the National Fisheries Research and Development Institute (marine ecosystem) are responsible for environmental risk assessment (ERA). According to the LMO Act, the MFDS implements risk assessment for human health on food, and the Korea Centre for Disease Control and Prevention (KCDC) does the same on feed for industrial use. The authorities indicated that there are neither overlaps of data requirements nor unnecessary delays in the LMO food approval process. GMAPs production and imports have been allowed since 2008. As of May 2016, food safety approval for GMAPs had been given to 139 varieties of soybean, maize, cotton, canola, sugar beet and alfalfa, out of 150 submissions. So far, no GM crops have been grown in Korea and, therefore, the process for crop and food approval has only been applied to imported products. By March 2016, MAFRA had completed a total of 131 out of 151 applications for review of environmental risks of LMOs; as of April 2016, it was conducting 11 reviews and had completed a total of 6 out of 14 applications for environmental risk assessment on food.

3.99. Korea implements the Advance Informed Agreement Procedure as well as labelling requirements for GMOs and LMOs (Section 3.2.9.3).

3.2.9.2.2 Quarantine regulations

3.100. Korea's main laws on quarantine requirements for imports (and exports) remain the Plant Protection Act, the Contagious Animal Disease Prevention Act, and the Aquatic Creatures Disease Control Act. As from March 2013, the Animal, Plant and Fisheries Quarantine and Inspection Agency was divided into the Animal and Plant Quarantine Agency (QIA) and the National Fishery Products Quality Management Service (NFQS). Thus, animal and plant quarantine and inspection are handled by the QIA under MAFRA, and fisheries by the NFQS under the Ministry of Oceans and Fisheries.

3.101. Imports of plants and plant products must have a phytosanitary certificate issued by the competent authority in the exporting country. Imports of soil, plants with soil, and certain plants or vegetable materials are banned. Imports of rice in the husk, chaff, and rice straw from all origins, except Japan and Chinese Taipei, are prohibited for pest reasons. Plants from most countries for planting are also prohibited or restricted. Following the disaster at the Fukushima nuclear plant, since March 2011, Korea has prohibited imports of 27 agricultural products from 13 prefectures that were under distribution restriction in Japan (Section 3.2.6.3).[118] Food products with possible radioactive contamination from these prefectures have been subject to certificate of origin requirements and a test certificate issued by the Japanese Government that proves the food products in question are not contaminated. Following the discovery of continuing leakages of contaminated water in 2013, Korea implemented temporary measures including the extension of the import ban and testing requirements. Some of these measures led to a dispute settlement case in 2015 (Sections 2.5.1 and 3.2.9.2.3). In August 2012, Korea prohibited the importation of

not provide a workable definition of adventitious presence. The authorities do not share this assessment. USDA Foreign Agricultural Service (2015c).

[117] Certain documentation requirements for biotech approvals seemingly go beyond the provisions of the Cartagena Protocol on Biosafety; it appears that data and information requests may lead to delays in the approval of new products and at times lack scientific justification. USTR (2015).

[118] The items subject to this action included rice, tea, spinach, mushrooms, chestnuts, kiwi, leafy greens, and bamboo shoots. Online MFDS information. Viewed at: http://mfds.go.kr/eng/eng/index.do?nMenuCode=75&searchKeyCode=134&page=1&mode=view&boardSeq=67404.

fresh potatoes from the states of Idaho, Oregon, and Washington (United States) due to the presence of zebra chip in the region.[119]

3.102. Animal and animal products are subject to inspection and quarantine. Document and organoleptic inspection, and laboratory testing, if necessary, are undertaken to verify that no contagious animal disease is brought into Korea and that no hazard is posed to public health. Korea bans the import of animals and their products from countries affected by exotic animal diseases such as foot-and-mouth disease and bovine spongiform encephalopathy (BSE). Upon request of the exporting country the import ban may be lifted depending on the outcome of import risk analysis. Imports from countries affected by HPAI (highly pathogenic avian influenza) are banned, but those of poultry meat that is heat-processed to kill the HPAI virus are allowed. According to the authorities, Korea applies the same animal quarantine and livestock product health requirements to domestic production and imports. On 19 November 2015, Korea lifted the import ban on poultry and poultry meat products from the United States that had been imposed in December 2014 due to the outbreak of HPAI.[120] Cheese imports must meet Korea's pasteurization requirements.[121] Under Article 14 of the Imported Food Inspection Instruction, the declared minimum import weight of "food" and "food apparatus, containers and packages" for sanitary inspection by MFDS is 100 kg.[122]

3.2.9.2.3 Transparency

3.103. Between January 2012 and mid-June 2016, 161 notifications were submitted under the WTO Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement). This includes 367 regular notifications, 4 emergency notifications, and 21 addenda/corrigenda. During the review period, STCs involving Korea's strengthened import restrictions on food and feeds with regard to radionuclides (first raised on 16 October 2013, Japan, STC 359) and import restrictions due to African swine fever (first raised on 15 July 2015, EU, STC 393) were raised at the meetings of the WTO SPS Committee.[123] On 21 May 2015, Japan requested consultations with Korea regarding: (a) import bans on certain food products; (b) additional testing and certification requirements regarding the presence of certain radionuclides; and (c) a number of alleged omissions concerning transparency obligations under the SPS Agreement.[124] As of February 2016, a panel was composed to examine the case (Sections 2.6.1 and 3.2.6.3); Brazil, Canada, China, the European Union, Guatemala, India, New Zealand, Norway, the Russian Federation, Chinese Taipei, and the United States reserved their third-party rights.

3.104. Korea maintains MoUs on food safety and quality standards with China's General Administration of Quality Supervision, Inspection and Quarantine (signed January 2003, revised November 2007), Chile (May 2009), Viet Nam (May 2009), Food Standards Australia New Zealand (FSANZ) (July 2011), and the Philippines (Manila) WHO Western Pacific Regional Office (WPRO) (July 2011).[125]

3.2.9.3 Labelling

3.105. During the review period, the MFDS introduced a traceability system for infant/baby food and health functional foods in three stages.[126] As the first stage, the MFDS mandated the

[119] USTR (2015); USTR (2016).
[120] USDA Foreign Agricultural Service (2015d).
[121] In Korea, low temperature pasteurization is regarded as 63-65°C for 30 minutes, 72-75°C for 15 seconds or equivalent methods.
[122] Imports of less than 100 kg may also be allowed but: they must undergo sanitary inspection by the MFDS upon the first importation; exemption for the same product from the same manufacturer may be applied thereafter. However, the exemption does not apply for subsequent imports over 100 kg, but the fees incurred from the test (inspection fee) are waived. This measure is intended to prevent manufacturers receiving approval for a small quantity of quality products and benefiting from import clearance for a large quantity that does not comply with the inspection standards.
[123] WTO document WT/TPR/OV/18, 17 November 2015.
[124] WTO online information, "Dispute DS495: Korea – Import Bans, and Testing and Certification Requirements for Radionuclides". Viewed at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds495_e.htm.
[125] KFDA online information. Viewed at: http://www.kfda.go.kr/eng/eng/index.do?nMenuCode=27&searchKeyCode=65&page=1&mode=view&boardSeq=66524.
[126] USDA Foreign Agricultural Service (2015d).

traceability for domestic manufacturers whose annual sales value exceeds ₩5 billion (approx. US$4.3 million) beginning 1 December 2014. From 1 December 2015, this requirement was expanded to those domestic manufacturers whose annual sales value exceeds ₩1 billion; it will be further expanded to business with annual sales of ₩0.1 billion by 1 December 2016, and all businesses by 1 December 2017. Importers will need to establish the traceability system from the entry point of products in Korea throughout their distribution in the country. For infant/baby food importers, as the first stage, the MFDS mandated the traceability for businesses whose annual sales value exceeded ₩1 billion in 2013 (approx. US$ 0.84 million) beginning 4 February 2016; as from 1 December 2016, it will be expanded to those with annual sales from ₩100 million to ₩1 billion in 2013 (approx. US$84,000 to 0.84 million), and to businesses with annual sales of ₩0.1 billion in 2013 (approx. US$84,000) as from 1 December 2017. For health functional food importers, the MFDS mandated the traceability for businesses whose annual sales value exceeded ₩5 billion in 2013 (approx. US$4.2 million) beginning 4 February 2016; as from 1 June 2016, this requirement will be expanded to those with sales of more than ₩1 billion in 2014 (approx. US$0.84 million), and to those with annual sales of more than ₩0.1 billion in 2015 (approx. US$84,000) from 1 June 2017 onwards. The revised National Health Promotion Act that makes it mandatory for tobacco makers to present stronger warning messages and pictures on the packaging of cigarettes was passed on 22 June 2015 and is to take effect on 23 December 2016 after years of controversy.

3.106. Genetically modified corn, soybeans, cotton, rape and sugar beet (including sprouts originating from these items), as well as foods suitable for consumption containing these products and notified as such by the MFDS, remain subject to mandatory GMO labelling requirements.[127] GMO foods for which identity preservation documents or government-issued certificates were submitted are exempted from GMO labelling requirements. On the other hand, concerning food from the United States, Korea accepts a notarized self-declaration, instead of requiring full documentation, to certify products that are exempt from biotechnology requirements. Importers or manufacturers must keep records for up to two years to prove that unlabelled foods subject to GMO labelling requirements are GMO free. On 24 April 2014, the MFDS combined the three existing labelling standards, i.e. the Labelling Standards for Recombinant Food, Guidelines for Labelling of Genetically Modified Agricultural Products, and Labelling Standards in the LMO Act (Section 3.2.9.2.1) to provide standards required for the labelling of biotech crops and food, including processed food products containing corn, soybeans, cotton, canola, and sugar beets with 3% or higher GMO content.[128] While several proposals to expand biotech labelling dating back to 2008 and 2013 are still pending in the National Assembly and/or the Prime Minister's Office, the MFDS announced its plan in early 2015 to expand mandatory biotech labelling to include all products with detectable biotech ingredients. Under the 31 December 2015 revision of the Food Sanitation Act and the Functional Health Foods Act, the scope of the GM labelling requirement was expanded to any food products that contain genetically modified DNA or genetically modified proteins on 3 February 2016, effective as from 4 February 2017. Under the current system, biotech labelling is not required for products that contain biotech ingredients beyond the top five ingredients. On the other hand, highly refined food such as sugars and oils will continue to be exempt from the mandatory biotech labelling requirement as genetically modified DNA and genetically modified proteins are removed during the processing procedures.

3.107. Origin labelling is mandatory for food and many other imports of 674 four-digit tariff lines (2015) (664 in 2011). The use of the term "Assembled in Country X" has been allowed since October 2010. The Korea Customs Service's Origin Mark Registration and Retrieval System enables users to check origin markings by trader or item.

3.2.10 Government procurement

3.108. Korea's government procurement market grew almost steadily from ₩104.4 trillion or 8.9% of GDP (2010) to ₩111.5 trillion (2014) or about 7.5% of GDP.[129] Although government procurement is directed at achieving "value for money", as of 2014, it also focused on: "future-oriented public procurement" promoting the development of new growth-driving industries;

[127] Following the 2013 government reorganization (Section 2.3), the authority for biotech labelling of unprocessed crops was transferred from MAFRA to MFDS without any change in labelling requirements. USDA Foreign Agricultural Service (2015d).

[128] USDA Foreign Agricultural Service (2015d); and USDA Foreign Agricultural Service (2015c).

[129] Public Procurement Service (2015).