PACIFIC RIM ADVISORY COUNCIL

Pacific Rim Advisory Council

OCTOBER 2022 e-Bulletin

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Virtual meeting - November 28, 2022

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Mexico City April 22-25, 2023
Hosted by Santamarina y Steta

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BENNETT JONES DEEPENS REGULATORY TEAM WITH NEW CALGARY PARTNERS

CALGARY - 04 October, 2022: Martin Ignasiak and Jessica Kennedy have joined Bennett Jones as partners in Calgary. They will work closely with the firm's clients across the country to develop and execute strategies for obtaining regulatory approvals for large scale projects and navigating the changing energy regulatory landscape. They have worked on some of the biggest and most complex oil & gas, pipeline, mining and electricity generation and transmission projects in Canada.

"We are thrilled to welcome Martin and Jessica to Bennett Jones. They will bring exceptional value to the firm's clients at a time of great opportunity in the Canadian energy, resources and power sectors," says Hugh MacKinnon, Chairman and Chief Executive Officer of Bennett Jones. "Our regulatory practice is already the deepest and most experienced in Canada and they will make it even stronger with their strategic and business-focused advice to clients."

Martin and Jessica regularly advise proponents throughout Canada on consultation requirements and strategies and have negotiated numerous benefit agreements with Indigenous groups and affected stakeholders in the project development process. They also advise on the burgeoning areas of CCUS, hydrogen, critical metals and energy storage, and represent clients before provincial and federal energy regulators, environmental boards and utilities commissions.

Martin was the national co-chair of the regulatory group of a Canadian law firm before joining Bennett Jones. He is a member of the bar in Alberta, the Northwest Territories and British Columbia. He has appeared before all levels of court in Alberta and federally, including the Supreme Court of Canada. Martin is highly ranked by Canadian and global legal directories including Chambers, Lexpert and Best Lawyers in oil & gas, regulatory, Aboriginal law and environmental law.

Jessica has experience in dealing with environmental, regulatory, tariff and Indigenous matters in judicial reviews at the Court of King’s Bench and appeals of administrative decisions before the Alberta and Federal Courts of Appeal. She is educated in environmental biology, law and business.

For additional information visit www.bennettjones.com

HAN KUN BOOSTS OVERALL CAPABILITIES IN THE YANGTZE RIVER DELTA REGION

BEIJING – 12 October, 2022: Han Kun is pleased to welcome to the firm Mr. Weiheng Jia and Mr. Cody Chen, who will be primarily based in the firm's Shanghai office. They have extensive experience in cross-border mergers and acquisitions, corporate compliance, and other specialized areas. The additions will further strengthen Han Kun's overall capabilities in the Yangtze River Delta region.

Mr. Weiheng Jia: Mr. Jia has focused on cross-border M&A, regulatory compliance, as well as labor and employment, and has over 20 years of practice in China and the United States. With about seven years of legal education in Japan and over four years of practice in the U.S., he is one of the few lawyers in China who can truly practice law in Chinese, Japanese and English. Blessed by his unique multicultural background and strong trilingual language skills, Mr. Jia has extensive experience in representing multinational corporations based in the U.S., U.K., Japan, and the EU nations, among many other jurisdictions, as well as PRC state-owned enterprises and private companies.

Mr. Jia has represented corporate clients on numerous deals involving M&A, formation and dissolution of joint ventures, and disposal of assets or business lines. Among these representations, more than half involved PRC state-owned enterprises, including some as national-level strategic projects. Mr. Jia has substantial experience in advising on regulatory and compliance matters covering a variety of issues, including anti-bribery and business ethics, anti-monopoly/ unfair competition, as well as data security and protection. Mr. Jia is one of the few Independent Compliance Monitors in China recognized by the multilateral banks, including World Bank Group and Asia Development Bank. He has assisted over a dozen of Chinese companies to meet the compliance criteria of multilateral banks and successfully had them released from multilateral bank sanctions.

Mr. Jia is licensed to practice law in China, New York State, and before a U.S. federal court of appeals. Prior to joining Han Kun, Mr. Jia was the National Leader of Deloitte Legal Greater China and the National Managing Partner of Qin Li Law Firm, a member of the Deloitte Legal global network. While practicing as a partner at top tier U.S.-based international law firm Squire Patton Boggs, he also served as the General Counsel and Chief Compliance Officer for Shanghai Environment Group, a PRC state-owned China stock exchange-listed enterprise group, as well as the China senior legal counsel and compliance officer for General Electric's C&I Group. In addition, Mr. Jia serves as a member of the Competition Law Committee of the Shanghai Bar Association. He was also recognized among CBLJ's "A-List of China's Elite 100 Lawyers for 2021" and among Notable Practitioners of 2021-2023 by the International Financial Law Review.

Mr. Cody Chen: Cody's primary practice areas include foreign direct investment, mergers and acquisitions, corporate restructuring, employment, regulatory compliance, anti-corruption. He advises Chinese and International companies on various legal matters, projects, and business transactions in China.

Following the regional industry reforms and global supply chain adjustments, Cody has also advised a number of clients on dealing with China divestment projects. In the meantime, he has also advised Chinese clients on their overseas investments and cross-border restructuring. Cody's extensive advisory experience covers a broad range of industries and sectors, including manufacturing, infrastructure, information technology, chemicals, life sciences, logistics, TMT, clean energy, real estate, and education.

Cody also focuses heavily on real property and construction matters. His experience covers the full life cycle of industrial property, including land acquisition, investment agreements with the local government or industrial park, planning advice, construction work, property due diligence, property disposition and acquisition, industrial facility relocation, government expropriation, and land reserve matters.

Cody is a member of the PRC Bar. Cody began his legal practice in a major PRC firm in Chongqing and then worked over a decade in the Shanghai office of an international law firm, where he headed the China real estate and construction practice. Prior to joining Han Kun, Cody worked as a partner in Shanghai Qinli Law Firm, member of the Deloitte Legal global network.

For additional information visit www.hankunlaw.com

GIDE ADDS EMPLOYEE SHAREHOLDING PRACTICE WITH ARRIVAL OF NEW PARTNERS AND TEAM

PARIS -18 October 2022: Gide is pleased to announce the arrival of Françoise Even and Sami Toutounji as partners, Barbara Streichenberger-Michel as Senior Counsel, as well as their team, to its Mergers & Acquisitions practice group to develop a new practice dedicated to employee shareholding.

With this new team, Gide is boosting the ability of its 500 lawyers, including 120 partners, to work alongside clients on their most strategic issues, with employee shareholding gaining in considerable momentum over these past few years.

This leading team behind the creation and development of this practice in Paris is one of the most active and respected players in the market. They advise listed and unlisted companies as well as European financial institutions on the design and international roll-out of their employee share ownership plans, as well as on the implementation of their compensation plans and related governance.

By joining Gide, Françoise Even, Sami Toutounji and Barbara Streichenberger-Michel and their team, Sonia Boulongne, Jérémy Lereau-Colonna and Maxime Ehrhart, will boost the practice of one of the largest M&A departments in the French market, with nearly 80 lawyers, including 23 partners, who have been involved in all the most significant transactions of the market.

They will also work closely with Gide's teams specialising in executive / management packages, securities and capital markets law, employment law and tax law.

Senior Partner Frédéric Nouel and Managing Partner Jean-François Levraud said: "We are delighted to welcome Françoise Even and Sami Toutounji to our firm. Together they have participated in establishing and developing this activity on the Paris market. The arrival of this new team is a natural complement to the firm's recognised practice in the field of managers and employees accessing the capital of their company, and strengthens our ability to support our clients as widely as possible".

Françoise Even and Sami Toutounji added: "We are very pleased to be joining the Gide teams in Paris. The reputation and quality of their various practices as well as the firm's international network are undeniable strengths that we will draw on to continue to provide the best possible support to our clients, both in France and abroad".

For additional information visit www.gide.com

HOGAN LOVELLS HIRES TELECOM PARTNER IN WASHINGTON, D.C. OFFICE

WASHINGTON, D.C.— 19 September 2022: Global law firm Hogan Lovells is pleased to announce that Katy Milner has joined the firm as a partner in the Global Regulatory & Intellectual Property, Media & Technology (IPMT) practice group in Washington, D.C. Milner joins the firm from Wiley Rein.

"We are delighted to welcome Katy to the team," said Janice Hogan, Global Head of Hogan Lovells' Global Regulatory & IPMT practice group. "Her addition is consistent with our commitment as one of Washington, D.C.'s largest law firms to continue to grow and strengthen our key regulatory practice areas."

Milner represents telecommunications and technology industry clients on regulatory, transactional, and compliance matters before the Federal Communications Commission (FCC), Congress, the Administration, and other federal agencies. She advises telecommunications clients on matters related to spectrum acquisition and utilization, wireless services regulation, data privacy and cybersecurity, and enforcement, as well as helps clients navigate the rapidly changing broadband and Internet policy landscape.

Ari Fitzgerald, Head of the firm's Communications, Internet, and Media (CIM) practice said: "Telecommunications is a key sector for the firm, and Katy has been widely recognized as a rising star among her peers. Her capabilities will allow us to not only maintain but expand the consistent, high-quality legal services we provide to our wireless and communications clients."

Mark Brennan, Head of the firm's Technology & Telecommunications industry sector group, added: "We are excited to welcome Katy to the firm and anticipate that our clients will benefit tremendously from her years of experience advising tech and telecoms clients on their most important matters."

Milner also brings significant experience advising established and emerging space ventures on complex satellite, earth station, and international telecommunications matters, as well as assisting satellite clients with applications, milestone compliance, and regulatory reporting requirements. She also advises clients on uncrewed aircraft systems (UAS) matters, particularly on FCC-related activity, which will serve to expand the firm's leading drone capabilities, including counseling the Commercial Drone Alliance and other UAS clients.

"I am thrilled to be joining Hogan Lovells, a long-time leader in helping clients navigate the intersection between business and government. Hogan Lovells has not only has a standout wireless and satellite practice, but also leading tech, UAS, and space teams, and I'm excited to leverage my experience and skills and collaborate with this stellar team to deliver top tier legal services to clients," said Milner.

Milner earned her J.D. from the Washington University in St. Louis School of Law and holds a B.A. from Emory University.

For additional information visit www.hoganlovells.com

HOGAN LOVELLS HIRES TELECOM PARTNER IN WASHINGTON, D.C. OFFICE

NautaDutilh boosts its funds practice with the arrival of partner Géraldine Léonard

LUXEMBOURG - 07 September, 2022: Géraldine Léonard has joined NautaDutilh's investment fund practice as of 1 September 2022.

Géraldine has more than ten years' experience in the investment management industry. She specialises in legal and regulatory matters related to Luxembourg based investment funds and investment fund managers. She advises domestic and international clients on the structuring, marketing and day-to-day operations of Luxembourg investment vehicles, with a particular focus on alternative investment funds and UCITS. She also has in-depth experience in fund managers' operations and restructuring transactions.

"We are very pleased to have Géraldine join NautaDutilh," says managing partner Lieke van der Velden. "With her arrival, we further strengthen our Benelux investment fund capabilities. Her arrival fits in perfectly with our approach of offering a wide range of services at the highest level. We look forward to work together and wish Géraldine all success."

"We are delighted to welcome Géraldine in our investment funds practice. Géraldine will work closely with all our departments at a Benelux level. Her arrival reflects the firm's continued commitment to developing a practice dedicated to expertly advising domestic and international clients. Géraldine's enthusiasm, knowledge and personalised client approach will undoubtedly be a huge asset to the firm," says Josée Weydert, managing partner of NautaDutilh Luxembourg.

Commenting on her arrival, Géraldine Léonard adds: "I am very pleased to join NautaDutilh, a leading international law firm, and to be able to contribute to the growth of the funds practice. I look forward to working together with the team to deliver outstanding services to our clients."

For additional information visit www.nautadutilh.com

SKRINE WELCOMES FOREIGN LAWYER

KUALA LUMPUR, 26 SEPTEMBER 2022: Please join us in welcoming our Foreign Lawyer, Harald Sippel to the firm.

Dr. Harald Sippel is an Austrian qualified lawyer who has been licensed by the Malaysian Bar to practise as a foreign lawyer at Skrine. He is a native speaker of German and is also fluent in English, French, Italian and Korean.

Harald specialises in dispute resolution and regularly deals with matters involving international arbitration and mediation. He has been engaged in many international arbitrations as counsel and as arbitrator. He holds a certificate in Supply Chain Management from Rutgers University and regularly advises companies on legal matters arising out of supply chain contracts. He also frequently deals with ESG-related supply chain questions, as well as compliance issues.

For additional information visit www.skrine.com

ALLENDE BREA

ASSISTS MARJOREL DELIVER GLOBAL CUSTOMER EXPERIENCE

BUENOS AIRES - 30 September, 2022: Allende & Brea in Buenos Aires helped multinational customer experience company Majorel acquire Madrid-based counterpart Findasense, including the target's operations in Latin America.

Findasense relied on Martínez-Echevarría in Madrid for the transaction, which was announced on 1 September for an undisclosed amount. Marjorel also relied on Cuatracasas; Perez Bustamante; Alta Melara; Alta Valdes Suarex & Velasco and Alta Batalia across various jurisdictions.

Counsel to Majorel - Allende & Brea Partner Valeriano Guevara Lynch and associates Mercedes Hel, Lucila Ana Lódola de San Martín, Juan Alberch and Bautista Dasso in Buenos Aires

For additional information visit www.allendebrea.com

ARIFA

ASSISTS BRAZIL'S INTERNATIONAL MEAL COMPANY WITH SALE OF ITS REMAINING ASSETS IN PANAMA

PANAMA CITY, 05 October 2022: Brazilian restaurant operator International Meal Company (IMC) enlisted Arias, Fábrega & Fábrega in Panama City to sell its remaining assets in Panama to offshore commercial catering company Inflight Holdings Cayman for US$40 million. Machado Mayer Advogados was engaged in São Paulo.

The buyer relied on Central Law (Benedetti CL Abogados) and the the deal signed mid September is pending approval from creditors and is expected to close in October. Following the completion of the deal, IMC will no longer hold assets in Panama, selling its entire operations at Panama's Tocumen International Airport. The company currently owns 13 stores in the airport's Terminal 1, while also holding the rights to manage 11 additional units in Terminal 2, which are expected to open later this year.

Until the completion of this divestment, IMC remains the largest restaurant operator at the Tocumen airport, running over half of the stores in Terminal 1.

The company will use the proceeds from the sale to substantially reduce its outstanding debt.

IMC, which is based in São Paulo, operates fast-food restaurants in several Latin American countries, including Brazil, Colombia and Mexico.

Counsel to International Meal Company (IMC) Arias, Fábrega & Fábrega (ARIFA) Partners Estif Aparicio and Fernando Arias, and associate Daniela Delvalle in Panama City.

For additional information visit www.arifa.com

CAREY

ASSISTS LENDERS IN MAINSTREAM US$294 MILLION LOAN TO BOOST BHILEAN RENEWABLES

SANTIAGO - 05 October 2022: Carey in Santiago helped European banks DNB and ABN AMRO lend €300 million (US$294 million) to Mainstream Renewable Power to fund the Irish company's operations in Chile.

Simmons & Simmons in London advised the borrower. The transaction closed on 20 September.

Mainstream will use the proceeds for general corporate purposes, including the expansion of its Chilean operations. The company owns a portfolio of Chilean solar and wind projects, both operating and under construction, generating over 4.4 gigawatts of energy.

Counsel to DNB and ABN AMRO Carey Partner Diego Peralta and associate Diego Lasagna in Santiago; Norton Rose Fulbright (London). Counsel to Mainstream Renewable Power Simmons & Simmons.

For additional information visit www.carey.cl

GIDE

ADVISES UNDERWRITERS ON THE €102.9 MILLION CAPITAL INCREASE BY VALNEVA

PARIS - 06 October 2022: Gide has advised the banking syndicate composed of Goldman Sachs, Jefferies, Guggenheim Securities and Bryan, Garnier & Co. on the capital increase by Valneva reserved to categories of investors, for an estimated total gross amount of €102.9 million, through an offering of American Depositary Shares (ADS), each representing two ordinary shares in the United States and a concurrent private placement in Europe of ordinary shares.

The ordinary shares are listed for trading on Euronext Paris and the ADSs are listed for trading on the Nasdaq Global Select Market.

Valneva is a specialty vaccine company focused on the development and marketing of prophylactic vaccines for infectious diseases with significant unmet medical needs, including Lyme disease, the Chikungunya virus, and Covid-19.

Gide also advised the underwriters on the initial public offering of Valneva on the Nasdaq Global Select Market in May 2021 and on its follow on offering for 102 million dollars in October 2021.

Gide advised the underwriters on French law aspects, with a team headed by partners Arnaud Duhamel and Guilhem Richard, working with associates Mariléna Gryparis and Mélanie Simon-Giblin.

The underwriters were advised by Goodwin Procter (NY office) on US law aspects; Valneva was represented by Cooley LLP on US law aspects and by Hogan Lovells on French law aspects.

For additional information visit www.gide.com

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DENTONS-RODYK

SECURES FINAL VICTORY IN BILLION-DOLLAR ESG RELATED CLAIM

SINGAPORE – 22 September 2022: The Singapore Court of Appeal dismissed an appeal against the High Court (General Division)'s decision in Ok Tedi Fly River Development Foundation Ltd and others v Ok Tedi Mining Ltd and others [2021] SGHC 205 to strike out the US$1.5 billion claim on behalf of some 150,000 affected by the environmental damage in Papua New Guinea's Western Province. The claim against a Singapore public company, PNG Sustainable Development Program Ltd (the "Company"), was mounted on the basis that the Company owed fiduciary duties to the affected communities, having allegedly undertaken to act in their interest. It was also asserted that some US$1.5 billion earmarked for the sustainable development of Papua New Guinea, was held on trust for them.

This appears to be the first time that a representative action of this nature and magnitude has been brought before Singapore's highest Court. The Court of Appeal will deliver written grounds of its decision in due course.

Mark Seah, Co-Head of the firm's Litigation Practice successfully led the Dentons Rodyk team comprising Andrea Gan, Martin See, Alexander Choo and Philip Teh. Mark maintained that the Company's mission was to promote sustainable development for all of Papua New Guinea. That mission was enshrined in the finely calibrated suite of contracts that the Company had entered into with the Independent State of Papua New Guinea and BHP, and remained the exclusive preserve of the contractual counterparties.

The various stakeholders including the Papua New Guinean Government and mining company BHP, had at the end of 2001, sought to balance the significant economic and social benefits that would be brought about by the continued operation of the Ok Tedi Mine, with their environmental concerns, when BHP exited the mine in 2002. As part of the exit arrangements, BHP's majority shareholding in the mining operator, Ok Tedi Mining Limited, was transferred to the Company. The Company embraced its mandate to use the dividend stream to advance the welfare of the Papua New Guinean people, particularly the Western Province. The Company's governance structures stood it in good stead to fulfil its aims, notwithstanding the challenges it faced. It has persevered in its endeavour in the face of earlier litigation in which Dentons Rodyk also successfully resisted attempts by the Independent State of Papua New Guinea following changes in government, to seize control of the Company and its sizeable funds.

The spotlight was again on ESG issues when the recent claims brought on behalf of the affected communities not only sought to upset the balance struck by contracting parties, but did so without legal footing. They were accordingly struck out last year on the ground that they were frivolous and vexatious, and that decision was upheld on appeal on 15 September 2022.

For additional information visit www.dentons.rodyk.com

HAN KUN

ADVISES TIMS CHINA DE-SPAC COMBINATION AND LISTING

BEIJING – 30 September, 2022: On September 28, 2022, TH International Limited, the exclusive operator of Tim Hortons coffee shops in China ("Tims China"), completed its business combination with Silver Crest Acquisition Corporation, a U.S. special purpose acquisition company ("SPAC"). Tims China officially became a publicly traded company on September 29, 2022, with its shares and warrants trading on NASDAQ under the symbol "THCH". The closing and related transactions will provide Tims China access to nearly US$ 200 million to support continued growth.

Han Kun provided legal services to Tims China throughout the de-SPAC combination and listing process. Previously, Han Kun advised Tims China on its multiple equity financing series.

Tims China is an emerging coffee champion in China with a vision to build the premier coffee and bake shop in mainland China. Tims China offers freshly brewed coffee, tea and other beverages, bakery and sides, and sandwiches through company-owned and -operated stores and franchised stores. Tims China had 390 system-wide stores across 21 cities in mainland China as of December 31, 2021 and aims to build a profitable network of 2,750 stores by 2026. Closing of the de -SPAC listing marks a notable milestone for Tims China, making it the "first Chinese coffee stock listed through a SPAC".

For additional information visit www.hankunlaw.com

SANTAMARINA

ADVISES FRENCH CHEMICALS COMPANY ARKEMA IN CROSS-ORDER CHEMCIAL MANUFACTURE ACQUISITION

MEXICO CIY - 29 September 2022: French chemicals company Arkema has enlisted Santamarina y Steta to buy Mexican counterpart Polímeros Especiales.

Polimeros was aided by Galicia Abogados for the deal, which closed on 1 September for an unclosed amount.

Arkema made the purchase via two of its subsidiaries – Arkema Mexico and Arkema Participations. Through the acquisition, the company intends to expand its coating solutions offerings in Latin America, while also stepping up its sustainability efforts. In addition to managing its carbon footprint as part of the American Chemical Council's Responsible Care programme, Arkema champions a range of solvent-free and bio-based products.

Counsel to Arkema Mexico and Arkema Participations Santamarina y Steta Partner Jorge León Orantes and associates Raziel Celis and Ilse Bolaños

For additional information visit www.s-s.mx

HOGAN LOVELLS

ADVISES VILLARIS THERAPEUTICS IN US $70 MILLION ACQUISITION FOR VITILGO ANTIBODY

WASHINGTON, D.C., 5 October 2022: Global law firm Hogan Lovells advised Villaris Therapeutics, a biopharmaceutical company focused on the development of novel antibody therapeutics for vitiligo, in a sale to global pharmaceutical company Incyte. Under the terms of the agreement, Incyte will acquire Villaris and the exclusive global rights to develop and commercialize Villaris' lead asset, monoclonal antibody auremolimab, for all uses, including for vitiligo and other autoimmune and inflammatory diseases. Further details can be found here.

Villaris' shareholders will receive US$70 million in upfront payments and be eligible for up to US$310 million upon achievement of certain development and regulatory milestones, as well as up to an additional US$1.05 billion in commercial milestones on net sales of the product.

Hogan Lovells' cross-office, cross-practice legal team was led by Washington, D.C.-based partner Meg McIntyre and Philadelphia-based partner Denis Segota, with support from the following: New York Office Managing Partner Michael DeLarco; Partner Matt Eisler, Denver, Partner Ajay Kuntamukkala, Washington, D.C., Counsel Robert Baldwin, New York, Senior Associate Caitlin R. Piper, Washington, D.C., Senior Associate Sarah Thompson Schick, Houston' Associate Maria Benvenuto, New York, Associate Jason Lee, New York, Associate Dan Ongaro, Minneapolis, Associate Shirley Ureña, New York, Law Clerk Elizabeth F. Adams, Washington, D.C.

For additional information visit www.hoganlovells.com

NAUTA DUTILH

ASSISTS RELIANCE NEW ENERGY LIMITED ON ITS ACQUISITION OF THE ASSETS OF LITHIUM WERKS

AMSTERDAM - 06-October 2022: Reliance New Energy Limited ("Reliance"), a wholly owned subsidiary of Reliance Industries Ltd, has acquired substantially all of the assets of Lithium Werks BV ("Lithium Werks") for a total transaction value of USD 61 million including funding for future growth. The assets include the entire patent portfolio of Lithium Werks, manufacturing facilities in China, key business contracts and hiring of existing employees as a going concern.

"We are pleased to have assisted Reliance on this transaction, as Reliance makes a bigger push towards clean energy and transport." says lead partner Rebecca Runa Pinto - Noome.

Reliance is India's largest private sector company, with a consolidated turnover of INR 539,238 crore (USD 73.8 billion), cash profit of INR 79,828 crore (USD 10.9 billion), and net profit of INR 53,739 crore (USD 7.4 billion) for the year ended March 31, 2021. Reliance's activities span hydrocarbon exploration and production, petroleum refining and marketing, petrochemicals, retail and digital services.

Reliance is the top-ranked company from India to feature in Fortune's Global 500 list of "World's Largest Companies". The company stands 55th in the Forbes Global 2000 rankings of "World's Largest Public Companies" for 2021 – top-most among Indian companies. It features among LinkedIn's 'The Best Companies to Work For in India' (2021).

Incorporated in 2017, Lithium Werks is a cobalt-free lithium battery technology and manufacturing company, with operations in the US, Europe and China and customers worldwide. Its batteries are used in industrial, medical, marine, energy storage, commercial transportation and other highly demanding applications, where its proprietary Nanophosphate® powder delivers unique power, safety and cycle life performance in addition to being more ESG friendly compared to competing technologies.

The NautaDutilh team further consisted of Jos Somers, Mariebelle Timmermans, Alexander Bevers (Corporate M&A), Elizabeth van Schilfgaarde, Janneke de Goeij - Prins, Diederik von Königslöw, Kalina Petrovski (Finance), Kees Koetsier, Florine Kuipéri (Notarial Law), Ramon Pop (Real Estate) and Daniël Kuiper (Employment and Pensions).

For more information visit www.nautadutilh.com

PRAC EVENTS
BULLETIN BOARD

Like millions around the globe, the COVID-19 pandemic has impacted our members and how we work.
Our industry follows others with a mix of restart and pause.
We meet in person where and when we can
while continuing to also meet and talk virtually face to face
Across the miles, oceans and regions
In varying places and at all hours of the day and night.
It isn't the same. We can all admit to that.
We pivot. We adapt.
What remains the same is our commitment to continue forming new bonds
and strengthening our long-standing ties with our friends and colleagues around the world.

Together, we will see it through.

PRAC Events and Event Connect

As we reboot our own in-person conferences in line with other industry related events ,
PRAC delegates can ***STAY CONNECTED!***
Let us know your plans to attend upcoming industry events and we will put you in touch
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PRAC LET'S TALK!

PRAC @ NEW DELHI MICRO-CONFERENCE HOSTED BY KOCHHAR & CO.

NEW DELHI - 2021: PRACites around the globe gathered online for PRAC @ New Delhi micro-conference hosted by member firm KOCHHAR & CO. Congratulations to the entire Kochhar Team for a successful e-hosting!

Agenda
Opening Remarks - Jaap Stoop, PRAC Chair; Marcio Baptista, PRAC Vice Chair; Jeff Lowe, PRAC Corp Secretary
Greetings & Welcome - Rohit Kochhar, Chairperson and Managing Partner
Country Update - India - Pradeep Ratnam
Visual Presentation - Essense of India!
Kochhar Practice Update - M&A - Chandrasekhar Tampi
Kochhar Practice Update - Banking & Finance - Pradeep Ratnam
Firm update - Rohit Kochhar
Panel Discussion on "Regulation of Content on Social Media" - Moderator, Stephen Mathias, Kochhar & Co (Bangalore); Mark Brennan, Hogan Lovells (Washington); Mauricette Schaufeli, NautaDutilh (Amsterdam)

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2019
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PACIFIC RIM
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PRAC @ Taipei 2014


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PRAC @ Vancouver


PRAC @ INTA


PRAC @ PDAC


PRAC @ IPBA

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ALLENDE
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Arias

ARIFA
ARIAS, FABREGA & FABREGA

Bennett Jones

Brigard Urrutia

/Carey

CITY-YUWA PARTNERS

GIDE
GIDE LOYRETTE NOUEL

Davis Wright Tremaine LLP

DENTONS RODYK

Hogan Lovells

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GOODSILL

HANKUN
汉坤律师事务所
Han Kun Law Offices

KIM, CHANG & LEE

理律法律事務所
LEE AND LI
ATTORNEYS-AT-LAW

LEGA
ABOGADOS

Mulla & Mulla
& Craigie Blunt & Caroe
Advocates, Solicitors and Notaries

ESTUDIO MUÑIZ
MUÑIZ OLAYA MELÉNDEZ CASTRO ONO & HERRERA
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ADVOGADOS

AFIP and the Commerce Secretariat restructure the system of administrative approvals for importing goods and services

Practice Areas:

Customs, International Trade and Dumping

Lawyers:

Carlos M. Melhem, Jorge I. Mayora, Mateo H. Leiva Onetto

By means of General Resolution No. 5271, the Federal Administration of Public Revenues ("AFIP") along with the Commerce Secretariat, created the Import System of the Argentine Republic ("SIRA") to regulate and monitor the granting of administrative authorizations foreseen for imports of goods and services, replacing the existing system as from October 17, 2022.

Subjects importing and/or accessing the FX market for service payments abroad must inform and prepare a sworn statement through the web-system applied by AFIP.

The information registered in SIRA will be analyzed and report the intervening agencies (Secretariat of Commerce, AFIP/Customs, Central Bank of the Argentine Republic) which must analyze and rule over the operation within a term not exceeding 60 (sixty) calendar days as from the registration in SIRA. The authorizations will have a validity term of 90 (ninety) running days, counted from the date on which the ?SALIDA? status of the operation is obtained. The different status of SIRA´s declaration will be available through the My Customs Operations ("MOA") service, on AFIP's web page.

The evaluation and analysis of import orders for goods and services will consist be acceptable if the following conditions are met:

? Information provided by the subject and authorization request.
? Risk Profile, and compliance with the commercial regime (detection of eventual under- or over-invoicing).
? Financial Economic Capacity (CEF system)

Within the presentation, the importer must include the proposed payment term (from the official dispatch). On this information, in the eventual approval the Central Bank and the Secretary of Commerce will establish and inform the term

of access in each case.

Regarding the submissions made under the SIMI in force, those with OFFICIALIZED or OBSERVED status will be cancelled and will have to be registered again through the SIRA. Those with OUTGOING status remain valid, unless they are observed by the General Customs Directorate. On the other hand, those importers that have made presentations within the framework of the Integral Monitoring System for Foreign Payments of Services ("SIMPES") and have an APPROVED status, shall remain valid.

This system is subject to regulation by the agencies involved.

This report cannot be considered as legal or any other kind of advice by Allende & Brea.

THE ANTI-DUMPING SUNSET REVIEW ON EXPORTS OF SEAMLESS CARBON STEEL PIPES FROM CHINA AND ROMANIA HAS BEEN INITIATED

On August 22, 2022, Circular SECEX No. 38/2022 (https://www.in.gov.br/en/web/dou/-/circular-n-38-de-19-de-agosto-de-2022-423854124) initiated the sunset review of the anti-dumping duties applied to exports from China and Romania to Brazil of seamless carbon steel line pipe, up to five inches in diameter, commonly classified under the NCMs codes 7304.19.00, 7304.31.90, 7304.39.10 and 7304.39.90.

Seamless carbon steel pipes are mainly used in the construction of oil and gas pipelines for conducting and storing fluids. They are also used in refineries, in chemical and petrochemical industries, in shipbuilding and shipyards, and in gas treatment and distribution plants. Additionally, they are used to transport petroleum products over small distances.

The petition was filed by Vallourec Tubos do Brasil S.A.

The analysis of the dumping's evidence considered the period from January to December 2021 and the injury analysis considered the period from January 2017 to December 2021.

Considering the possibility of resumption of dumping during the validity of the anti-dumping duty, the average domestic normal values in the Brazilian market and the average sales price of the similar domestic product in the same market in the analysis period of resumption of dumping were constructed. The difference between both in relative and absolute terms were not disclosed for both countries.

Thus, it was concluded that there were indications that the termination of anti-dumping duties would most likely lead to continuation of dumping on exports from China and Romania of the product subject to the anti-dumping measure, as well as sufficient indications as to the likelihood of resumption of injury caused by these imports in the event of termination of the anti-dumping duty.

A public interest procedure will be optional, upon request submitted based on a duly completed Public Interest Questionnaire or ex officio at the discretion of SDCOM (Subsecretariat of Trade Defence and Public Interest). The public interest procedure aims to identify possible impacts of the imposition of the anti-dumping measure on economic agents, which could be potentially more harmful when compared to the positive effects of the application of the trade defense measure. It has the same deadlines as the anti-dumping sunset review.

The interested parties (Exporters, Importers, and other Domestic Producers) can cooperate with the investigation by submitting their response to the Questionnaire, ensuring that the final decision is based on precise data, and benefiting from an individual dumping margin, which tends to be lower than the margin calculated based on the facts available.

Regulatory Obligations Concerning the Disposal of Outdated Hard Drives and Servers

Written By Ruth Promislow

The disposal of hardware in the wrong manner can leave an organization offside its regulatory obligations under privacy legislation. Depending on the residence of the individuals or entities whose personal data is stored by organizations, improper disposal of hardware storage devices may be offside of regulatory obligations in several countries.

Morgan Stanley recently agreed to pay US$35 million to the U.S. Securities and Exchange Commission (SEC) further to an inquiry by the SEC regarding the alleged improper removal of computer devices from the Morgan Stanley offices. The SEC alleged that the company hired a moving and storage company with no expertise in data protection to decommission thousands of servers and hard drives. The SEC further alleged that the moving company sold those devices, which included the personal identifying information of millions of customers. Morgan Stanley has not admitted the allegations.

This case raises an important risk which is often overlooked. Hardware used by an organization typically contains substantial amounts of personal and confidential information. If not wiped properly, that information can be subject to unauthorized access. If an organization outsources the task of removal and destruction without taking the appropriate steps, that organization is exposed.

Typically the manner in which hardware is disposed of by an organization is left to the IT department. However, the risks inherent in this exercise call for management oversight on how this task will be carried out, including for example the vetting of third-party suppliers who may be retained to dispose of the equipment, contractual obligations and indemnity terms in the agreement with those suppliers, and limitations on the supplier's ability to outsource its obligations.

The Office of the Privacy Commissioner of Canada (OPC) recommends the following (among other things) in its guidance document entitled *Personal Information Retention and Disposal: Principles and Best Practices*:

- Personal information must be securely destroyed or removed before disposing of hardware that contains such information.
- If the organization has to dispose of electronics, it should have a designated person responsible for arranging appropriate data

destruction and instruct employees to direct all electronic material and devices to that person.

- An organization should carefully assess the respective risks and benefits of destroying personal information on-site or off-site.
- When considering using a third party to dispose of personal information, an organization should take into account the sensitive nature of the personal information and take commensurate steps to manage the risks accordingly.
- An organization should ensure that the third-party contractor has verifiable credentials and can guarantee both a secure transfer of records from the organization's office to their own destruction facility, and a secure destruction method that matches the media and information security.
- If an organization decides to contract out, it should keep in mind that it remains responsible for the information to be disposed of. Best practices when dealing with third parties include:
  - privacy protection clauses in contracts to ensure that third parties to which personal information is transferred for processing (and any possible subcontractors) provide the same level of protection under the law as your organization does; and
  - monitoring and auditing clauses to ensure track record and quality control.

Privacy and confidentiality issues require careful planning and consideration at every step of the data life cycle, from collection to disposal. The consequences of failing to do can be significant.

The Bennett Jones Privacy and Data Protection group would be pleased to assist you with any questions you may have.

Authors

Ruth E. Promislow
416.777.4688
promislowr@bennettjones.com

Posted on: August 3, 2022

TRIGGERING THE DOCTRINE OF EQUITABLE CONTRIBUTION

By: Salona Nainaar

Oftentimes an individual or business may have more than one insurance policy cover the same issue that could potentially arise. A recent decision from the Ontario Court of Appeal provided guidance when both policies cover the same loss and include language claiming to be excess insurance over the other.

In *Northbridge General Insurance Company v. Aviva Insurance Company*, 2022 ONCA 519 the court re-affirmed that if two insurance policies apply to an insured's loss and are irreconcilable, then both insurers are expected to share equally the costs of defence and indemnity.

The court outlined that the doctrine of equitable contribution between insurers applies when two insurance policies are irreconcilable to the extent that they both cover the loss at issue and neither is clearly in excess to the other. When these circumstances occur both insurers will be required to equally contribute to the insured's defence and indemnification.

Background

In *Northbridge* the plaintiff sought a declaration that the defendant be required to contribute equally to the defence and indemnification of an insured party that was sued in the underlying action.

The underlying action involved a pharmacist who was sued for professional misconduct. The pharmacist's employer, a pharmacy, was also named as a defendant in the action. The plaintiff had issued a professional liability insurance policy to members of the Ontario Pharmacists Association (the "Association Policy") that included the pharmacist. The defendant had issued a commercial general liability policy to the pharmacy (the "CGL Policy"). The CGL Policy included a Pharmacists Professional Liability Endorsement that extended liability coverage to the pharmacy's employed pharmacists. As such, the pharmacist was an insured covered by two policies.

The plaintiff settled the underlying action without contribution from the defendant and thereafter sought a declaration from the court that the defendant must contribute equally to the defence and indemnification of the pharmacist.

The Association Policy contained as a general condition an "other insurance" clause that stated "This

insurance is excess over any other valid and collectible insurance…[and] does not apply to insurance which is purchased by the insured to apply in excess of the Policy". The CGL policy contained an Additional Condition that stated "The insurance provided under this endorsement is excess over any other valid and collectible insurance available to individual pharmacists…".

At trial the court found that the two policies were irreconcilable because they covered the same loss and had equivalent "other" insurance clauses wherein each policy claimed to be excess to the other. These two findings led the court to apply the doctrine of equitable contribution and grant the application that both insurers equally split the cost of the defence and indemnification.

The defendant appealed the trial judge's decision arguing that he erred in his conclusion that the two policies were irreconcilable.

Ruling

The Court of Appeal upheld the decision and found it was not in error, whether reviewed on the standard of palpable and overriding error or the standard of correctness.

In the context of the standard of appellate review, the court affirmed that matters of contractual interpretation are questions of mixed fact and law unless those questions involve the interpretation of standard form contracts or contracts with precedential value and there is no meaningful factual matrix relevant to the interpretation. In this case, the court concluded that the "other insurance" and other relevant provisions of the policies at issue are not "standard form contracts' or contracts with significant precedential value. This conclusion meant that the deferential standard of palpable and overriding error applied.[1]

The court cited *Family Insurance Corp. v. Lombard Canada Ltd*, 2002 SCC 48 and noted In this case the Association Policy and the CGL Policy both had the intention of achieving the same goal; rendering them excess if other insurance was available. This goal made them irreconcilable. Further, since the pharmacist was not the one that purchased the CGL Policy it did not fit within the Association Policy's other insurance exception. Finally, the "individual pharmacists" language in the CGL Policy, though intended to require pharmacists to have a separate professional liability policy, did not alter the CGL Policy's scope or context to one of a true excess insurance policy.

Consequently, the court dismissed the appeal.

Practical Considerations

This decision flags for insurers that when it comes to other insurance clauses and clauses aimed at limiting insurer obligations, specificity of language and the intention of specific clauses, though clearly important, may not be determinative. Perhaps more determinative is the "contextual analysis" the court referred to from *McKenzie v. Dominion of Canada General Insurance*, 2007 ONCA 480 at para 39. That analysis requires that an insurance policy be considered as a whole and that the availability of primary coverage, including a duty to defend obligation, cannot operate to change the nature of a policy to an excess or umbrella policy. This contextual analysis, if applied in a pre-eminent fashion, will render much of the competing "other insurance" clause litigation largely moot as most policies in these disputes can readily be found as primary insurance thus triggering the equitable contribution doctrine.

Finally, evidentiary care must be taken when advancing these types of applications in order to ensure, as much as possible, that any appellate review can proceed on the correctness, as opposed to palpable and overriding error, standard.

[1] *Northbridge General Insurance Company v. Aviva Insurance Company*, 2022 ONCA 519 at paras 15-16.

For more information about this article, contact the author, Salona Nainaar here.

News Alerts

Law No. 21,488 sanctions the crime of timber theft

On September 27th, 2022, Law No. 21,488 was enacted, incorporating new crimes in the Chilean Criminal Code sanctioning the theft of timber.

The new regulation, in its first article, adds the "Paragraph IV ter. of the theft of timber" in the Chilean Criminal Code to grant a special regulation of these crimes. Thus, if the value of the timber obtained through the theft exceeds approximately USD 615.00, an accessory penalty will be applied consisting of a fine of USD 4,615.00 to USD 6,154.00.

Additionally, in those cases in which the stolen timber exceeds approximately USD 3,077.00, or it was committed in a consistent pattern or as an organized act, the Public Prosecutor's Office is authorized to make use of special investigation techniques, such as undercover agents and informants (Section 226 bis of the Criminal Procedure Code).

At the same time, the new law sanctions as theft of timber anyone who possesses timber pieces or logs without being able to justify its licit origin, or whoever is discovered with timber on someone else's property without the owner's consent.

Carey y Cía. Ltda.
Isidora Goyenechea 2800,
43rd Floor
Las Condes, Santiago, Chile.
www.carey.cl

Regarding the use of false documentation to illegally transport or trade timber, the New Law imposes a penalty of up to 5 years imprisonment.

To prevent the perpetration of timber thefts, the new law imposes new obligations on the timber industry. Those who produce, sell, store or stockpile logs of wood, need to implement electronic dispatch guides, following the regulation to be issued by the Treasury Department -within 4 months from the new law was published in the Official Gazette- which must be signed by the Home Office Department (Ministerio del Interior y Seguridad Pública), and the Agriculture Department. The electronic dispatch guides will be enforceable 6 months after the publication of such regulation in the Official Gazette.

The supervision of the new law will be in charge of Carabineros de Chile (Police Department) and the Corporación Nacional Forestal, but the Tax Revenue Office may also conduct inspections according to the general rules, especially regarding the control of the sale tax.

Please consider that the theft of timber may generate criminal liability for legal entities, as they are included in the list of crimes of Law No. 20,393 (“Corporate Criminal Liability Law”). However, it is important to mention that the new law did not establish the sanction that would apply to the commission of these crimes and, therefore, for the moment, it would be inapplicable to legal entities until Congress amend this legislative error.

AUTHORS: ***Guillermo Acuña, Rodrigo Aldoney, Pablo Albertz, Eduardo Alcaíno.***

Legal Commentary

September 13, 2022

HAN KUN
汉 坤 律 师 事 务 所
Han Kun Law Offices

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CAC Issues Guidelines for Data Export Security Assessment

Authors: Kevin DUAN | Kemeng CAI | Zihuan XU | Ziqian ZHANG

On August 31, 2022, the Cyberspace Administration of China (the "**CAC**") issued the *Application Guidelines for Security Assessment of Cross-border Data Transfer (1st Edition)* (the **"Application Guidelines"**), which specify and implement the provisions on cross-border data transfer security assessments ("**security assessments**") in the *Measures for Security Assessment of Cross-border Data Transfers* (the "**Assessment Measures**"). The Application Guidelines clarify the application scope of security assessments, stipulate the means, procedures and required materials for the application, and provides contact information for inquiries regarding the application. The Application Guidelines also contain template documents, including the Cross-border Data Transfer Security Assessment Application Letter (the "**Application Letter**") and the Cross-border Data Transfer Risk Self-Assessment Report Template (the "**Self-Assessment Report Template**"), which offer effective guidance and assistance to data handlers who seek a security assessment.

This article briefly analyzes the new requirements set out in the Application Guidelines and highlights critical issues throughout the security assessment application while building on the key points of the Assessment Measures explained in our July 19 article, *CAC Formally Promulgates the Assessment Measures for Data Export.*

Reaffirming the scope of security assessments

The Application Guidelines reaffirm the circumstances subject to mandatory security assessments in accordance with Article 4 of the Assessment Measures[1], and further clarify the criteria for determining cross-border data transfer activities, which is:

[1] Article 4 of the Assessment Measures: "Where a data handler transfers data abroad under any of the following circumstances, it shall, through the local Cyberspace Administration at the provincial level, apply to the State Cyberspace Administration for security assessment for the outbound data transfer: (1) a data handler who transfers Important Data abroad; (2) a critical information infrastructure operator, or a data handler processing the personal information of more than 1 million individuals, who, in either case, transfers personal information abroad; (3) a data handler who has, since January 1 of the previous year cumulatively transferred abroad the personal information of more than 100,000 individuals, or the sensitive personal information of more than 10,000 individuals, or (4) other circumstances where the security assessment for the outbound data transfer is required by the State Cyberspace Administration."

- Data handlers who transfer and store data collected and generated in the course of operations in Chinese Mainland to overseas;
- Data handlers who store data collected and generated in Chinese Mainland, but provide overseas institutions, organizations, and individuals with right of access, retrieve, download and export;
- Other cross-border data transfer activities prescribed by the CAC.

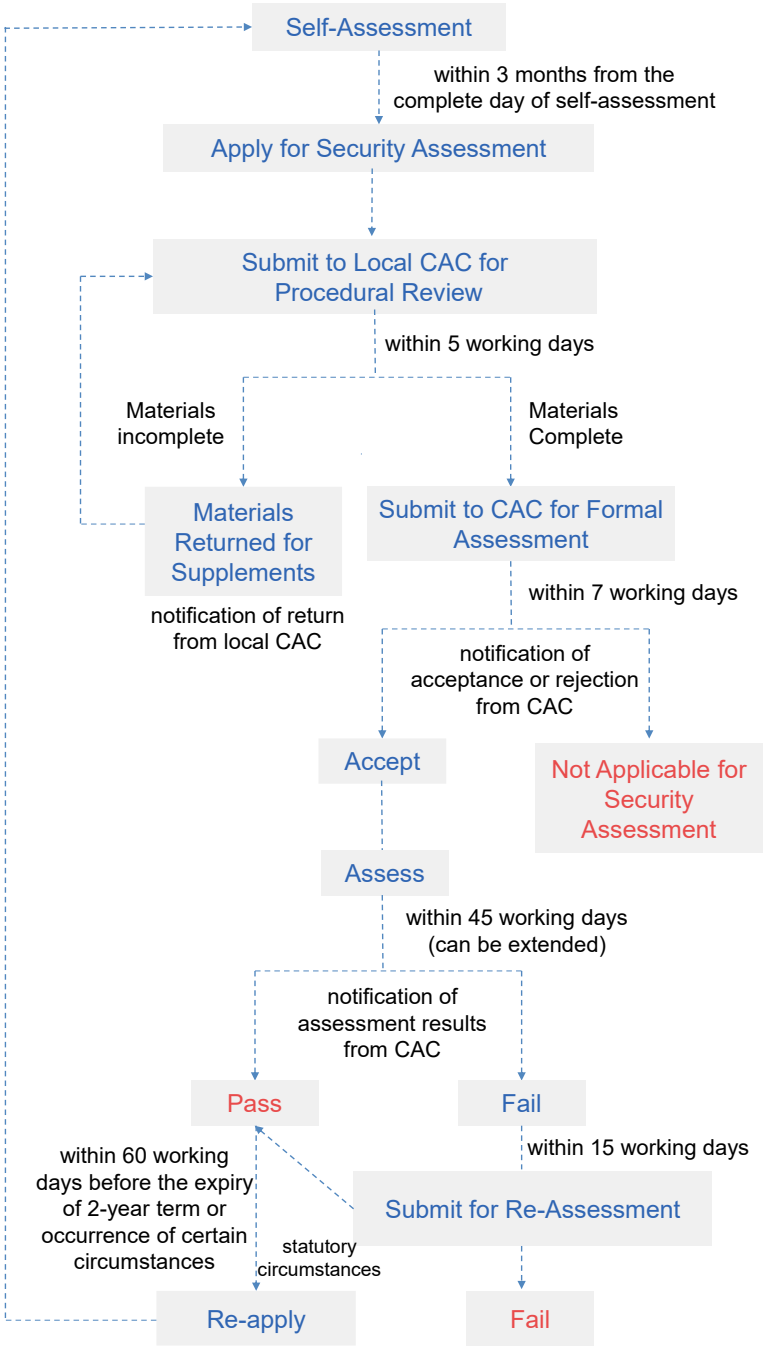
Compared to the CAC's introduction in a press briefing on July 7, 2022[2], in which the second circumstance was described as "provide overseas institutions, organizations, and individuals with the right to access and use such data", the Application Guidelines further specify remote access as "providing overseas institutions, organizations, and individuals with the right of access, retrieve, download, and export".

Notably, the Application Guidelines add a miscellaneous provision to cover "other cross-border data transfer activities prescribed by the CAC", which leaves room for future interpretations when the regulatory authorities deal with complicated data export situations. However, the Application Guidelines do not directly address the direct collection of data from overseas, i.e., where overseas entities directly collect personal information from personal information subjects residing in Chinese Mainland. Therefore, it is advisable for relevant enterprises to closely monitor regulatory developments in this regard and to take corresponding compliance measures when appropriate.

Specifying the application method and procedures

On the basis of Article 7 and Articles 11-13 of the Assessment Measures, the Application Guidelines detail the method and procedures for applying for security assessments with the CAC. The basic process is illustrated by the following diagram:

[2] CAC's press briefing on the Assessment Measures, published on July 7, 2022; for more details, please refer to: http://www.cac.gov.cn/2022-07/07/c_1658811536800962.htm (last accessed on September 7, 2022).



Key points of the aforementioned procedures are as follows:

I. Self-assessments must be completed within three months of the date of application

According to the templates provided as annexes to the Application Guidelines, the Letter of Commitment and the Self-Assessment Report Template both require that a cross-border data transfer risk self-assessment ("**self-assessment**") be completed within three months of the date of application, and no significant changes have occurred on or before the date of application.

II. Applications to be submitted on-site

According to Application Guidelines, data handlers will submit application materials to the provincial-level CAC in written form and also attach a digital version. A digital version of materials is to be

submitted via a compact disc.

III. Three types of notifications may be sent during the application process

On the basis of the Assessment Measures, the Application Guidelines provide three notifications that data handlers may receive at three important stages during the application process. These notifications are as follows:

- When data handlers fail to pass the completeness check, the CAC at the provincial level will send a notification to return the materials and to request supplements.
- When the formal assessment is completed, the CAC will send a written notification to inform the data handlers whether their application is accepted.
- When the security assessment is completed, the CAC will send data handlers notification of the assessment results. If there is no objection to the results, the data handlers will regulate their cross-border data transfer activities in accordance with the relevant laws and regulations and requirements stipulated in the notification. In case of any objection, data handlers have a 15-day period to submit for a re-assessment, starting from the date of receipt of the notification of the assessment results, according to Article 13 of the Assessment Measures.

Regarding the official assessment period, Article 12 of the Assessment Measures provides a 45-working-day period, while permitting an extension in the case of complicated situations or material supplements and corrections. However, an abundance of applications may be expected in the short term, given the generally low thresholds for mandatory security assessments as stipulated in the Assessment Measures and the short six-month cure period. Hence, it is possible that the regulatory authorities will not conduct a substantive review in certain cases and permit data exports within a relatively short time for applications that are from less sensitive industries, present a high level of need to engage in cross-border transfer activities, and contain less sensitive outbound data.

IV. Application inquiries may be made

To provide the enterprises a channel to seek official instructions in case of practical problems, the Application Guidelines contain contact information for inquiries related to the security assessment as follows:

- E-mail address: sjcj@cac.gov.cn
- Tel: 010-55627135

As of the date of this newsletter, the Beijing Cyber Administration has set up a hotline for inquiries regarding the security assessment application (010-67676912) and some other provincial-level CACs release their own contact information accordingly. It is advisable for enterprises to take notice of the relevant information disclosed by the regulatory authorities.

Specifying the requirements of the application materials

Compared with Article 6 of the Assessment Measures, the Application Guidelines further specify the

application materials that data handlers should submit when applying for a security assessment and provide corresponding templates, including:

- Photocopy of unified social credit code certificate;
- Photocopy of ID card of the legal representative;
- Photocopy of ID card of the case handler;
- Power of attorney for the case handler;
- Application letter for Security Assessment, including the letter of commitment and the Application Form;
- Photocopies of cross-border transfer related contracts or other legally binding documents to be concluded with the overseas receivers;
- Self-Assessment report on cross-border data transfer risks;
- Other relevant supporting materials.

Key points of the aforementioned materials are as follows:

I. Security assessment "case handler" is introduced for the first time

The Application Guidelines introduces the role of "case handler" for the first time. According to the power attorney for the case handler and the Application Letter of the Security Assessment in the appendix, the case handler shall be the authorized employee of the data handler and in charge of the application work on behalf of the data handler, including filing in the Application Letter of the Security Assessment.

II. Both the data transferor and the data receiver should appoint personnel and a management department responsible for data security

Pursuant to the Application Letter annexed to the Application Guidelines, data handlers need to provide information regarding their personnel and management department responsible for data security and those of their overseas receivers.

This data security personnel and management department requirement is imposed on data handlers who process important data or personal information, and who are critical information infrastructure operators, by Article 27 of *Data Security Law*, Article 52 of *Personal Information Protection Law,* and Article 14 of *Regulation on Protecting the Security of Critical Information Infrastructure*. In addition, *Information security technology-Personal Information Security Specification (GB/T35273-2020)* [3]

[3] Article 27 of Data Security Law: "The carrying out of data handling activities shall be in accordance with laws and regulations, establishing and completing data security management systems for the entire process, organizing and carrying out education and training on data security, and employing corresponding technical measures and other necessary measures to safeguard data security. The carrying out of data handling activities through information networks, i.e., the Internet, shall fulfill the duties to protect data security on the basis of the multi-level protection system for cybersecurity.

Those processing important data shall clearly designate persons responsible for data security and data security

further specifies the criteria for determining whether a person and a department responsible for personal information protection are needed. Building on these laws and regulations, the Application Guidelines require data handlers to fill in the information of data security personnel and management department. However, this may raise the question what information data handlers should provide if they are not required to designate data security personnel and management department under the aforesaid laws, regulations and standard, and we consider such handlers may provide the information of the IT responsible personnel instead.

In addition, it should be highlighted that information should be submitted regarding the personnel and management department of the overseas data receiver. Therefore, enterprises who may be involved in applying for security assessments due to use of overseas data processing services are advised to take into account the conditions of responsible personnel and organization when selecting their service providers. Enterprises should also consider including relevant clauses to guarantee that providers appoint the personnel and department as required, so as to fulfil the requirements of the security assessment.

III. Applications can be made for exports of important data and personal information at the same time

In column "09 Information of Proposed Cross-border Data" in the annexed Application Form, applicants are allowed to fill in the cross-border transfer information of both important data and personal information at the same time. Also, the "Information of Proposed Cross-border Data" section in the Application Letter no longer requires their distinction. This implies that personal information and important data transferred to the same overseas receiver can be the subject of the same application for security assessment. However, it remains unclear whether this is applicable in cases where data is provided to multiple overseas receivers within the corporate group under the same export circumstances, which is an issue facing many multinationals. The Application Guidelines have left this issue for future clarification as the regulations are implemented in practice.

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management bodies to implement responsibilities for data security protection."

Article 52 of the PIPL: "A personal information processor that processes the personal information reaching the threshold specified by the national cyberspace administration in terms of quantity shall appoint a person in charge of personal information protection to be responsible for overseeing personal information processing activities as well as the protection measures taken, among others.

The personal information processor shall disclose the contact information of the person in charge of personal information protection, and submit the name and contact information of the person in charge of personal information protection to the authority performing personal information protection functions."

Article 14 of the Regulation on Protecting the Security of Critical Information Infrastructure: "The operator shall set up a special security management organization, and conduct security background examination on the person in charge of the special security management organization and the personnel in key positions. During the review, the public security organ and the state security organ shall provide assistance."

Information security technology personal information security specification (GB/T 35273-2020) 11.1: "Organizations meeting one of the following conditions shall set up full-time personal information protection director and personal information protection work organization to be responsible for personal information security: (1) the main business involves personal information processing, and the number of employees is more than 200; (2) the organization meets one of the following conditions: Processing personal information of more than 1 million people, or expected to process personal information of more than 1 million people within 12 months;(3) Processing sensitive personal information of more than 100,000 people. "

IV. "Legal Documents" defined

Article 8 of the Assessment Measures[4] lists "the legal documents to be concluded between the data handler and the overseas receiver" as one of the key contents of the security assessment, but does not define the "legal documents" concept. The Application Guidelines clearly interpret the concept as "cross-border data transfer-related contracts or other legally binding documents".

Pursuant to the Application Guidelines, to complete the application form, data handlers need to provide the clauses in accordance with the necessary contents one by one as required by Article 9 of Assessment Measures[5].

In view of the strict legal document requirements for a security assessment, it is advisable that enterprises refer to or use the standard contractual clauses of cross-border transfer of personal information issued by the CAC, or ensure that relevant provisions are introduced strictly as prescribed in the Assessment Measures in other legal documents (such as the unilateral letters of commitment from the overseas receiver, or the data security management system or policy of the groups of the parties in Chinese Mainlandor overseas).

In addition, the Application Guidelines clearly state that the Chinese version of legal documents shall prevail. In the case where only a non-Chinese version is available, an accurate Chinese translation is required to be submitted alongside.

V. Compliance with Chinese laws and regulations is highlighted

The Application Guidelines require data handler to submit in its application form its "compliance with Chinese laws, administrative regulations and department regulations". In particular, the data handler is required to briefly describe the administrative penalties and the investigation and rectification by the relevant competent regulatory authorities in its business operations over the past two years, focusing on data security and cybersecurity.

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[4] Article 8 of the Assessment Measures: "Prior to applying for the security assessment for the outbound data transfer, a data handler shall, in advance, conduct a self-assessment on the risks of the outbound data transfer, and the self-assessment shall focus on the following matters:…(5) whether the responsibilities and obligations for data security protection are fully agreed in relevant contracts for the outbound data transfer, or other legally binding documents to be concluded with the foreign receiver…"

[5] Article 9 of Assessment Measures: "A data handler shall expressly agree on the responsibilities and obligations for data security protection in the Legal Documents concluded with the foreign receiver, which shall, at least, include the following matters: (1) the purpose, method and scope of the data to be transferred abroad, and the purpose and method for processing the data by the foreign receiver; (2) the location and duration for the storage of the data located abroad, as well as how to process the data located abroad upon the expiry of the storage period, achievement of the agreed purpose, or termination of the Legal Documents; (3) restrictions on the foreign receiver's re-transfer of the data located abroad to another organization or individual; (4) security measures which should be taken in case of a material change to the actual control or business scope of the foreign receiver, or in case of a change to the data security protection policies or regulations, or network security environment of the country or region where the foreign receiver is located, or in case that the data security cannot be guaranteed as a result of any other force majeure event; (5) remedial measures, liability for breach of contract and dispute resolution mechanism in the event of a violation of data security protection obligations as agreed in the Legal Documents; and (6) requirements on properly responding to a data security incident, as well as channels and method to safeguard individuals' personal information rights, when the data located abroad is tampered with, destroyed, leaked, lost, transferred, illegally obtained or illegally used."

Providing the Self-Assessment Report Template

According to Article 5 of the Assessment Measures[6], data handlers must conduct a cross-border data transfer risk self-assessment ("**self-assessment**") prior to submitting an application for security assessment. Furthermore, Article 6 requires the data handlers to submit the cross-border data transfer risk self-assessment report to the competent authorities, which means that the self-assessment report is a significant subject of the security assessment process. Annex 4 to the Application Guidelines contains the Self-Assessment Report Template, in which the factual materials to be submitted and evaluation criteria are to be addressed are clarified through instructions.

I. Submission of the Self-Assessment Report

When applying for a security assessment to the CAC at the provincial level, the data handler shall submit a complete and authentic Self-Assessment Report alongside. It should be noted that if a third-party organization involves in the Self-Assessment, its basic information and involvement shall be stated in the Self-Assessment Report. Meanwhile, official seals of the third-party organization on relevant pages are mandatory. Analyzing from the overall requirements of the Application Guidelines, "basic information of the third party organization" may include the name, nature of entity, main business situation, registered address and business address, while "participation" may refer to the work and role of the third party in the Self-Assessment.

II. Coverage and new requirements in the Self-Assessment Report Template

The Self-Assessment Report Template is divided into four parts: a brief introduction of self-assessment work, the overview of cross-border data transfer activities, the risk assessment of proposed cross-border data transfer activities, and a conclusion of the risk assessment.

The first part of the Self-Assessment Report Template mainly summarizes the self-assessment work, including the start and end time, organization, implementation process, and methods, etc. We believe third-party involvement may be disclosed in this section. The second part is intended to cover the business of the data handler and the facts of the cross-border data transfers, including the basic information of the data handler, the design of the transfer business, the conditions of the information systems, the overview of proposed cross-border data transfer, the security assurance capabilities of the data handler, the information of the overseas data receiver, data security protection obligations and responsibilities agreed in the legal documents, and other circumstances the data handler considers

[6] Article 5 of the Assessment Measures: "Prior to applying for the security assessment for the outbound data transfer, a data handler shall, in advance, conduct a self-assessment on the risks of the outbound data transfer, and the self-assessment shall focus on the following matters: (1) the legality, legitimacy and necessity of the purpose, scope and methods of the outbound data transfer, and the processing of the data by the foreign receiver; (2) the scale, scope, type and sensitivity of the outbound data transfer, and the risks to national security, the public interest or to the legitimate rights and interests of individuals or organizations, caused by the outbound data transfer; (3) the duties and obligations which the foreign receiver commits to perform, and whether the foreign receiver's organizational and technical measures and capabilities in terms of performing the duties and obligations can guarantee the security of the outbound data transfer; (4) the risks of the data being tampered with, destroyed, divulged, lost, transferred, illegally obtained or illegally used during and after the outbound data transfer, and whether there is a smooth channel for safeguarding personal information rights and interests; (5) whether the responsibilities and obligations for data security protection are fully agreed in relevant contracts for the outbound data transfer, or other legally binding documents to be concluded with the foreign receiver; and (6) other matters that may affect the security of the outbound data transfer."

necessary to describe. Among them, the "data security protection obligations and responsibilities agreed in the legal documents" are in line with Article 9 of the Assessment Measures concerning the data security protection responsibilities and obligations. It should be stressed that the second part of the self-assessment report has extended the coverage of the material facts related to cross-border data transfers. The added items are as follows:

- In addition to the facts involved in the cross-border data transfer activities, other basic information of the data handler, other than the enterprise information open to the public, are to be submitted, including basic information of organization or individual, information of equity structure and actual controller, information of organization structure, information of data security management department, overall information of business and data, information of domestic and overseas investment;
- The basic information of the facilities that may be involved in the cross-border data transfer activities shall be introduced comprehensively, including information of data assets related to the business of cross-border data transfers, information of information system in Chinese Mainland and overseas, information of data centers (including cloud services) related to cross-border data transfers, information of cross-border data transfer links (such as the provider, number and bandwidth of the links);
- It is necessary to disclose information about providing cross-border data to other overseas receivers through onward transfers after the cross-border data transfer;
- In terms of the security assurance capabilities of the data handler, the self-assessment report builds on the *Information Security Technology- Guidelines for Data Cross-Border Transfer Security Assessment (Draft for Comments)* and further requires the data handler to illustrate its internal categorization and classification of data, the development of its risk assessment system, as well as its compliance with laws and regulations pertaining to data and cyber security;
- As regards to the overseas receiver, the self-assessment report adds that it shall include a "description of the whole process of data processing by the overseas receiver", which covers the data life cycle from the collection by the overseas receiver from Chinese Mainland, to the use, retention, disclosure and deletion.

The third part of the Self-Assessment Report Template basically restates the requirements of the cross-border data transfer risk assessment in Article 5 of the Assessment Measures, which instructs data handlers to conduct risk assessment based on the facts specified in the second part. Meanwhile, the Self-Assessment Report Template adds a requirement to explain the risk assessment and focus on the problems and potential risks found in the assessment, as well as the corresponding rectification measures and rectification effects. Thus, in addition to the risk assessment of the proposed cross-border data transfer, the data processor also needs to disclose the rectification measures taken to mitigate the risk and the outcomes therefrom.

Our comments

As the Assessment Measures take effect, enterprise cross-border data transfers are entering a phase of compliance rectification, for which the Application Guidelines offer detailed instructions and a roadmap. Pursuant to the Assessment Measures and the Application Guidelines, it is advisable for enterprises to mitigate compliance risks for their data exports by addressing the following:

- Specify the circumstances of cross-border data transfers throughout data processing activities and examine the relevant facts. Determine whether these circumstances fall within the scope of the security assessment and select a data export strategy accordingly (such as to pursue complete data localization or apply for a security assessment as prescribed by laws and regulations);
- Refer to the second part of the Self-Assessment Report Template to conduct a self-assessment in a timely manner. Identify the potential risks and take corresponding mitigation measures so as to pass the security assessment within the six-month period provided in the Assessment Measures;
- Prepare the application materials as required by the Application Guidelines and submit to the relevant CAC at the provincial level, including the photocopy of unified social credit code certificate, photocopy of ID card of the legal representative, photocopy of ID card of the case handler, power of attorney for the case handler, the Application Letter for Security Assessment, including the letter of commitment and the Application Form, photocopies of cross-border transfer related contracts or other legally binding documents to be concluded with the overseas receivers, a self-assessment report, etc.;
- Establish an internal compliance system for cross-border data transfer security assessments. Continue to monitor the conditions of all data exports. Update the submitted materials and re-apply for a security assessment when required.

Important Announcement

This Legal Commentary has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

If you have any questions regarding this publication, please contact:

Kevin DUAN

Tel: +86 10 8516 4123
Email: kevin.duan@hankunlaw.com

Kemeng CAI

Tel: +86 10 8516 4289
Email: kemeng.cai@hankunlaw.com

Brigard Urrutia

The Congress of Colombia approves the Escazu Agreement

12 of October

Escazu Agreement

The Congress of Colombia approved in fourth debate the draft bill approving the Regional Agreement on Access to Information, Public Participation and Justice in Environmental Matters, adopted by 24 Latin American and Caribbean countries on March 4, 2018, in Escazú, Costa Rica (the "Escazú Agreement").

Thus, Colombia joins the list of 14 countries to approve the Escazú Agreement and starts the path towards the implementation of its provisions, among which are the following:

Antigua and Barbuda

Argentina

Bolivia

Chile

Ecuador

Guyana

Mexico

Nicaragua

Panama

Saint Vincent and the Grenadines

Saint Lucia

Uruguay

The Escazú Agreement aims to ensure the full and effective implementation of the rights of access to environmental information, public participation in environmental decision-making processes and access to justice in environmental matters, as well as the creation and strengthening of capacities and cooperation in Latin America and the Caribbean. The Escazú Agreement seeks to contribute to the protection of the present and future generations' right to a sustainable development and to live in a healthy environment.

Although this draft bill must now go through a conciliation process between the two chambers of the Congress of the Republic to be finally approved by the legislator, after which it must be sanctioned by the President of the Republic and submitted to the Constitutional Court's constitutionality review, no significant changes are expected in its content that may affect the meaning or main objective of the Escazú Agreement. This is further supported by Article 23 of the Escazú Agreement, which expressly establishes that reservations are not admitted.

To see the original version of the Escazú Agreement, please click on the following LINK https://www.cepal.org/es/organos-subsidiarios/regional-agreement-access-information-public-participation-and-justice/texto-acuerdo-regional

FOR MORE INFORMATION CONTACT OUR TEAM
info@bu.com.co
www.bu.com.co

Arias

COSTA RICA

NOTES ON THE PROCESSES OF PURCHASING MEDICINES IN THE CCSS IN LIGHT OF THE NEW GENERAL LAW OF PUBLIC PROCUREMENT

October/2022

A new General Public Procurement Law in Costa Rica will enter into force on December 1, 2022, along with its Regulations.

One of the great milestones of this new contracting or public procurement regulation in the country is the uniformity and homogenization that will exist. As a rule, all State institutions must follow the procedures and provisions established therein, excluding the possibility of having different public procurement processes depending on the institution being analyzed.

In the case of the Costa Rican Social Security System, the procedures regulated in the Administrative Contracting Law and its Regulations are currently applied, supplemented by the "General Conditions for the Institutional Administrative Contracting of Goods and Services Developed by all the Decentralized Units and not Decentralized of the CCSS)". Additionally, the institution applies a special procedure to directly import, manufacture, buy, sell, and export medications, raw materials, and conditioning and packaging materials required in their preparation, in accordance with articles 71 and 72 of the Constitutive Law of the CCSS and the "Regulation for the Purchase of Medicines and Raw Materials, Containers and Reagents".

The new General Law on Public Procurement will oblige the CCSS to implement all public procurement processes in accordance with the new provisions. This creates the challenge for companies supplying medicines, equipment and supplies to the CCSS, to have a comprehensive understanding of the new provisions applicable.

The following are some practical tips for CCSS provider companies in this context:

It is convenient to permanently prepare and train the technical teams and personnel involved in the purchasing processes regarding the new rules that operate these processes in the CCSS, based on the General Law of Public Procurement and its Regulations.

Ensure that they are listed as suppliers in the unified digital system regulated by the new Law. Although there are currently regulations that require the use of the SICOP for all public purchases, with the new Law there is no possibility of exceptions and even a contracting that is not done within the framework of the unified digital system could be considered void.

It is convenient to ensure constant training of company personnel involved in public procurement processes on the use of the unified digital system.

Companies are recommended to work with the CCSS to get involved in the market studies that will be carried out to determine the existence of a single supplier. With the new Law, the determination of sole supplier is an exception to the contest rule and must be preceded by a verification in the unified digital system, as well as a market study, and an invitation that must be made in said system, to know if there is more than one potential offeror to provide the contractual object and thus verify uniqueness.

Explore the possibility of proposing new procurement mechanisms to the CCSS that may result in improved access to medicines for patients with complex diseases, based on the concepts of strategic contracting and innovative public procurement.

Prepare for additional steps to be carried out from the moment the Law and its Regulations come into force, as:

Register in the Registry of suppliers and subcontractors and in the Registry of Reduced Tenders (previously called direct contracting for small amounts).

Prepare and present the necessary Affidavits to register in the Registry of suppliers.

Verify the planning for each budget period and the CCSS projected procurement program (in the first month of each budget period), which must be published in the unified digital system by the Institution.

Give inputs to the Price Bank that must be created in the unified digital system to have a catalog of services and goods to determine the budgets in the purchase of medicines. This will serve to feed market studies and verify reference prices.

Consider some other relevant modifications of the new Law, such as:

The possibility of unilateral modification for no more than 20% of the amount and term of the original contract (exceptionally for 50%).

The possibility of contractual assignment without a maximum percentage or the need for prior authorization by the CGR.

The elimination of the sanction of warning to supplier companies and only the possibility of disqualification (simple sanction from 6 months to 2 years and qualified sanction from 2 to 10 years).

The possibility of termination of the contract due to the inactivity of the Administration or the contractor, for a period that reaches six months, either continuously or the sum of the partial suspensions.

Luis Diego Obando
Senior Counsel
luis.obando@ariaslaw.com

EL SALVADOR

MINISTRY OF FINANCE ISSUES LIST OF TAX HAVENS APPLICABLE FOR 2023

October/2022

EL SALVADOR - THE MINISTRY OF FINANCE ISSUES LIST OF TAX HAVENS APPLICABLE FOR THE YEAR 2023

The Ministry of Finance, through the General Directorate of Internal Taxes and through the Orientation Guide No. DGII-006.006/2022 dated September 26, 2023, issued the list of countries, states or territories that will be considered Low or Null Taxation, or Tax Havens, for tax purposes in the Fiscal Year 2023.

With the aforementioned publication, the Ministry of Finance complies with the provisions of Section 62-A of the Tax Code, which obliges the Salvadoran Tax Administration to publish no later than September of each year, the list of countries, states or territories considered to have Low or Null Taxation or Tax Havens, which will be the current list for the following year.

The main novelties contained in the new list are the following:

No countries or states have been added, removed or replaced, both in the lists of Low and Null Taxation. Therefore, the same countries and states mentioned in the list of the Orientation Guide published last year remain.

This new list does not include countries classified as Tax Havens according to the Organization for Economic Cooperation and Development (OECD), nor the Financial Action Task Force (FATF).

The Kingdom of Spain continues to be the only country with which El Salvador has signed an Agreement to Avoid Double Taxation. The Guide also includes the list of countries with which El Salvador has signed the Mutual Assistance and Cooperation Agreement between the Tax and Customs Administrations of Central America, which are: Costa Rica, Guatemala, Honduras and Nicaragua.

Access this link and you will find a file that contains the comparative tables in the areas of Low Taxation, Null Taxation and Tax Havens of the new list applicable to 2023 in relation to the list applicable to 2022.

Download the list of countries, states or territories with preferential tax regimes, low or zero taxation, or tax havens applicable for the year 2023, here. (Document available only in spanish).

Do not hesitate to contact us if you have any doubts about this subject.

Marco Suvillaga Schönenberg
Associate | Marco.Suvillaga@ariaslaw.com

Contacts

Romain Rard

Didier G. Martin

Adoption of the CSRD: sustainability, a new pillar of businesses' performance?

20 July 2022

The topic of non-financial information as such is not new; the so-called "Non-financial Reporting Directive" (Directive 2014/95/EU) already requires a number of companies to disclose and include in their management reports a non-financial statement containing information relating to at least environmental matters, social and employee-related matters, respect for human rights, anti-corruption and bribery matters.

Transposed into French law in 2017,[1] the companies[2] in scope are required to publish a "*declaration of extra-financial performance*" (the "**DPEF**"), integrated into their management report, which presents information regarding how they take into account the social and environmental consequences of their activities.

However, the implementation of these requirements has highlighted significant shortcomings: many companies do not provide reliable, comparable and relevant information on sustainability risks, opportunities and impacts.

These shortcomings prove all the more problematic in light of the European Green Deal and the European Commission's objectives of promoting sustainable finance and investment, and ensuring a just transition.

This is the context in which the European Commission published its legislative proposal (April 2021) which aimed to thoroughly revise applicable rules on non-financial reporting (renamed "corporate sustainability reporting") in view of improving the flow of information on sustainability matters. On 21 June, after several months of negotiations, the Council and the European Parliament reached a political agreement on this new directive - the *Corporate Sustainability Reporting Directive*) (the "**CSRD Directive**").

The CSRD, which broadens the scope of non-financial reporting, will oblige more companies to disclose precise information, on the basis on harmonised standards and subject to reinforced control. Thus, the CSRD will require companies to communicate with respect to both sustainability risks to which they are exposed as well as and about their own impact on people, the environment and society at large. In that respect, sustainability can be of relevance for the measure of companies' performance.

1. **Extending the scope of non-financial reporting**

The CSRD will require the following entities to disclose information on sustainability matters :

- all companies listed in EU regulated markets (with the exception of micro-companies[3]), including those not established in the Union but whose securities are listed on a European regulated market;

- non-listed companies with more than 250 employees and either a balance sheet total or a turnover of more than EUR 20 million or EUR 40 million, respectively.

European subsidiaries and sub-groups whose parent company is not established in an EU Member State will also be required to disclose sustainability information. Small and medium-sized companies[4] are also encouraged to publish sustainability information according to simplified standards. Finally, all parent companies of large groups will have to publish sustainability information.

As a result, it is estimated that an additional two thousand French companies will have to publish sustainability information.

2. **Towards more granularity and greater comparability of sustainability information**

The CSRD strengthens significantly the list of sustainability indicators that companies will be required to report on.

From now on, companies will notably have to provide information about i) their business strategy and the resilience of the undertaking's business model and strategy to risks related to sustainability matters; ii) any plans they have developed to ensure that their business strategy and model are compatible with the transition to a sustainable and climate-neutral economy; iii) their targets related to sustainability matters and the progress made towards achieving those targets; as well as iv) the role of the administrative, management and supervisory bodies with regard to sustainability matters.

This information will have to be clearly identifiable in a specific section of the management report and will have to include precise descriptions, including for example the plans defined by the company to ensure that its business model and strategy are compatible with the transition to a sustainable economy and with the limiting of global warming to 1.5 °C in line with the Paris Agreement and climate-neutrality.

Although certain derogations may apply in exceptional cases (impending developments, matters under negotiation, information seriously prejudicial to the commercial position of the company) and transitional periods are provided for, the spirit of the reform is undeniably to move towards greater transparency and comparability of the information provided by companies in scope of the CSRD.

In this respect, sustainability reporting standards[5] will be prepared on the basis of technical advice and contributions from the working group set up by the European Financial Reporting Advisory Group (EFRAG). They will be adopted by the European Commission by means of delegated acts and will aim to ensure that the information disclosed is understandable, relevant, verifiable, comparable and is represented in a faithful manner.

The adoption of these standards will face both opportunities and challenges: the standards could pave the way to the emergence of a sustainability data ecosystem, and contribute to the coherence of the legal and regulatory framework relating to the European Taxonomy and the so-called SFDR[6], all while striving to find the right balance by taking into account to the greatest extent possible the work of global standard-setting initiatives for sustainability reporting, as well as existing standards and frameworks.[7]

The CSRD will therefore result in a double upheaval: an amendment of the current non-financial reporting provisions under French law, in particular the Commercial Code, and the emergence of a new body of harmonised standards at EU level. The new legal framework is bound to have strategic implications and be demanding for companies, under the guise of the concept of "sustainability", and will require all activities of companies in scope to factor in the objective of sustainable development. It is therefore a real revolution which companies face, which they will have to adapt to and prepare for by 2024.[8]

3. **Strengthening the audit and assurance of sustainability reporting**

The absence of an assurance requirement on sustainability reporting would undermine their credibility and fail to meet the needs of the investors and other users of sustainability information for whom they are intended. It is therefore appropriate to consider a gradual increase in the level of assurance required for sustainability disclosures, starting with a requirement for the statutory auditor or audit firm to give an opinion on the compliance of sustainability disclosures with EU requirements, based on a limited assurance engagement.

The co-legislators also wanted to offer undertakings a broader choice of independent assurance services providers for the assurance of sustainably reporting. Member States should, therefore, be allowed to accredit independent assurance providers to provide an opinion on published sustainability information.

It should be noted that French law already provided such an assurance mechanism for a certain number of companies.

Conclusion

The European Commission's ambition, with the proposed CSRD, was to ensure a consistent flow of sustainability information within the financial system, in order to achieve the transition objectives and prevent greenwashing.

The broader scope of CSRD, the principle of greater comparability through common benchmarks for sustainability reporting, and the assurance mechanism agreed by the co-legislators should all be welcomed and will contribute to deliver on the Commission's objectives. Companies may now start preparing and assessing the operational impacts resulting from the CSRD.

That said, the reform is not complete yet: the Union is still to adopt the European sustainability standards which will have to further transcribe the principle of double materiality and provide a common framework for the latest waves of sustainability-linked rules and regulations. This will be the true test that will determine whether the EU can become a front-runner in setting global sustainability reporting standards, and whether sustainability can become a new pillar of businesses' performance.

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[1] Article L.225-102-1 of the French Commercial Code.

[2] These are companies which employ, on average, more than 500 employees and whose turnover or balance sheet total exceeds (i) for companies listed on a regulated market, their turnover or balance sheet total must exceed 40 million euros or 20 million euros respectively and (ii) for other companies, their turnover or balance sheet total must exceed 100 million euros.

[3] Namely, companies that employ less than 10 people and whose annual turnover or annual balance sheet total does not exceed 2 million euros.

[4] These are companies that employ less than 250 people and whose annual turnover does not exceed 50 million euros or whose balance sheet total does not exceed 43 million euros.

[5] Simplified standards will apply to SMEs.

[6] Cf. Regulation (EU) 2019/2088.

[7] Including existing standards and frameworks for natural capital accounting and for greenhouse gas accounting, responsible business conduct, corporate social responsibility, and sustainable development.

[8] From 1st of January 2024 for companies already subject to the non-financial reporting directive; from 1st of January 2025 for large companies that are not presently subject to the non-financial reporting directive; and from 1st of January 2026 for listed SMEs, small and non-complex credit institutions and captive insurance undertakings.

GUATEMALA

AMENDMENT TO THE COLLECTION OF CONTRIBUTIONS TO THE SOCIAL SECURITY REGIME

October/2022

GUATEMALA - AMENDMENTS TO THE COLLECTION OF CONTRIBUTIONS TO THE SOCIAL SECURITY REGIME

Through Government Agreement Number 239-2022 of the Ministry of Labor and Social Welfare published in the Diario Oficial (Official Gazette) on September 28 of this year, Agreement 1520 of the Board of Directors of the Guatemalan Institute of Social Security -IGSS- was approved, through which amendments to Agreement Number 1421 of the Board of Directors of the Guatemalan Institute of Social Security -IGSS- "Regulation on the Collection of Contributions to the Social Security Regime". Likewise, said Agreement 1520 was published in the Official Gazette on September 28 of the current year. Both Agreements entered into force on the day of their publication.

The reforms introduced in Articles 4 and 5 concern the setting of a base amount for the calculation of the minimum monthly contribution to Social Security, in cases where the worker earns a salary lower than said base. The amount will be determined in accordance with the amount established as the minimum monthly salary set by the Executive Branch for the corresponding activity (agricultural, non-agricultural, manufacture). The employer will oversee paying the corresponding amount between the minimum contribution and the sum of the labor and employer contributions calculated based on the salary earned by the worker. Consequently, the employee who does not earn the minimum monthly salary must only make his contribution to social security on the amount of the salary he earns, and the employer must contribute on the difference between the employer and labor quota (expansion factor) necessary to cover the minimum monthly contribution to social security that is established on the corresponding minimum wage.

The Agreement establishes that the base amount for the calculation of the minimum monthly contribution to Social Security is defined as the amount resulting from multiplying the minimum salary set by the Executive Branch, in daytime work according to the corresponding economic activity, calculated on a minimum of eight hours a day, by the given expansion factor, according to the calculation table included in said Agreement. Likewise, the distribution of income from the cases described above to the accounts of the Sickness, Maternity and Accidents -EMA- and Disability, Old Age and Survival -IVS- programs is included.

Additionally, Article 9 is reformed in the sense that it adds the provision related to the obligation of the IGSS to maintain the discretion not to disclose, except in writing from a competent authority, the data or individual reports provided to the Collection Directorate for being considered under guarantee. Confidential. Statistics or general reports prepared with individual data and figures can only be provided or published by the IGSS Management when deemed appropriate.

Liz Gordillo
Partner
Liz.gordillo@ariaslaw.com

Hogan Lovells

A disappointing sequel? Hong Kong court dismisses challenge to SFC restriction notice regime

12 October 2022

The Court of First Instance has dismissed a judicial review application against certain provisions in the Securities and Futures Ordinance (Cap. 571) (SFO) which empower the Securities and Futures Commission (SFC) to issue restriction notices to freeze assets in trading accounts during investigations of market misconduct.

The proceedings in *Tam Sze Leung and Others v Secretary for Justice and Another* [2022] HKCFI 2330 can be regarded as a 'sequel' to similar proceedings earlier this year , where the same applicants made a constitutional challenge against the use of "letters of no consent" by the Commissioner of Police to informally freeze bank accounts associated with suspected fraudulent activities (see Hogan Lovells client alert Unfrozen – Hong Kong court rules "informal freezing" of bank accounts unlawful). In that action, the court found that the letters of no consent regime was unconstitutional.

In what may at first appear to be somewhat of a U-turn, on this occasion, the court upheld the constitutionality of the restriction notice regime. The court found that the scope of the SFC's powers and the manner in which they are exercised under the SFO are sufficiently clear.

The court found that, unlike the letter of no consent regime, the restrictive notice regime has sufficient legislative safeguards in place to guard against potential abuse of powers. The restrictions or limitations imposed by restrictive notices are no more than necessary to accomplish the legitimate aim of protecting investors' and the public's interests and strike a balance between encroaching on an individual's constitutionally protected rights and benefits to society.

Different approaches

The letter of no consent regime as operated by the police pursuant to their internal guidelines relates to sections 25 and 25A of the Organized and Serious Crimes Ordinance (Cap. 455) (OSCO).

Section 25 provides that it is an offence to deal with property known or is reasonably believed to represent the proceeds of crime. Section 25A requires a person to make disclosure (often by way of Suspicious Transaction Reports) to an authorised person if they know or suspect the property to be the proceeds of crime. Section 25A(2) provides a statutory immunity to the section 25 offence, where the person concerned has made a disclosure but obtain consent of an authorised officer to deal with the property in question.

As such, sections 25 and 25A of OSCO do not expressly create a letter of no consent regime and empower the police with an informal power to freeze assets. In practice, the letter of no consent regime created a lot of uncertainty as to the progress of the police's investigation, the considerations are taken into account by the police and how long the freezing measures will remain in place.

In *Tam Sze Leung (No.1)*, the court held that such informal freezing powers cannot be implied into the statute as necessary and the letter of no consent regime was held ultra vires (i.e. unconstitutional). On the other hand, sections 204, 205 and 206 of the SFO expressly authorise the SFC to restrict and prohibit the dealing with assets held in accounts maintained with licensed corporations. Section 207 provides for the circumstances in which the SFC can issue a restrictive notice under sections 204 and 205. Sections 207(a) to (d) relate to market misconduct by licensed corporations while the scope of section 207(e) is much wider in that captures the clients of the licensed corporations for the purpose of protecting the interest of the investing public and general public.

The effect of a restrictive notice is similar to that of a Mareva injunction. It can apply to any property held by a licensed corporation and is not limited to what is suspected to be proceeds of crime or property derived through illegal means.

Grounds for challenge

The focus of argument in the present case is section 207(e) – whether the SFC considers the imposition of the restrictive notice to be "desirable" in "the interest of the investing public and in the public interest" based on the materials it has uncovered in its investigations.

The applicants in these proceedings raised two grounds of challenge:

1. Prescribed by Law - The relevant SFO provisions did not meet the "prescribed by law" requirement as the scope of powers and the manner of their exercise lacked sufficient clarity and the restrictive notice regime lacked proper safeguards against abuse and misuse.

2. Proportionality Test - Even if the relevant SFO provisions are considered sufficiently certain, the interference with an individual's property rights guaranteed by Articles 6 and 105 of the Basic Law goes further than is reasonably necessary.

The "Prescribed by law" requirement

What "prescribed by law" means is that the law must be adequately accessible and sufficiently precise to enable the citizen to regulate their conduct so that they can foresee the consequences which a course of action will entail.

(a) Broad construction of legislation does not mean insufficiently clear

The present case arose from an ongoing investigation in relation to a suspected "ramp and dump" scheme . The court first considered the scope and evidentiary threshold of section 207(e) of the SFO and formed the view that the issuance of restrictive notices can be triggered after balancing (1) the stage of the investigation, (2) the potentiality of the unfavorable outcome which has been identified by the materials generated by the investigation, (3) the apparent need to safeguard the rights of others or protect the public interest, and (4) what the impact will be from the prohibition or requirement in mind.

(b) What is "desirable in the interest of the investing public"

In considering the "desirability" of a restrictive notice in the context of a "ramp and dump" scheme, the issue of a restrictive notice is considered by the SFC to be in the interests of the investing public to preserve funds for possible repayment to those investors who fall victim to the scheme.

(c) Concept of "public interest"

The judgment discussed the concept of "public interest" in section 207(e) of the SFO, which is the "yardstick" guiding the SFC's decision making process. The court did not take this opportunity to provide a definition of "public interest" (and understandably so because the broad drafting of section 207(e) is meant to give flexibility to the SFC decision making process). Instead, the court found that the existence of the review mechanism by the Securities and Futures Appeals Tribunal (SFAT), which publishes reasoned decisions, provides an infrastructure which is conducive to the gradual development on the meaning of section 207(e).

It is worth noting that the meaning of "public interest" differs in different statutory contexts. In previous case law considering section 33 of the Telecommunications Ordinance (Cap. 106), which gives the Chief Executive in Council (CEIC) power to order interception of telecommunications "whenever he considers that the public interest so requires", the court found that section 33 is not formulated with sufficient precision to provide independent judicial oversight of the CEIC's powers and that there are no legislative safeguards against abuse of executive power. However, this is not the position with regards to the restrictive notice regime.

(d) Safeguards

The court considered that there are sufficient safeguards against the abuse and misuse of the SFC's administrative powers. For example, the relevant enforcement division of the SFC carries out periodic reviews of each case where a restrictive notice has been issued. After a restrictive notice is issued, a person can seek consent from the SFC to deal with the assets or seek further review by the SFAT which is a de novo full merits review conducted by a sitting or retired judge and two lay members. With regards to judicial oversight, the SFC's exercise of powers and decisions of the SFAT are subject to judicial and appellate reviews.

It is important to note that the SFAT is composed of a judge and financial industry professionals which makes the SFAT an expert and informed tribunal. While the powers granted to the SFC under the restrictive notice regime are highly intrusive to the individual property rights, the SFAT is well placed to not only take into account the intrusion into individual's property rights, but also to decide the proper weight that should be accorded to that factor.

(e) No time limit

The effect of a restrictive notice can last until trial or further order. In the present case, the restrictive notices affecting the applicants had been maintained for 16 months and yet no charges had been pressed.

In addressing the argument on the lack of time limit of restrictive notices, the court referred to previous case law which stated that the time during which an individual's property right is restricted, will be circumscribed by the requirements of reasonableness in the public law sense and proportionality on a constitutional law level. In other words, instead of considering whether the restrictive notice has been in force for too long, the SFAT will decide whether the duration continues to be reasonable.

Furthermore, it was appreciated that more complex cases require more time for investigation and collection of evidence by the SFC, so it is impossible to predict how long the investigations will take before a decision can be made. Hence, it is unrealistic to set an arbitrary expiry date for a restrictive notice. Yet, the lack of time limit of letters of no consent under OSCO was one of the many factors that contributed to the court taking the view that the letter of no consent regime was unconstitutional.

The Proportionality test

Many aspects of the analysis on the "prescribed by law" requirement overlap with the proportionality analysis.

With regard to the appropriate standard of review, the SFC advocates the "manifestly without reasonable foundation" standard while the applicants advocate the "not more than necessary" standard. In a socio-economic context as the present case, the court tends to adopt the "manifestly without reasonable foundation" standard, in recognition of the government's institutional capacity in making decisions and to allow the government a broad margin of discretion.

It is well established in case law that the four steps of the proportionality test are:

(1) Whether the intrusive measure pursues a legitimate aim.

(2) If so, whether it is rationally connected with advancing that aim.

(3) Whether the measure is no more than necessary for that purpose.

(4) If the intrusive measure passes the first three steps, whether a reasonable balance has been struck between the societal benefits of the encroachment and the inroads made into the constitutionally protected rights of the individual concerned, asking in particular whether pursuit of the societal interest results in an unacceptably harsh burden on the individual.

As regards the first step, the legitimate aim of Part X of the SFO is the protection of investors, creditors of the licence corporation and the public interest. Pending the outcome of an investigation into misconduct in the securities and futures market, the preservation of funds that might otherwise be dissipated, prevention of dealing in proceeds of crime and general deterrence are ways in which the restrictive notice regime under the relevant SFO provisions all can be said to pursue a legitimate aim.

In terms of the second step, although the restrictive notice temporarily deprives a licensed corporation of its funds in the frozen accounts, it ensures that those funds remain available for future orders to be made in respect of them. As such, the restrictive notice regime is rationally connected to the legitimate aim.

With regard to the third step, the court found that the review mechanism by the SFC and the appeal mechanism to the SFAT are "very real" and "not so inadequate as to cause the [restrictive notice] regime to be transparently disproportionate to the problem it seeks to address". The fact that these remedies do not provide immediate redress does not make the regime disproportionate. With the legislative safeguards in place, the restrictive notice regime is no more than necessary to accomplish the legitimate aim.

As for the fourth step, the remedies that the legislation provide do not produce a result that is extremely unbalanced or unfair or one that imposes an unacceptably harsh burden on the individual.

Implications

Ultimately, the outcome of this judicial review boils down to legislative intent and the statutory provisions themselves. In contrast to the letter of no consent regime, where the police's powers to freeze assets is without legal basis, the SFC is given wide discretion and power under the SFO to freeze assets with the use of restrictive notices.

To cite the Honourable Mr. Justice Coleman, "the very nature of discretionary power means that it might not always be predictable with certainty as to its application". It is enough that the SFC's discretionary powers can be exercised within a certain scope and in a particular manner with adequate safeguards, including review mechanisms and judicial oversight. As Coleman J put it, "absolute certainty is unattainable, and would entail excessive rigidity...the law must be able to keep pace with changing circumstances."

The legislature envisaged the flexibility required for financial regulators to further their regulatory objectives and discharge their statutory functions in a timely manner. The need for a broadly drafted basis is precisely because trading activities that are subject to the SFC's oversight are dynamic and fluid, and these activities give rise to various forms of misconduct that may fall outside the ambit of those already regulated under the SFO but which deserve to be regulated by the SFC in the public interest.

Authored by Mark Lin, Stephanie Tsui, and Vanessa Hung.

Contacts

Chris Dobby
Partner
Hong Kong
chris.dobby@hoganlovells.com

Mark Lin
Partner
Hong Kong
mark.lin@hoganlovells.com

Antonia Croke
Partner
Hong Kong
antonia.croke@hoganlovells.com

Byron Phillips
Partner
Hong Kong
byron.phillips@hoganlovells.com

Stephanie Tsui
Senior Associate
Hong Kong
stephanie.tsui@hoganlovells.com

Vanessa Hung
Paralegal
Hong Kong
vanessa.hung@hoganlovells.com

Nigel Sharman
Senior Knowledge Lawyer
Hong Kong
nigel.sharman@hoganlovells.com


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Swiss Challenge Method: A brief discussion

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By Samiron Borkataky and Kritika Angirish

This write-up is a brief discussion on the Swiss Challenge Method (**"SCM"**) for selecting a resolution plan under a corporate insolvency resolution process initiated under Chapter II of the Insolvency and Bankruptcy Code, 2016 ("**Code**").

First things first, what is SCM

SCM is a form of public procurement by way of a bidding process, *wherein a bidder (original bidder) makes an unsolicited Bid to the auctioneer. Once approved, the auctioneer then seeks counter-proposals against the original bidder's proposal and chooses the best amongst all options including the original Bid. The original builder in most cases is granted the right to first refusal. If the original bidder match its offer to the challenging proposal, the Bid is awarded to him, else it is awarded to the challenging bidder*[1].

Judicial recognition of SCM in India-

In 2009, the Supreme Court decided on a challenge[2] made by Ravi Development and Maharashtra Housing and Area Development Authority ("**Ravi Development**") against a common order of the High Court of Bombay whereby the tender and conferring preferential treatment by use of SCM to Ravi Development was deemed to be unfair, unreasonable, arbitrary and illegal. In this case, the Supreme court while holding that the contract offered in favour of Ravi Development was correct, clarified that the decision to apply the mode of SCM clearly fell within the realm of the executive discretion and that there was due application of mind by the Housing and Area Development authority, and hence did not foul of Article 14 of the Constitution of India. Further, in the said judgment the Supreme Court also suggested steps that may be kept in mind to avoid ill effects of SCM and encourage transparency and proper execution of the scheme. Since then, many states/ authorities have with time also adopted their own guidelines for SCM.[3]

Advent of SCM under the Indian insolvency regime

On August 27, 2021, the Insolvency and Bankruptcy Board of India's ("**IBBI**") published a discussion paper ("**Discussion Paper**"), whereunder amongst others, the use of SCM was suggested to tackle the issue of delay in passing of resolution plans.

The Discussion Paper observed that while Regulation 39 of the Insolvency and Bankruptcy Board of India (Insolvency Resolution Process for Corporate Persons) Regulations, 2016 ("**CIRP Regulations**") provides the mechanism for approval of resolution plan by the Committee of Creditors ("**CoC**"), and sub-regulation 3(a) *thereof* provides that CoC shall evaluate the resolution plans

[1] https://ibbi.gov.in/Discussionpaper-CIRP-27Aug2021.pdf.
[2] *Ravi Development vs Shree Krishna Prathisthan & Ors*. [S.L.P.(c) Nos. 11229, 11355-11356,21754-21755 & 21756-21757 of 2008] decided on May 11, 2009.
[3] RBI (guidelines on sale of stressed assets by banks dated September 1, 2016 and draft comprehensive framework of for sale of loan exposures dated June 8, 2020); Haryana (SCM Guideline GoH, 2016); Madhya Pradesh (SCM Guideline GoMP, 2014[6]); Karnataka (para 29 of Suo moto/ innovative proposal for setting up an infrastructure project)

received as per the evaluation matrix, the said regulation was however silent on the exact method to be used for the selection of the best resolution plan.

The Tribunals ("**NCLT/ NCLAT**[4]") had on previous occasions approved Resolution Plans received by the use of SCM, where:

a) the SCM process was approved by the CoC, and it was not based on any *suo moto* process adopted by the successful resolution applicant[5];
b) the process document was prepared as per the mandate of Section 25(2)(h) of the Code read in conjunction with Regulation 36B of the CIRP Regulations[6];
c) The SCM procedure to select the 'Resolution Plan' was fair, transparent and in consonance to the object of the Code was followed by CoC and RP; and
d) there was sufficient time granted to the resolution applicants to follow the process.

While it is true that resolution professionals, COCs and resolution applicants were already resorting to SCM for maximization of the value of the assets of corporate debtors, and the Tribunals were allowing resolution plans selected basis SCM, there was a looming uncertainty on its acceptance without *ado*, owing to certain precedents which disapproved the use of SCM while selecting a resolution plan.[7]

Owing to the above, the Discussion Paper proposed certain amendments to the CIRP Regulations, including to bring in a provision that the CoC could decide whether it considers appropriate to opt for an SCM and if it so decides, then such decision should be provided in the request for resolution plan ("**RFRP**") on *ex-ante* basis.

Process determined for SCM within the Code

Accordingly, Regulation 39(1A)(b) was introduced in the CIRP Regulations on September 30, 2021[8], which provides that, "*The resolution professional may, if envisaged in the request for resolution plan-*

(a) […]; or
(b) use a challenge mechanism to enable resolution applicants to improve their plans.

In view of the above amendment, a resolution professional can now resort to using the SCM or any other such challenge procedure as a statutory mandate for selecting the best resolution plan. However, it is imperative to note that as per the said regulation, such challenge procedure can be used only if the same is envisaged in the RFRP.

Kochhar & Co. view

As per the Discussion Paper, out of 4541 CIRPs which were initiated till June 2021, only 396 CIRPs culminated in the approval of a Resolution Plan. Here it is important to keep in mind that till June 2021, SCM was being implemented during the CIRP where the CoC was in agreement of its implementation. However, if we look at the CIRPs where the same was implemented, owing to lack of defined guidelines for implementation of the same, there were several objections that were preferred by stakeholders during the CIRP, thus causing a delay which was unavoidable. It is also important to note that in the past, the risks of lack of transparency, favouritism and adequate competition along with absence of symmetry in the bidding process, did cause speculations against SCM. However, with the amendment to the CIRP Regulations, the prospective resolution applicants can at least be aware beforehand that a challenge procedure is envisaged, if at all, under the RFRP for improvement of their plans.

One question however which begs an answer is, can a resolution professional use the SCM or any other challenge procedure if the RFRP for a corporate debtor does not explicitly provide for the same. Considering the number of precedents upholding the commercial wisdom of CoC, one would like to believe that if in the opinion of CoC and resolution professionals, the best outcome of the

[4] National Company Law Tribunal/ National Company Law Appellate Tribunal
[5] Saket Tex Dye Private Limited v. Kailash T. Shah [C.P.1981(IB)/MB/2019] decided on May 12, 2020 - para 12
[6] Binani Industries Limited vs. Bank of Baroda [CP (AT) (Insolvency) No. 82 of 2018] decided on Nov 14, 2018
[7] *Ibid* Fn 5
[8] Notification No. IBBI/2021-22/GN/REG078, dated September 30, 2021.

resolution plan is achieved by SCM, in our view, the CoC ought to be free to negotiate with the prospective resolution applicants by way of such SCM. In other words, even if possible use of SCM is not mentioned in the RFRP, if the CoC considers it appropriate to use SCM where there is enough time and a transparent process is followed, the said process should be allowed to achieve the maximization of assets of the corporate debtor. However, owing to the statutory requirement under Regulation 39(1A)(b) to stipulate the possibility of using such challenge procedure in the RFRP itself, it will have to be seen if the Tribunals will go by a strict interpretation or will allow use of SCM de hors such stipulation, by deferring to the commercial wisdom of the CoC.

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SKRINE

Tax exemption for Malaysian shipping business extended with new conditions

14 OCTOBER 2022

The exemption from income tax on statutory income derived by a person from a business of a Malaysian ship[1] has been extended for a further period of three years from year of assessment 2021 to year of assessment 2023 under the Income Tax (Exemption) (No. 7) Order 2022 [P.U.(A) 312/2022] ('**the Exemption Order**').

The Exemption Order extends the tax exemption granted for years of assessment 2014 to 2020 under the Income Tax (Exemption) Order 2018 [P.U.(A) 38/2018] and Income Tax (Exemption) (No. 2) Order 2018 [P.U.(A) 48/2018] ('**Previous Exemption Orders'**) but imposes additional conditions that have to be fulfilled in order to qualify for exemption under the Exemption Order.

To qualify for tax exemption under the Exemption Order and the Previous Exemption Orders, the person must be a resident in Malaysia who carries on the business of (a) transporting passengers or cargo by sea on a Malaysian ship, or(b) letting out on charter a Malaysian ship owned by him on a voyage or time charter basis.

The new conditions introduced under the Exemption Order are the requirement for the person to obtain annual certification from the Ministry of Transport Malaysia that:

1. an annual operating expenditure of at least RM250,000 has been incurred for each Malaysian ship; and

2. each Malaysian ship has the following number of full-time employees in Malaysia:

- the majority of on-shore employees, including the chief executive officer, an administrative and finance officer, an operating officer and an officer in charge of health, protection, safety and environmental affairs, are Malaysian citizens; and
- the employees who are ship personnel as provided under Part III of the Merchant Shipping Ordinance 1952, shall be subject to the minimum requirement as specified in the Safe-Manning Certificate issued by the Marine Department Malaysia.

Alert by Siva Kumar Kanagasabai (Partner and Head) and Dhanyaa Shreeya Sukumar (Associate) of the Maritime and Shipping Practice of Skrine

[1] A "Malaysian ship" is defined in section 54A(6) of the Income Tax Act 1967 as *"a sea-going ship registered as such under the Merchant Shipping Ordinance 1952, other than a ferry, barge, tug-boat, supply vessel, crew boat, lighter, dredger, fishing boat or other similar vessel."* Therefore, a sea-going ship (save for the exceptions mentioned in section 54A(6) of the Income Tax Act 1967) registered under Part IIA (Malaysia Shipping Registry) and Part IIC (Malaysian International Shipping Registry) of the Merchant Shipping Ordinance 1952 will qualify as a Malaysian ship for the purposes of the Exemption Order.

SyCip Salazar Hernandez & Gatmaitan

SyCipLaw Center, 105 Paseo de Roxas
Makati City 1226, Philippines
T: +632 8982 3500 | +632 8982 3600 | +632 8982 3700
F: +632 8817 3570 | +632 8848 2030
www.syciplaw.com

1. Can a corporation which availed itself of the tax amnesty under Republic Act No. 9480 be held liable for deficiency withholding taxes?

Yes. In *Bureau of Internal Revenue vs. Samuel Cagang* (G.R. No. 230104, March 16, 2022), the Supreme Court upheld the deficiency withholding tax assessment against a taxpayer, notwithstanding the fact that the taxpayer availed itself of a tax amnesty. In this case, the Bureau of Internal Revenue (*BIR*) assessed deficiency income taxes, VAT, and expanded withholding taxes against CEDCO, Inc., where Samuel Cagang (*Cagang*) acted as treasurer. CEDCO argued that since it had already filed its amnesty tax return and paid the corresponding taxes thereon, it cannot be assessed deficiency taxes.

The Supreme Court ruled that the tax amnesty under Republic Act No. 9480 applies only to income taxes, VAT, estate taxes, donor's tax, capital gains tax, excise tax, and other percentage taxes. It does not extend to withholding taxes. As provided in Republic Act No. 9480, the following are disqualified from availing themselves of the tax amnesty:

a) Withholding agents with respect to their withholding tax liabilities;

b) Those with pending cases falling under the jurisdiction of the Presidential Commission on Good Government;

c) Those with pending cases involving unexplained or unlawfully acquired wealth, revenue or income under the Anti-Graft and Corrupt Practices Act;

d) Those with pending cases filed in court involving violation of the Anti-Money Laundering Law;

e) Those with pending criminal cases for tax evasion and other criminal offenses under Chapter II of Title X of the National Internal Revenue Code of 1997, as amended, and the felonies of frauds, illegal exactions, and transactions, and malversation of public funds and property under Chapters III and IV of Title VII of the Revised Penal Code; and

f) Tax cases subject of final and executory judgment by the courts.

When CEDCO availed itself of the tax amnesty, only its liabilities for unpaid income taxes and VAT were deemed fully settled. Its liabilityfor deficiency withholding taxes remained since Republic Act No. 9480 expressly disqualified withholding agents from availing of the taxamnesty with respect to their withholding tax liabilities.

SyCipLaw TIP 1:

A taxpayer who wishes to avail itself of a tax amnesty under a law must review the law granting the amnesty and its implementing rules to ensure that, first, it is qualified and not disqualified from availing itself of the amnesty and, second, all of its tax liabilities are covered by the amnesty. Tax amnesty laws typically provide who are disqualified from availing of the tax amnesty. While nothing prevents the Congress from declaring otherwise, withholding agents are usually disqualified from availing themselves of a tax amnesty with respect to their withholding tax obligations. This is because a withholding agent collects and pays taxes on behalf of another person and not for his/her own behalf. Therefore, a tax amnesty usually does not apply to the liability of a withholding agents as such.

SyCip Salazar Hernandez & Gatmaitan

Managing Partner:
Hector M. de Leon, Jr.

Tax Department Head:
Carina C. Laforteza

Tax Department Partners:
Carlos Roberto Z. Lopez
Ramon G. Songco
Benedicto P. Panigbatan
Russel L. Rodriguez
Ronald Mark C. Lleno
Hiyasmin H. Lapitan
Leah C. Abutan
John Christian Joy A. Regalado
Ma. Patricia B. Paz-Jacoba
Joanna Marie O. Joson
Maria Viola B. Vista
Maria Christina C. Ortua-Ang

Of Counsel:
Rolando V. Medalla, Jr.

Special Counsel:
Catherina M. Fernandez

Tax Department Senior Associates:
Austin Claude S. Alcantara
Mark Xavier D. Oyales
Camille Angela M. Espeleta-Castillo
Kristina Paola P. Frias
Hailin D.G. Quintos-Ruiz
Renz Jeffrey A. Ruiz

Tax Department Associates:
Spencer M. Albos
Diane Elaine B. Bataller
Kevin Joseph C. Berbaño
Roman George P. Castillo

Editor:
Ronald Mark C. Lleno (Partner)

Contributors:
Carina C. Laforteza
Benedicto P. Panigbatan
Russel L. Rodriguez
Ronald Mark C. Lleno
Leah C. Abutan
Joanna Marie O. Joson
Maria Viola B. Vista
Maria Christina C. Ortua-Ang
Catherina M. Fernandez
Rei Luis Anton A. Domingo
Mark Joshua L. Faderguya
Monica Therese B. Lee

Coordinators:
Marie M. Ingcoco
Joanne V. Lacsina
Angelita O. Dizon

For more information regarding the issuances discussed in this briefing, please contact:
Carina C. Laforteza
cclaforteza@syciplaw.com

2. May a company treasurer be held criminally liable for the corporation's failure to withhold taxes?

Yes. In the *Cagang* case discussed above, as the treasurer of CEDCO, Cagang was criminally prosecuted for failure to file tax returns and pay taxes of CEDCO. Cagang's main defense was that CEDCO cannot be assessed deficiency taxes since CEDCO availed of the tax amnesty under Republic Act No. 9480, which covers "all unpaid internal revenue taxes for the taxable year 2005 and prior years, with or without assessments duly issued therefor, and have remained unpaid as of December 31, 2005".

The Supreme Court held that, since withholding taxes were not covered by the amnesty, CEDCO remains liable for deficiency withholding taxes. As the treasurer of CEDCO, Cagang may be criminally charged for failure to file tax returns and pay taxes as regards withholding taxes.

3. Is a court order allowing the production and inspection of documents considered a separate tax audit if a Letter of Authority has been previously issued against the taxpayer for the same taxable period?

No. In *Smart Communications, Inc. v. Hon. Arreza* (CTA EB No. 2386, August 15, 2022), the Court of Tax Appeals (*CTA*) En Banc upheld the grant of a motion for production and inspection of documents in a case pending in court, notwithstanding that a Letter of Authority (*LOA*) had already been issued against the taxpayer.

In this case, the City of Makati issued a Notice of Assessment against the taxpayer for deficiency franchise taxes, fees, and charges for taxable years 2012 to 2015. The taxpayer contested the assessment, asserting that it already paid its tax liabilities. Previously, the City of Makati issued a LOA, which compelled the taxpayer to produce its books of account, financial statements, summary/breakdown of gross sales per calendar year, and proof of payment of franchise taxes in other localities. As the taxpayer was unable to produce a summary/breakdown of gross sales, as well as proof of payment of franchise tax in other localities, despite repeated demands, the City of Makati assessed the taxpayer deficiency franchise taxes based on the total gross receipts of the taxpayer appearing on its financial statements. The assessment is based on Section 7A.08 of the Revised Makati Revenue Code, which provides for a presumptive assessment.

The taxpayer assailed the assessment before the Regional Trial Court of Makati (*RTC*). The City of Makati filed with the RTC a motion for production and inspection of documents, seeking to compel the taxpayer to produce its books of account, financial statements, summary/breakdown of gross sales per calendar year, and proof of payment of franchise taxes in other localities. The RTC granted the motion.

On appeal to the CTA, the taxpayer questioned the grant of the motion for production and inspection of documents arguing that it is tantamount to another examination or audit of the taxpayer's books of account for the same taxable period, as well as the conduct of anexamination without a valid LOA, which are not allowed by the Local Government Code and the Revised Makati Revenue Code.

SyCipLaw TIP 2:

If a corporation violates certain provisions of the National Internal Revenue Code, as amended (*Tax Code*), criminal liability may be imposed on the partner, president, general manager, branch manager, treasurer, officer-in-charge, and the employees responsible for the violation. The identity of these officers may be established based on corporate records, including board resolutions appointing such officers and the General Information Sheets submitted by corporations to the Securities and Exchange Commission. For these named corporate officers, the mere fact of having occupied the position during the period of the corporation's tax violation is sufficient to give rise to probable cause to file criminal charges against such officers for the corporation's violations of the Tax Code.

In ruling that the motion for production and inspection of documents was properly granted, the CTA held that when the taxpayer contested the tax assessment before the RTC, the City of Makati had every right to assert its power to examine the taxpayer's records to ascertain the correct tax liabilities due. The grant of the motion would not amount to another tax audit since it was an exercise of the RTC's power of judicial review. As a court of competent jurisdiction, the RTC has the authority to look into the correctness of the tax assessment against the taxpayer and to require the production of material and relevant evidence necessary for its determination of the factual issues involved in the assessment case, such as the documents in this case.

SyCipLaw TIP 3:

A taxpayer should properly maintain and keep records of its books of account and other accounting records and should be ready to present such books of account and accounting records in the event of a tax audit. In case a court case is filed as regards a disputed assessment, the court can still compel the production of these documents even if the taxpayer did not present the documents to the BIR or the local government during the tax audit. Failure to obey the court's order may result in contempt of court, which is punishable by imprisonment and/or fine.

4. Can a local taxing authority require the production and inspection of documents of a taxpayer's nationwide sales and receipts, as well as its sales and receipts in other localities?

Yes. In the *Smart* case discussed above, the CTA ruled that the City of Makati cannot simply accept the taxpayer's self-assessment as a true and accurate declaration of the taxpayer's income. The local taxing authority has the power to issue a LOA to compel the examination of books, records, and other accounts to ascertain the amount paid, including books, records, and other accounts pertaining to other localities. In this regard, the local taxing authority's examination power under Section 171 of the Local Government Code and Section 7A.07 of the Revised Makati Revenue Code is extensive and necessary to enforce local tax laws. Accordingly, the City of Makati has the authority to compel production of documents showing nationwide sales and receipts, including those documents in localities other than the City of Makati as these documents are relevant and material to the determination of the correct basis and computation of any deficiency local tax in the City of Makati.

SyCipLaw TIP 4:

Taxpayers should be mindful that, while a local government unit (*LGU*) exercises taxing power only within its territorial jurisdiction, it can request the production and inspection of documents showing nationwide revenues, as well as revenues in other localities outside of the LGU's territorial jurisdiction, in order to determine the correct amount of taxes due to the LGU.

5. Is an audit investigation conducted pursuant to a Mission Order, but without a Letter of Authority, valid?

No. An audit and examination of a taxpayer's books and accounting records, to be valid, must be based on a valid LOA.

In *Commissioner of Internal Revenue v. Autostrada Motore, Inc.* (CTA EB No. 2375, July 21, 2022), the CTA En Banc invalidated an assessment that was based solely on a Mission Order and conducted without a LOA. The CTA En Banc ruled that the absence of an LOA violates the taxpayer's right to due process and renders the entire assessment void.

An LOA is the authority given to the appropriate revenue officer assigned to perform assessment functions. Unless authorized by the Commissioner of Internal Revenue (*CIR*) himself, or by his duly authorized representative, through a LOA, an examination of the taxpayer cannot ordinarily be undertaken. Due process requires the identification of the names of the tax agents authorized to conduct the examination and assessment of the taxpayer's books and accounting records through a LOA. Identifying the authorized revenue officers in the LOA is a jurisdictional requirement of a valid audit or investigation by the BIR. There must be a link between the LOA and the revenue officer who will conduct an examination of the taxpayers' books of accounts and accounting records.

The CTA En Banc explained that the purpose of a Mission Order is different from a LOA. A Mission Order is issued to authorize the surveillance pursuant to Section 6(C) of the Tax Code, not the audit and the assessment of the taxpayer. The allowable acts covered by a Mission Order include the tax agent's observation and surveillance of the taxpayer's business operations, verification of specific documents, and the determination of whether the taxpayer complies with the pertinent tax laws and regulations, without conducting a full-blown audit.

In this case, the authority of the revenue officers under the Mission Order was limited to the exercise of the CIR's verification and surveillance powers. The revenue officers were not authorized by a LOA to conduct an examination and inspection of the taxpayer's books of accounts. Thus, the assessments resulting therefrom are void.

SyCipLaw TIP 5:

Taxpayers undergoing an audit investigation should first check whether a LOA has been issued, granting authority to the revenue officer or tax agent conducting the audit investigation. The revenue officer named in the LOA must be the same officer conducting the examination and assessment of the taxpayer's books of accounts and accounting records. Otherwise, the audit investigation and resulting assessment is void for violating the taxpayer's right to due process.

6. Can the reversal of a Bureau of Internal Revenue ruling be given retroactive application if the same would be prejudicial to the taxpayer?

No. Section 246 of the Tax Code prohibits the retroactive application of a reversal of a BIR ruling if the same would be prejudicial to the taxpayer, unless the exceptions under the provision are present, namely, misstatement or misrepresentation of material facts and bad faith. Any change of opinion or position by the CIR with respect to a BIR ruling, which is prejudicial to the taxpayer, shall only be applied prospectively.

In *Commissioner of Internal Revenue v. Meridien East Realty & Development Corporation* (CTA EB No. 2287,July 14, 2022), the CTA En Banc rejected the retroactive application of Revenue Memorandum Circular No. 20-2010 (*RMC No. 20-2010*), which overturned BIR Ruling No. DA-245-05. In the BIR ruling, the BIR initially opined that the transaction was not a sale subject to income tax, expanded withholding tax, documentary stamp tax, and value-added tax. However, RMC No. 20-2010 abandoned the prior position and set out a new one declaring that the transaction was part of a pre-selling arrangement, hence, subject to the aforementioned taxes. Accordingly, the retroactive application of RMC No. 20-2010 would be prejudicial to the taxpayer.

SyCipLaw TIP 6:

A taxpayer has the right to rely upon a BIR ruling issued in his favor until the same has been reversed, amended or overruled by the CIR or by the Supreme Court. However, a reversal of a BIR ruling cannot be retroactively applied if doing so would be prejudicial to the taxpayer, unless the taxpayer deliberately misstates or omits material facts from his return or any document required of him by the BIR, the facts subsequently gathered by the BIR are materially different from the facts on which the ruling is based, or the taxpayer acted in bad faith in securing the BIR ruling. While the general rule is that the government cannot be estopped by mistakes or errors by its officials or agents, this rule is not without an exception, such as the provision in the Tax Code on the non-retroactivity of a revocation, modification, or reversal of a BIR ruling.

In this case, the CTA En Banc ruled that the CIR failed to prove the existence of any of the exceptions under Section 246 of the Tax Code which would allow retroactive application of the RMC. The CIR failed to adduce evidence that: (1) the taxpayer deliberately misstated or omitted material facts from its return or in any document required of it by the BIR; (2) the facts subsequently gathered by the BIR are materially different from the facts on which the BIR ruling was based; or (3) that the taxpayer acted in bad faith. The CTA En Banc found that the change of position made by the CIR was not brought about by a subsequent learning of a fact misrepresented or withheld by the taxpayer. Rather, the reversal was merely due to a change of opinion by the CIR on the tax consequences of the same set of facts, which the taxpayer presented in obtaining the ruling. Thus, the deficiency tax assessments against the taxpayer were declared null and void as they arose from the retroactive application of the RMC.

7. If a taxpayer believes that an action taken by one or both contracting states to a Double Taxation Agreement (*DTA*) will subject him to double taxation or taxation in contravention of the DTA, can he avail himself of the Mutual Agreement Procedure provided in the DTA?

Yes. Revenue Regulations No. 10-2022 (*RR No. 10-2022*) provides for the guidelines and procedures for requesting Mutual Agreement Procedure (*MAP*) assistance in the Philippines. A MAP provides the procedure by which the competent authorities of contracting states to a Double Taxation Agreement (*DTA*) may, through mutual agreement, resolve disputes arising from differences or difficulties in the interpretation or application of the DTA.

Typical Scenarios Requiring MAP Assistance

RR No. 10-2022, sets out the typical examples of scenarios that would necessitate a MAP assistance:

a) The withholding tax rate imposed on an item of income earned by a domestic corporation or resident citizen is beyond the maximum rate fixed under the DTA.

b) A taxpayer is deemed a resident of the Philippines and of the other contracting state based on their domestic laws (which triggers the application of the tiebreaker rules under the DTA).

c) A domestic corporation or a resident citizen is taxed in the other country on the business profit or income from independent services despite not having a permanent establishment or a fixed based in that country under the tax convention.

d) A resident citizen or domestic corporation has been or will be subject to taxation not in accordance with the provisions of the applicable tax treaty regarding the amount of profit attributable to the permanent establishment or fixed base.

e) A taxpayer is uncertain whether the convention covers a specific item of income or is unsure of the characterization or classification of the item related to a cross-border issue.

f) A taxpayer is subject to additional tax in one country because of a transfer pricing adjustment to the price of goods or services transferred to or from a related party in the other country.

Filing of a MAP Request

The taxpayer may file a formal request with the BIR International Tax Affairs Division (*ITAD*). The request must be in writing and signed by the taxpayer or its authorized representative. It must also contain the minimum required information and documentation specified by the BIR.

Subject to the provision of the relevant DTA, the taxpayer may file the MAP request with (i) the competent authority of the contracting state of which the taxpayer is a resident, (ii) the competent authority of the contracting state of which the taxpayer is a citizen (only if the DTA with the United States of America is invoked), or (iii) the contracting state of which the taxpayer is a national if the case falls under the Non-Discrimination article of the DTA.

The request must be filed within the time limit specified in the applicable DTA. If the DTA is silent on the time limit, the request must be submitted within three (3) years from the first notification of the action resulting in taxation not in accordance with the provisions of the DTA, *i.e.*, the date of receipt of the Final Assessment Notice, or of a ruling denying the claim for treaty benefit, or any equivalent document which contains the action that results in double taxation.

MAP Process

The MAP request shall be assessed preliminarily to determine compliance with the following requisites: (i) the minimum information and documentation; (ii) existence of a DTA which contains a MAP article; and (iii) the request was filed with the proper competent authority within the prescribed time limit. If any of the requisites is missing, the request shall not be considered as valid. If only the first requisite is missing, the taxpayer shall be notified of the deficiencies to be completed and submitted.

Once the request is determined to be valid, the Rulings and MAP Section of the ITAD (*MAP Office*) shall determine if the taxpayer's objection is justified. If the objection is justified, the MAP Office will then determine whether the Philippine Competent Authority (the BIR Commissioner) could resolve the case unilaterally. Note that MAP requests arising from measures taken in the Philippines may be resolved unilaterally by the Philippine Competent Authority.

Consultation between Competent Authorities

If the MAP Office determined that the request cannot be unilaterally resolved, the Philippine Competent Authority shall endeavor to resolve the case with the competent authority of the other contracting state. Note, however, that both competent authorities are under no obligation to enter into a mutual agreement for every MAP case.

An agreement reached between the competent authorities must be communicated to the taxpayer within thirty (30) days after the consultation or meeting. The taxpayer shall have another thirty (30) days from receipt of notice to convey its acceptance or disapproval to the agreement. Should the taxpayer accept the agreement, the Philippine Competent Authority shall give effect to such mutual agreement and ensure its implementation. If the taxpayer rejects the agreement, it may proceed with any available domestic remedies, *i.e.*, judicial or administrative appeal.

If no agreement is reached between the competent authorities, the taxpayer may pursue any available domestic remedies after receiving a notice of the failure to reach an agreement.

Resolution of a MAP Case

The MAP request may result in any of the following outcomes:

a) Access to MAP is denied (*i.e.*, not an admissible request or denied for any other reasons);

b) Objection is not justified;

c) Objection is resolved via domestic remedy;

d) Unilateral relief will be granted;

e) Competent authority agreement for full or partial elimination of double taxation;

f) Competent authority agreement stating that there is no taxation not in accordance with the tax treaty;

g) No competent authority agreement is reached; and

h) Any other outcome.

All MAP requests must be resolved within an average timeframe of twenty-four (24) months from the receipt of a complete MAP request.

SyCipLaw TIP 7:

MAP provides a new remedy to taxpayers in contesting double taxation arising from the action of a competent authority of a contracting state to a DTA. Taxpayers should take note of the instances where MAP assistance is available and consider whether it may be beneficial in a particular case (considering, among others, any other available domestic remedy and the speed by which such remedy may be completed).

MAP Request and Domestic Remedies

MAP requests may be filed even when there is a pending judicial or administrative appeal, and even where a decision, ruling, or final assessment has already been rendered by the BIR. Moreover, audit settlements reached between the tax authority and the taxpayers do not preclude access to MAP assistance.

However, a MAP request cannot proceed simultaneously with the determination of a judicial or administrative appeal. Hence, the taxpayer must indicate which process shall be held in abeyance pending the outcome of the preferred process. Cases decided by the courts with finality can no longer be a subject of a MAP request.

Taxpayers who avail themselves of the MAP Assistance may request for the suspension of the collection of taxes if a tax assessment is involved. The Philippine Competent Authority may grant such request pursuant to the Tax Code and relevant rules and regulations. In case the request for suspension is granted, but the MAP Office upholds the tax liability, the enforcement of the collection of taxes shall proceed after the MAP decision had been released, mailed, or sent by the BIR to the registered address of the taxpayer.

8. Can the Bureau of Internal Revenue share taxpayer-specific rulings with other jurisdictions?

Yes. Revenue Regulations No. 11-2022 (*RR No.11-22*) provides the procedure for the Spontaneous Exchange of Taxpayer-Specific Rulings (*Transparency Framework*). Under DTAs entered into by the Philippine Government, a competent authority is mandated to exchange information which are necessary to carry out the provisions of the DTA or domestic laws concerning taxes to which the DTA applies.

The Exchange of Information (*EOI*) Section of the BIR ITAD is responsible for exchanging taxpayer-specific rulings to the foreign tax authority of the potential exchange jurisdictions on or before the prescribed deadline.

Information Subject to the Exchange and Potential Exchange Jurisdictions

The rulings subject to the spontaneous exchange of information and the potential exchange jurisdictions are summarized in the table below:

Type of Ruling	Potential Exchange Jurisdictions
Rulings related to a preferential regime	i. The countries of residence of all related parties (subject to a 25% threshold), with which the taxpayer enters into a transaction for which a preferential treatment is granted, or which gives rise to income from related parties benefiting from a preferential treatment; and ii. The residence country of (a) the ultimate parent company and (b) the immediate parent company.
Cross-border unilateral Advance Pricing Arrangements (*APA*) and any other cross-border unilateral tax ruling (such as an Advance Tax Ruling) covering transfer pricing or the application of transfer pricing principles	i. The countries of residence of all related parties with whom the taxpayer enters into transactions covered by the APA or cross-border unilateral tax ruling; and ii. The residence country of (a) the ultimate parent company and (b) the immediate parent company.
Cross-border rulings giving a unilateral downward adjustment to the taxpayer's taxable profits in the country giving the ruling	i. The countries of residence of all related parties with whom the taxpayer enters into transactions covered by the ruling; and ii. The residence country of (a) the ultimate parent company and (b) the immediate parent company.
Permanent Establishment (*PE*) rulings	i. The residence country of the head office, or the country of the PE, as the case may be; and ii. The residence country of (a) the ultimate parent company and (b) the immediate parent company.
Related party conduit rulings	i. The country of residence of any related party making payments to the conduit (directly or indirectly); ii. The country of residence of the ultimate beneficial owner (which in most cases will be the ultimate parent company) of payments made to the conduit; and iii. To the extent not already covered by (ii), the residence country of (a) the ultimate parent company and (b) the immediate parent company.

Deadline for the Exchange of Information

The EOI Section of ITAD shall ensure that the exchange of information is transmitted to the relevant jurisdiction within the following timelines:

i. Past rulings – as soon as possible after identifying the potential exchange jurisdictions; and

ii. Future rulings – as soon as possible and no later than three (3) months after the issuance thereof.

Past rulings are limited only to PE rulings or rulings concerning the existence or absence of a PE of a foreign enterprise in the Philippines that were issued either:

a) January 1, 2015 to August 31, 2017; or

b) January 1, 2012 to December 31, 2014, provided they were still in effect as of January 1, 2015.

Future rulings refer to rulings issued beginning September 1, 2017 on the following:

a) Rulings related to a preferential regime;

b) Cross-border unilateral APAs and any other cross-border unilateral tax ruling (such as an Advance Tax Ruling) covering transfer pricing or the application of transfer pricing principles;

c) Cross-border rulings giving a unilateral downward adjustment to the taxpayer's taxable profits in the country giving the ruling;

d) PE rulings; and

e) Related party conduit rulings.

Power of the BIR to Request Information

To properly identify the countries with which the information shall be exchanged, the BIR or its responsible offices may request information and other relevant documents from the taxpayer, both domestic and foreign. Note, however, that all requests for information in relation to the exchange of past rulings must be signed by the Assistant Commissioner for Legal Service of the BIR. For future rulings, the request for information must be signed by the respective heads of offices responsible for the issuance of the taxpayer-specific ruling.

SyCipLaw TIP 8:

Requests for information in relation to the exchange of information on future rulings must have the signature of the respective heads of office of the BIR while requests for information in relation to past rulings must have the signature of the Assistant Commissioner for Legal Service of the BIR. In the absence of the signature of these officers, a taxpayer may resist any request for information in connection with the spontaneous exchange of taxpayer-specific rulings.

9. Are there guidelines and procedures on the manner and payment of penalties for violations by Registered Business Enterprises in the Information Technology-Business Process Management sector of the Work-From-Home requirements?

Yes. The BIR issued Revenue Memorandum Circular No. 120-2022 (*RMC No. 120-22*) on August 18, 2022 providing guidelines and procedures on the manner and payment of penalties relative to violations incurred by Registered Business Enterprises (*RBEs*) in the Information Technology-Business Process Management (*IT-BPM*) sector of the Work-From-Home (*WFH*) arrangement allowed under the Fiscal Incentive Review Board Resolution No. 17-2022 (*FIRB Resolution No. 17-2022*) for the period April 1, 2022 until September 12, 2022.

FIRB Resolution No. 17-2022 allows RBEs to continue implementing the WFH arrangement without adversely affecting their fiscal incentives from April 1, 2022 until September 12, 2022 provided the number of employees under the WFH arrangement shall not exceed thirty percent (30%) of the total workforce of the RBE while the remaining seventy percent (70%) of the total workforce shall render work or service within the geographical boundaries of the ecozone or freeport zone being administered by the investment promotion agency (*IPA*) with which the project or activity is registered. The total workforce refers to the total employees directly or indirectly engaged in the registered project or activity but excludes third-party contractors rendering janitorial or security services and other similar activities.

RMC No. 120-22 took effect immediately and will remain in force until September 12, 2022, which is the end of the current FIRB-sanctioned WFH arrangement.

a) Would a violation of the WFH arrangement for one day result in the suspension of the RBE's income tax incentives for the month?

Yes. Non-compliance of the RBE with the 70:30 WFH arrangement prescribed under FIRB Resolution No. 17-2022 even for only one (1) day shall result in the suspension of its income tax incentives for the month when the violation took place. The RBE will thus be liable to pay as penalty the regular income tax rate of twenty-five percent (25%) or twenty percent (20%) (as applicable) for the month of violation.

RMC No. 120-22 provides sample illustrations for the computation of the penalty for non-compliant RBEs.

b) How will RBEs with violation of the WFH arrangement file and pay their Quarterly Income Tax Returns?

RBEs with violations shall continue to file their Quarterly Income Tax Returns and pay their quarterly income tax following their usual procedure of computation of the tax due as if no violation was committed; however, such non-compliant RBEs must attach an additional schedule showing a separate computation for the penalty on the WFH arrangement violation and the RBEs must pay the penalty using BIR Form No. 0605.

c) When is the deadline to pay the penalty?

The penalty must be paid on or before the due date prescribed for the filing and payment of the quarterly income tax, subject to adjustment upon the filing of the annual income tax return.

SyCipLaw TIP 9:

RBEs in the IT-BPM sector should closely monitor compliance with the 70:30 WFH arrangement because even a single day of violation will result in a penalty. RBEs with violations must file their Quarterly Income Tax Returns and pay their quarterly income tax as if no violation was committed, but they must also pay the penalty using BIR Form No. 0605 on or before the due date prescribed for the filing and payment of the quarterly income tax; otherwise, the RBEs will also be subject to administrative penalties for late payment of the penalty.

d) How will non-compliant RBEs file their annual income tax returns?

RBEs with the Income Tax Holiday (*ITH*) incentive shall continue to file their annual income tax returns (*AITR*) using BIR Form No. 1702-EX. RBEs enjoying the Gross Income Tax (*GIT*) incentive or those with mixed transactions shall continue to file their AITR using BIR Form No. 1702-MX.

However, these RBEs are mandatorily required to complete the required information pertaining to allowable deductions pursuant to existing tax laws and regulations, *i.e.*, RBEs with ITH incentive should complete Part VI-Schedule I of BIR Form No. 1702-EX, while RBEs with the GIT incentive should complete Part IV-Schedule 5 of BIR Form No. 1702-MX.

e) If an RBE committed violations of the WFH arrangement but did not pay the penalty when it filed its quarterly income tax returns, can the RBE still pay the penalty?

Yes. For the fiscal quarter with month/s subject to the penalty that already ended, and returns have been filed, but no penalty has been paid, RBEs may file BIR Form No. 0605 and pay their penalty within ten (10) days after the issuance of RMC No. 120-22 or until August 28, 2022. If the penalty is paid beyond the said period, administrative penalties will be imposed.

Light at the end of the tunnel – A case study of a successful restructuring

October 3, 2022

Introduction

In his opening remarks at the SICC INSOL seminar on debt restructuring in the Asia-Pacific held on 22 September 2022, Second Minister for Law Edwin Tong SC cited the court sanctioned schemes of arrangement of Singapore-listed Pacific Radiance group as an example of the Singapore insolvency framework facilitating successful outcomes. He mentioned that these schemes tied in with a wider consensual restructuring negotiated earlier this year. This consensual restructuring recently completed with the resumption of trading of the securities of Pacific Radiance Ltd (Pacific Radiance) on the Singapore Exchange Securities Trading Limited (SGX-ST) on 26 September 2022. It was the culmination of close to five years of restructuring efforts by Pacific Radiance, in which Dentons Rodyk played a key role as its legal counsel.

The story

The Pacific Radiance group was an owner and operator of a diverse fleet of offshore vessels, as well as a provider of offshore support services, principally engaged in the offshore support services business, subsea business and shipyard business.

Between 2010 and 2013, the Pacific Radiance group anticipated that there would be an increase in demand for offshore vessels arising from an increase in oil and gas spending globally, and actively pursued business growth by expanding its fleet of vessels in order to increase market share. The fleet of vessels were mainly financed by bank borrowings, which were secured against mortgages on the vessels, assignment of charter and charter earnings, amongst others. The company also established a Medium Term Note Programme late 2014 under which the company issued S$100 million 4.30 per cent. Notes due 2020 comprised in Series 001 (ISIN: SG6SF2000004) (Notes).

In 2015, the offshore and marine industry began to decline as oil prices plummeted. The systemic decline in the oil and gas sector led to languishing charter rates and vessel utilisation, putting tremendous stress on the group's operations and finances, and pushed its debt to an unsustainable level. To make matters worse, over the first half of 2020, the COVID-19 epidemic sharply deteriorated into a global pandemic. That led to a global economic downturn. Oil prices also dramatically collapsed around early March 2020 to unprecedented negative prices. The weakness and volatility of the oil price environment also led to a worldwide reduction in activities in the exploration, development and production of oil and natural gas, which in turn led to depressed charter rates and reduced charter utilisation. The ill after-effects of the pandemic persisted into 2021. Revenue was impacted as the group had to continue grappling with charter cancellations and delays to the commencement of charter contracts.

The culmination of these factors resulted in little or no returns from the group's business activities, contributed to liquidity constraints, and resulted in its dire financial position. Its debt level was unsustainable. It could not meet its

debt obligations.

The long restructuring journey

In the second half of 2017, the Pacific Radiance group started discussions with bank lenders to review its financial position and capital structure, and to restructure its secured financial indebtedness. It also sought potential investors to raise fresh funds as part of its debt restructuring. An informal arrangement was reached with major lenders to temporarily suspend certain debt obligations. Stakeholder engagement was difficult, to say the least. The company's shares were suspended from trading on the Mainboard of the SGX-ST in 2018.

In August 2019, potential investors, debt funders and owners of a vessel-owning and logistics service provider gave the company hopes for a breakthrough. The restructuring plan entailed the extension of debt financing of US$180 million and raising of additional equity funds of another US$180 million through new share issuances. Funds raised would be used to finance the acquisition of 100% of a target company (which owned vessels and logistics services business in the Middle East) as well as to repay indebtedness. Our firm advised on the restructuring proposals, conducted due diligence on the target, prepared and negotiated definitive agreements, as well as SGX-compliance documents. Much to everyone's disappointment, discussions stalled around December 2019.

Pacific Radiance underwent three rounds of consent solicitation exercises to restructure the Notes, which included multiple extensions of the maturity date of the Notes, waiver of payment covenants and redemption of the Notes through the issuance of securities and debt instruments (such as new shares in the counter, warrants, convertible bonds and promissory notes). Our firm handled the consent solicitation documentation for all three rounds, including for the issue of warrants, convertible bonds and promissory notes.

The debt restructuring plan

Pacific Radiance managed to secure a successful debt restructuring plan with the ENAV group (ENAV), a Mexican offshore support vessel owner and operator that services the Mexican and international offshore industry. In October 2021, Pacific Radiance announced the debt restructuring plan which had the following features:

- disposal of 33 vessels to ENAV in exchange for consensual discharge of US$200 million secured indebtedness;
- collaboration by its key management with ENAV's buyer entity through minority share participation;
- securing ship management agreements with ENAV to manage the majority of its vessels after the sale of the 33 vessels;
- restructuring of remaining debt obligations of approximately US$229 million via schemes of arrangement;
- consensual restructuring of the loan associated with its office and shipyard complex of approximately US$52 million, and other unsecured debt obligations with its secured lenders;
- consensual restructuring of the Notes via a 4^{th} consent solicitation exercise, so that the Notes would be redeemed through the issue of new shares in Pacific Radiance and the issue of new perpetual securities;
- consensual restructuring of various cross-currency swap facilities with some of its secured lenders via the issue of ordinary shares in Pacific Radiance;
- allotment of new shares in Pacific Radiance to its key management to satisfy certain conditions of the ship management agreements;

- issue of two classes of warrants (to existing shareholders and to the key management of Pacific Radiance); and
- housekeeping corporate actions e.g. share consolidation.

With the successful completion of the debt restructuring plan, the liabilities of the Pacific Radiance group were settled, discharge and restructured, allowing the group to pivot to an asset-light full-fledged ship manager business.

Dentons Rodyk advised the Pacific Radiance group on their debt restructuring plan and the transactions thereunder, negotiated the definitive agreements, undertook the consent solicitation exercise to restructure the Notes, and prepared the documentation for the SGX-related corporate actions (such as the issue of new shares, perpetual securities issuance, warrants issues, applications for listing of the new shares and resumption of trading). The Notes restructuring Extraordinary Resolution (in the 4th consent solicitation exercise) was successfully passed in April 2021. Shareholders approved the transactions under the debt restructuring plan in February 2022. Court sanction of the schemes of arrangements was obtained in August 2022. The numerous securities issuances and share consolidation was completed in September 2022, and trading resumed on 26 September 2022 amidst congratulatory messages and heartfelt thanks from shareholders and management.

Concluding remarks

The offshore marine sector took a beating and many good companies, several larger and stronger than Pacific Radiance, fell victim to the downturn. In the words of our clients, it was a very long journey. But it was a journey that our firm was happy to walk with them, supporting them every step of the way.

Your Key Contacts

Valerie Ong
Senior Partner, Singapore
D +65 6885 3625
valerie.ong@dentons.com

Ian Low
Associate, Singapore
D +65 6885 2751
ian.low@dentons.com

Amended Business Mergers and Acquisitions Act to Take Effect on December 15, 2022

08/31/2022

Eddie Chan/ Yuan-Yuan Lo

The latest of amendments to the Business Mergers and Acquisitions Act ("Amended BMAA") were promulgated by the President on June 15, 2022 and will come into force six months thereafter (i.e., on December 15, 2022) pursuant to Article 54 of the BMAA. The key changes under the Amended BMAA aim to strengthen the protection of shareholders' rights and interests, expand the defined scope of whale-minnow mergers, and increase the flexibility of the relevant tax arrangements, as detailed below:

1. Strengthened protection of shareholders' rights and interests

In order to strengthen the protection on shareholders' rights and interests and to ensure the information transparency of M&A transactions, Article 5 of the Amended BMAA stipulates that, where a director has a conflict of interest in a proposed merger/acquisition ("M&A") transaction, the company must disclose the material information of said conflict and the rationale for approving/opposing such transaction in the notice for the shareholder meeting convened therefor.

Further, Article 12 of the Amended BMAA expands the scope of application for dissenting shareholders' appraisal rights to allow the shareholders who have not abstained from voting (i.e., have voted against the proposed M&A transaction) at the shareholder meeting to exercise the appraisal rights so that such shareholders can also enjoy the exit mechanism.

2. Expanded scope of whale-minnow M&A

Under the prevailing BMAA, a whale-minnow M&A can only be waived from seeking the approval of the shareholder meeting when it meets the following criteria: (i) the new shares issued by the acquiring company for the purpose of the merger do not exceed 20% of its total number of its outstanding voting shares; and (ii) the total

value of the shares, cash and other properties paid by the acquiring company for the M&A does not exceed 2% of the net value of the acquiring company. However, in order to increase the flexibility and efficiency of M&A transactions, the Amended BMAA expands the scope of such waiver by increasing the limit on the total value of the shares, cash and other properties paid by the acquiring company for the M&A to a percentage of 20%. Also, for the avoidance of doubt, the Amended BMAA clear states that a whale-minnow M&A that meet either one of such two criteria to enjoy such waiver. To implement a whale-minnow M&A, a company only needs the approval of its board of directors and not that of the shareholder meeting.

3. Increased flexibility of the relevant tax arrangements

The newly added Article 40-1 under the Amended BMAA stipulates that the types of assets that may be recognized as intangible assets, in terms of an M&A transaction, are limited to business rights, copyrights, trademark rights, patent rights, integrated circuit layout rights, plant variety rights, fishing rights, mineral rights, water rights, trade secrets, computer software and various concessions. Also, under the Amended BMAA, the period of amortization for intangible assets acquired through an M&A is expanded to the remaining period of the legal entitlement thereof or ten years, which rectifies the current conundrum that some M&A costs cannot be deducted from taxable income.

Furthermore, Article 44-1 of the Amended BMAA provides that, upon a corporation's dissolution due to a merger/spin-off, for individual shareholders who acquire the shares of the surviving company, the newly incorporated company or the foreign corporation as a result of a merger/spin-off, the tax assessment of the dividend income under the Income Tax Act may be deferred until the third year following the year of acquisition and taxed in equal installments over three years with an aim to promote a friendly regulatory environment for the M&A of startups. Constitutional Court Found National Health Insurance Database Lacking Proper Privacy Protection and Ordered Relevant Laws be Amended or New Laws be Promulgated within Three Years

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BLOG POST / FINANCIAL SERVICES LAW ADVISOR

Financial Services

FinCEN Releases Final Rule on Beneficial Ownership Information Reporting Requirements

By Alexandra J. Marinzel, Andrew J. Lorentz, and Margaret Haggerty

10.14.22

In a purported effort to close supposed loopholes that allow illicit actors to use corporate structures such as shell companies to hide their identities and launder their ill-gotten gains in or through the United States, the U.S. Treasury's Financial Crimes Enforcement Network (FinCEN) recently issued a final rule establishing beneficial ownership information reporting requirements pursuant to the Corporate Transparency Act (CTA).

The rule addresses an important deficiency in the U.S. anti-money laundering regime identified for some time by the Financial Action Task Force, which establishes international standards in the sector. FinCEN also anticipates that the new rule "will enhance the ability of FinCEN and other agencies to protect U.S. national security and

the U.S. financial system from illicit use and provide essential information to national security, intelligence, and law enforcement agencies...." Which entities are subject to the rule?

The new rule will apply to most corporations; limited liability companies; limited partnerships; limited liability partnerships; and business trusts formed in, or registered to do business in, the United States (known as reporting companies). The impact of the rule will be widespread, affecting millions of businesses already operating in the United States and millions more formed each year. The rule will require the collection of sensitive personal information from the vast majority of those businesses.

What must reporting companies disclose?

The rule will require reporting companies to identify the beneficial owners and applicants of the entity. Beneficial ownership is defined as any individual who, directly or indirectly, either exercises substantial control over a reporting company or owns/controls at least 25% of the ownership interests of a reporting company.

The rule also contains a list of activities constituting "substantial control" of a reporting company, purportedly designed to capture anyone who is able to make important decisions on behalf of a reporting company and to close loopholes that previously allowed corporate structing to obscure owners and/or decision makers.

The new rule defines a "company applicant" as the individual who files the document creating the entity (or, in the case of foreign company registered to do business in the United States, the person who first registers the entity to do business in the United States), or the individual who is primarily responsible for directing or controlling the filing of the aforementioned documents by another person.

When filing beneficial ownership reports with FinCEN, reporting companies will be required to identify themselves and report the following information for each beneficial owner: name, birthdate, address, and a unique identifying number from an acceptable identification document such as a driver's license or a passport. Reporting companies created after January 1, 2024, will be required to provide the same information for company applicants.

Critically, the final rule exempts 23 types of entities from the definition of reporting company (and therefore from the beneficial ownership reporting regime). These exempt entities include:

1. securities reporting issuers,
2. governmental authorities,
3. banks,
4. credit unions,
5. depository institution holding companies,
6. money services business,
7. brokers or dealers in securities,
8. securities exchanges or clearing agencies,
9. other Exchange Act registered entities,
10. investment companies or investment advisers,
11. venture capital fund advisers,
12. insurance companies,
13. state-licensed insurance producers,
14. Commodity Exchange Act registered entities,
15. accounting firms,
16. public utilities,
17. financial market utilities,
18. pooled investment vehicles,
19. tax-exempt entities,
20. entities assisting a tax-exempt entity,
21. large operating companies,
22. subsidiaries of certain exempt entities, and
23. inactive entities.

When does the new rule go into effect?

The new rule will take effect on January 1, 2024. Reporting companies created or registered prior to that date will have one year to file their initial reports. However, reporting companies created or registered after January 1, 2024, will only have 30 days after receiving notice of the creation or registration to file their initial reports.

All reporting companies will have 30 days to report changes to information filed in previous reports or to correct inaccurate information after becoming aware of the inaccuracy.

What is the anticipated burden on reporting companies?

FinCEN intends to develop compliance and guidance documents to help reporting companies comply with the new rule.

According to FinCEN, the rule aims to minimize burdens on small businesses and other reporting companies. The anticipated cost on companies with simple management and ownership structures, which FinCEN expects to be the majority of reporting companies, will be about $85 to prepare and submit an initial beneficial ownership report. FinCEN did not report anticipated costs for companies with more complex management and ownership structures.

What are FinCEN's next steps?

FinCEN plans to engage in further rulemaking, addressing who can access beneficial ownership information and how such information will be safeguarded, among other things. FinCEN also intends to revise its customer due diligence rule following promulgation of the new beneficial ownership "access" rule.

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3 Options When Creating a Business Succession Plan

October 12, 2022

On Behalf of Goodsill | Oct 11, 2022 | Business Succession

Whether you are the sole owner or one of several with a stake in the business, chances are you have a lot on your plate. Owning and operating a successful company can keep you so busy that you fail to consider who will take over once you retire or pass away.

Business succession planning allows you to determine who is best suited to operate your company in your stead. You have several business succession strategies to choose from once you are ready to put a plan on paper.

Selecting an heir

Many owners dream of passing the family business to an adult child or other relative. Unfortunately, only about 30% of family-inherited companies continue to succeed. Before you choose a family member, make sure they want to take over and have the skill and business savvy to run the company successfully.

Passing the business to a co-owner

If you are one of two or more business partners or owners, it might make sense to pass your shares to one of them. Before putting this succession plan in writing, speak to your candidates in advance. It will help them prepare to receive or buy your shares at a moment's notice.

Selling the company to an outsider

Sometimes, the current owner of a business cannot find an appropriate party to succeed them. When this happens, selling to an outside party can solve your succession problems. To pass on the company as smoothly as possible, take steps to formalize your operating procedures and get your business finances in order.

Learning more about business succession planning and Hawaii business law can ensure your business remains in good hands long after you leave the company.

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FDA to regulate more AI & software tools as devices, guidance indicates

FDA also seeks new digital health regulatory paradigm in Pre-Cert Program report

11 October 2022

In the waning days of FDA's fiscal year, the U.S. Food and Drug Administration (FDA) issued the greatly anticipated final guidance "Clinical Decision Support Software," which aims to clarify the scope of the FDA's oversight of clinical decision support (CDS) software intended for use by health care professionals. Compared to the September 2019 draft version, the new final guidance notably eliminates FDA's prior approach of leveraging risk factors to guide the agency's willingness to exercise enforcement discretion over some categories of products that qualify as medical devices. This updated approach appears to position more software products and AI tools within the realm of FDA regulatory authority than was the case under the September 2019 draft guidance.

At the same time, FDA made minor conforming revisions to the Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices final guidance, as well as the Policy for Device Software Functions and Mobile Medical Applications final guidance, and FDA indicated that those guidances will continue to apply to CDS software that supports or provides recommendations to patients or caregivers.

FDA also recently issued a report on its Digital Health Software Precertification (Pre-Cert) Pilot Program concluding that the approach described in its working model is not practical to implement under current statutory and regulatory authorities. We analyze these developments below.

Device vs. non-device CDS

The 21st Century Cures Act amended Section 520 of the Federal Food, Drug, and Cosmetic Act (FDCA) to exclude certain software functions, including some CDS, from classification as a medical device and, consequently, FDA regulation. To be considered non-device CDS under the Cures Act, software functions must:

1. Not acquire, process, or analyze medical images, signals, or patterns (Criterion 1),
2. Display, analyze, or print medical information about a patient or other medical information (*e.g.*, clinical practice

guidelines) (Criterion 2),

3. Support or provide recommendations to a healthcare professional (HCP) about prevention, diagnosis, or treatment of a disease or condition (Criterion 3), *and*
4. Enable independent review of its recommendations so that the HCP need not rely primarily on the software's recommendations to make a clinical decision about a patient (Criterion 4).

If a CDS product does not meet *all four* of these Cures Act criteria, then, unless some other guidance or policy applies, it would be considered "device CDS" that is regulated by FDA.

Notably, the September 2019, draft guidance "Clinical Decision Support Software," updated the framework for FDA's oversight of CDS products, and, among other things, emphasized clarifying how Criterion 4 above applies to machine learning-based and proprietary algorithms. The final guidance goes even further in illustrating how each criterion should be interpreted, in particular providing more helpful explanations of which functions do and do not meet each specific criteria – something industry and stakeholders had complained was lacking in the draft guidance.

Specifically, as it relates to Criterion 1, FDA provides greater granularity as to what is considered "medical images, signals, or patterns". A "medical image" not only includes those images generated by use of medical imaging systems (e.g., computed tomography (CT), x-ray, ultrasound, magnetic resonance imaging (MRI)) to view any part(s) of the body or images acquired for a medical purpose (e.g., pathology, dermatology) but also those that were not originally acquired for a medical purpose but are being processed or analyzed for a medical purpose. A "signal" includes those signals that typically require use of either: · An IVD or a signal acquisition system that "measures a parameter from within, attached to, or external to the body for a medical purpose and often includes but is not limited to the use of sensors (e.g., electrocardiogram (ECG) leads) along with electronics and a software function that is used for signal generation (e.g., ECG); Collections of samples or specimens such as tissue, blood, or other fluids (e.g., conducting a pathological study using software such as digital pathology); or use of radiological imaging systems (e.g., computed tomography (CT)) and a software function for image generation." A "Pattern" refers to multiple, sequential, or repeated measurements of a signal or from a signal acquisition system. Where a software function assesses or interprets the clinical implications or clinical relevance of a signal, pattern, or medical image, the software functions do not meet Criterion 1 because they "acquire, process, or analyze" and are therefore considered a device function.

Criterion 2 includes software functions that display, analyze, or print patient-specific information, such as demographic information, symptoms, certain test results, patient discharge summaries, and/or other medical information (such as clinical practice guidelines, peer-reviewed clinical studies, textbooks, approved drug or medical device labeling, and government agency recommendations). Here, FDA elaborated on what it considers "medical information" for purposes of determining non-device CDS; characterizing it as the type of information that "normally is, and generally can be, communicated between HCPs in a clinical conversation or between HCPs and patients in the context of a clinical decision" and generally includes data or results from devices (including IVD test(s)) that are provided as a single discrete test or measurement result. The same test or measurement result, however, if provided in a more continuous sampling would be considered a pattern or signal and the CDS function would remain a device function. By way of example, consider the distinction between providing the results of a blood glucose lab test and a continuous glucose monitor reading. The first might be viewed as displaying medical information and a non-device function while displaying the latter would be a device function because the continuous sampling transforms the information into a pattern or signal.

With respect to Criterion 3, FDA states that in determining whether a software function supports or provides recommendations to an HCP, it will consider (1) the level of software automation, and (2) the time-critical nature of the decision the HCP will be taking. FDA explains that these factors impact whether a software function enhances, informs, or influences an HCP's decision-making (satisfying Criterion 3), or instead, substitutes, replaces, or directs the HCP's decision-making (failing Criterion 3). FDA also introduced the concept of "automation bias" as part of Criterion 3, in that the more singular or specific the software output, the more likely an HCP is to over-rely on it, positioning the software beyond merely informing the HCPs decision making. FDA further explains that it considers software that provides a specific preventive, diagnostic, or treatment output or directive as not satisfying Criterion 3 because such software is intended to direct the HCP to take a specific action. This includes software that

provides a specific preventative, diagnostic or treatment course, treatment plan, or follow-up directive, and additionally contemplates software that merely informs the HCP that a specific patient "may exhibit signs" or has a certain risk probability or risk score for a specific disease or condition. What's more, the final guidance explains that the more time-critical the ensuing clinical decision, the more likely the HCP is to not independently review the software's recommendation – which also makes it fail Criterion 4.

FDA also further clarifies the expectations surrounding Criterion 4, whereby the agency appears to permit greater flexibility in how the software can enable independent review of its recommendations so that the HCP need not rely primarily on the software's outputs to make a clinical decision. FDA recommends that the software or software labeling include the purpose or intended use of the product, along with the intended HCP user and patient population and should not be intended for use in critical, time-sensitive tasks or decisions, because under such use an HCP is unlikely to have sufficient time to independently review the basis for the recommendations. FDA also recommends that the software or software labeling identify the required input medical information, with plain language instructions on how the inputs should be obtained, their relevance, and data quality requirements. The software or software labeling should provide a plain language description of the underlying algorithm development and validation that forms the basis for the CDS implementation, and the software output should provide the HCP user with relevant patient-specific information and other knowns/unknowns for consideration (e.g., missing, corrupted, or unexpected input data values), including how the algorithm logic was applied for the patient, in order to enable the HCP to independently review the basis for the recommendations and apply his or her judgment when making the final decision.

Other notable changes between the draft and final guidance

In the earlier draft guidance FDA stated its intention to leverage factors developed by the International Medical Device Regulators Forum (IMDRF) to apply a risk-based policy for defining CDS software functions it considered to be a device and determining whether CDS devices will be actively regulated. Notably, the final guidance removes nearly all mentions of this risk-based policy, along with the draft guidance's lengthy discussion of CDS software functions that would be considered subject to FDA enforcement discretion (*i.e.,* technically a medical device but which FDA chooses not to actively regulate) "based on [the agency's] current understanding of the risks of these devices." In the final guidance, FDA merely references the IMDRF framework as a potential input into its assessment of CDS risk and associated regulatory implications but does not use it to create a category of software that it believes meets the definition of a medical device but for which it plans to exercise enforcement discretion. With just a brief mention it is unclear how or if FDA intends to utilize the IMDRF framework or how it should be considered by software developers. The final guidance further modifies FDA's position from the draft guidance by eliminating the potential for agency enforcement discretion for software that does not provide the HCP with a means to evaluate the underlying basis of its output recommendation and software that is intended for use by patients or caregivers. Software developers are therefore left to rely on FDA's Policy for Device Software Functions and Mobile Medical Applications and General Wellness guidance documents to potentially avoid active FDA regulation in such instances.

The final version of the guidance also significantly departs from the draft in the "Examples" section, where FDA details specific types of CDS functions that it will and will not regulate as medical devices, asserting with greater clarity the kinds of software products and uses where FDA intends to exercise its authority. Relatively consistently with the draft guidance, FDA indicates that software functions which apply reviewable reference information or clinical guidelines to patient symptoms/data are not considered medical devices. These include:

- Software that provides diagnostic or treatment options for a particular disease/condition (*e.g.,* pneumonia) based on clinical guidelines or other established evidence
- Software that notifies clinicians of drug-allergy contraindications or interactions between drugs that may cause adverse reactions
- Software that analyzes patient demographic data and clinical notes in order to provide an HCP with a list of follow-up

options for consideration

Alternatively, products that FDA says in the final guidance it *does* intend to regulate include:

- AI tools designed to analyze images, vital sign patterns, and other physiological information to detect abnormalities or identify patients that may develop a certain condition
- Tools designed to warn caregivers of sepsis
- Software that analyzes a provider's report to identify whether the HCP should initiate a particular type of therapy based upon a scoring algorithm

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Additional resources

In conjunction with the issuance of the final guidance, FDA also published a graphic to provide a visual overview of certain policies described in the guidance and examples of non-device and device CDS software functions.

FDA also simultaneously issued a "Digital Health Policy Navigator" aiming to help stakeholders better understand how to interpret the agency's various digital health policies. This tool guides users through a series of questions based on the published digital health policies, to help a user assess whether a particular software function meets the device definition and, if so, whether it is likely to be actively regulated by FDA as a device. The tool directs users to the appropriate policies (guidance documents) to learn more.

In accordance with the finalized CDS software guidance, FDA also issued minor conforming updates to the following related guidances:

- Policy for Device Software Functions and Mobile Medical Applications
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices
- Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in - Premarket Notification (510(k)) Submissions
- Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions
- Display Devices for Diagnostic Radiology

Digital health needs new regulatory paradigm, Pre-Cert report says

FDA has also just published a report on its 2017 Digital Health Software Precertification (Pre-Cert) Pilot Program, which is an effort by FDA to fast-track digital health products by reducing regulatory hurdles for developers of Software as a Medical Device (SaMD), i.e., software-only products that meet the FDCA definition of a medical device through up-front evaluation of the company's processes and capabilities. In April 2018, as we discussed here, FDA released updates to its Software Precertification (Pre-Cert) Pilot Program, including a working model (v0.1) reflecting the agency's vision of the pilot and outlining its most critical components. Subsequently, in January 2019, this working model was updated (v1.0) and a corresponding Test Plan released to guide the Pilot program.

Then, in September 2020, FDA released an eight-page update on the status of Pre-Cert, which ran in 2019 with nine company participants. The update, which we summarized online here, highlighted what FDA learned from activities conducted to test the program as presently envisioned, and how it will use this information for the next iteration of building and testing. FDA's update indicated that "more work is needed" to understand how information collected to address the product's total life cycle namely during Excellence Appraisals, Review Determination, and Real-World Performance monitoring can be leveraged to support the Streamlined Review for introduction of new devices to market.

In its latest report on Pre-Cert, FDA similarly spotlighted the limitations of the pilot program, citing how the agency was unable to use a broad sample of devices and could not limit the scope of any resulting device classifications. FDA further opined that it was limited by its ability to collect only information from program participants that was submitted voluntarily.

Nevertheless, the pilot program showed that the "rapidly evolving" digital health technologies "in the modern medical device landscape could benefit from a new regulatory paradigm, which would require a legislative change," according to the report. FDA said that "excellence appraisals" in such a new paradigm could benefit from these attributes:

- The ability to keep pace with the speed of technology innovation, leveraging information that exists across the total product lifecycle to provide timely assurance of safety and effectiveness of devices, including modified devices, for public health.
- The ability to objectively and continually assess an organization's ability to deliver devices with a commitment to a culture of quality and organizational excellence.
- Ongoing visibility into Key Performance Indicators (KPIs), Real-World Performance (RWP) metrics, and other data that are transparent and objective, enabling timely and targeted actions to resolve issues, creating opportunities to prevent adverse events, and increasing regulatory compliance.
- Regulatory decision support tools that clearly and consistently communicate FDA regulatory policies, which support frameworks for transparent organizational appraisals and communication of device performance by manufacturers to advance safe and effective use of devices by users.

FDA concluded that the approach described in the Pre-Cert working model "is not practical to implement under our current statutory and regulatory authorities."

Next steps

On October 18, FDA will host a webinar for industry, health care providers, and others interested in learning more about the CDS final guidance. While the final CDS guidance provides more clarity, it also brings a significant change in the agency's treatment of health related software and as a result brings many more software functions into the realm of FDA regulation. As the CDS document appears to increase the world of products regulated by the agency, medical device and software developers will want to carefully review the guidance to ascertain whether additional actions may be necessary to ensure compliance with FDA regulations.

If you have any questions about clinical decision support software, the Pre-Cert program, or FDA's regulation of digital health products more generally, please contact the Hogan Lovells attorney with whom you regularly work or any of the authors of this alert.

Authored by Jodi K. Scott, Suzanne Levy Friedman, and Wil Henderson

Contacts

Jodi Scott
Partner
Denver
jodi.scott@hoganlovells.com

Suzanne Levy Friedman
Senior Associate
Washington, D.C.
suzanne.friedman@hoganlovells.com

Wil Henderson
Senior Associate
Denver
wil.henderson@hoganlovells.com