

Japan: Paving Its Way to a Regulatory Environment to Promote the Alternative Protein Industry

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15 JUNE 2023

Speakers



- David Ettinger counsels multinational companies on food (with a unique emphasis on alternative proteins including plant- and cell-based foods) and food packaging, as well as consumer and tobacco-related products. He assists clients in navigating the import and export of goods to ensure compliance with regulations in the U.S., Europe, and Asia. David counsels companies in China and throughout Asia on matters ranging from ingredient and labeling, to product seizure and detention, to food and consumer product recalls and consumer complaints.
- David is the chief representative in Keller and Heckman's Shanghai, China office and previously worked in the firm's Washington, DC and Brussels offices. His global experience uniquely positions him to counsel foreign companies who need to navigate the regulatory landscape in Asia. To further enhance his and Keller and Heckman's global capabilities, David is the Chair of Mackrell International, a global legal network of over 90 international independent law firms. Mackrell International's member base spans more than 60 countries, which provides Keller and Heckman clients with access to legal support in all major world markets. In addition, David is past Chair and current Vice Chair of the American Chamber of Commerce Shanghai's (AmCham Shanghai) Food, Agriculture & Beverage Committee and serves as a moderator and presenter for many of its seminars and conferences.



Speakers





Mr. Hideki Katagiri is a certified Japanese lawyer and co-founder of the Agri Food Practice Group at Nishimura & Asahi, the largest law firm headquartered in Japan. He advises on regulatory matters, M&A, private investment deals, inbound/outbound strategies and contract matters within the agri/food space. He has been actively engaged as a mentor with accelerator programs focusing on agri/food tech startups, and has developed a sizeable network of startups, venture capitalists and other innovators in the agri/food space in Japan and globally. He is currently relocated in Wageningen University & Research of the Netherlands to research food law and policy matters within agri/food space with special focus on sustainability in the EU and globally. He is also working for the Dutch food tech startup as a regulatory affairs lead.

Speakers





- Megumi Avigail Yoshitomi is the Representative Director of the Japan Association for Cellular Agriculture (JACA). JACA is an industrial group based in Japan, to focus on policy-making to make food products produced by cellular-agriculture technology sellable in Japan.
- JACA has c.40 membership companies, mainly domestic food and industrial majors, but also includes overseas players such as Aleph Farms and Upside Foods.
- JACA communicates with Ministries, politicians, existing meat industry players, consumer organizations, and various business operators who are interested in this area.
- JACA is the administrator of the "Cellular Agriculture Working Team" under the Food-tech Public-Private Council, hosted by the Ministry of Agriculture, Forestry, and Fisheries.
- Megumi is one of the seven advisory boards for the Ministry of Economy, Trade and Industry's strategy to promote the biotechnology industry in Japan. Megumi is awarded Forbes Japan 30 Under 30 in 2020.



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- Our practice in China, and Asia generally, is regulatory in nature
- K&H has prepared many applications for product approval before the following government agencies:
 - China National Health Commission (NHC)
 - Singapore Food Agency (SFA)
 - Food Standards Australia New Zealand (FSANZ)
 - Indonesia Food and Drug Authority (BPOM)







Existing China food regulatory updates are available on the K&H website:

https://www.khlaw.com/CRM

We also distribute articles focusing on the development of alternative proteins in Asia.

Special Focus on Alternative Proteins

The South Korean Food Authority Releases New Rules and 03.30.23 Policies Supporting the Development of the Alternative Protein Industry

- China Announces Draft Standard on Nutritional Fortification 02.28.23 Substances: What Will its Impact Be on Alternative Protein Foods?
- 01.04.23 Foods Produced from Animal Cells: What's in a Name?
- 11.29.22 Singapore Updates Guidelines for the Safety Assessment of Novel Foods
- 11.23.22 BREAKING NEWS: U.S. FDA Completes First Pre-Market Consultation for Food Made by Cultured Animal Cells
- 10.27.22 Australian Food Agency is Ready to Approve Cultured Meats, Are You?
- 07.20.22 South Korea Promotes Alternative Proteins in Its National Plan

PUBLICATION 06.01.2023

Israel Approves the First Animal-Free Protein for Food Use



Israel has recently taken a significant step forward in approving alternative proteins. Nonanimal β-Lactoglobulin produced by Komagataella phaffi became the first animalfree protein to receive approval from the Israeli Ministry of Health (MOH),[1] filed by the

company, Remilk[2].

Foods Produced from Animal Cells: What's in a Name?

Author: David J. Ettinger Jenny Xin Li

01.04.2023

PUBLICATION

Industry and government authorities continue to debate the regulatory pathway regarding the approval framework for foods produced from animal cells, also known as cell-based foods. One of the topics yet to reach consensus is nomenclature: what do we call these new foods made by animal cell culture technology? Let's take a closer look to see how this is playing out across the globe. Australian Food Agency is Ready to Approve Cultured Meats, Are You?

This past August, Cellular Agriculture Australia (CAA), a non-profit organization, founded in 2020, that aims to promote cellular agriculture in Australia through awareness, education, research, and advocacy,



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KH Webinar Series on Alternative Proteins







U.S. and China: The Regulatory Pathway for Alternative Proteins Begins to Unfold WEBINAR









Important Note

The content of this presentation is not intended to as, and does not constitute, legal advice for particularized facts. Regulatory counsel should be consulted in advance for advice on any specific compliance issues.



Agenda

- I. Food Regulatory Landscape and Alternative Protein Development in Japan
- **II. Market-entry for Alternative Protein Industry**
- III. Q&A Session





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Alt protein in Japan -Market opportunities and regulatory landscape-

Hideki Katagiri, Nishimura & Asahi

June 15, 2023

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Our Agri-Food practice group (AFPG)



Nishimura & Asahi has a dedicated agrifood practice consisting of more than 20 lawyers with strong expertise in the food, and agriculture, forestry and fisheries sectors, and extensive experience handling cross-border matters. Our practice focuses on three pillars - agri-food tech; global food value chain; and agriculture, forestry and fisheries.

We help develop new businesses and devise customized financing frameworks for the expansion and development of our clients' agri-food businesses. We have a particularly strong presence in Southeast Asia and leverage our global network of offices to support our clients' international growth.

Sustainability Finance (decarbonization, (venture capital investments, human rights due diligence) financial transactions, funds) Rulemaking Startups (establishment of self-(fundraising/financing, regulation) business strategies) **Agriculture, Forestry and Fisheries Communication with** Corporate **Agri-Food Tech Regulatory Authorities** (setting up a business, **Global Food Value Chain** (license application support) legal support for business operations, JV) Compliance **Intellectual Property** (food sanitation and (trademark, brand **Overseas/Cross-border** labeling, fair trade) protection, patent) (import/export transactions. establishment of overseas subsidiaries. inbound/outbound M&A)

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Commended Innovation in Transforming Industries

at *FT Innovative Lawyers Asia-Pacific Awards 2023* Our pioneering work in the agri-food industry was commended by the *Financial Times* and its research partner Hideki Katagiri

- 2014- Nishimura & Asahi (Co-Founder of AFPG)
- 2021- Wageningen University (Master Food Law & Regulatory Affairs)
- 2023- Dutch food tech startup (Regulatory Affairs Lead)
- > Regulatory, Investment, Partnership development
 - Support A&F business to make an impact in Japan







- 1. Outline of market opportunities in Japan
- 2. The current regulatory landscape of the alt protein industry in Japan
- 3. Future development of cell-based meat industry in Japan (by JACA)



1. Market opportunities in Japan

What do we eat as a protein source in Japan?

Meat

Diverse protein source per capita per year (2020) - Japan VS other countries



Milk & dairy

Source: Our World in data

What do we eat as a protein source in Japan?



Changes in a Japanese protein consumption pattern per capita per day

Source: Agriculture & Livestock Industries Corporation, 2020

* Data in 2019 is an approximate figure.

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What is the current issue about animal protein in Japan?

Vulnerable food system: relying significantly on imported feed for animal production.

| Protein source | Ratio of protein source grown by feed produced only in Japan to protein source consumed in Japan (%), 2020 |
|----------------|--|
| Beef | 9 |
| Pork | 6 |
| Poultry | 8 |
| Egg | 11 |
| Milk & dairy | 26 |

Source: Agriculture & Livestock Industries Corporation, 2020

- To produce all imported feed (e.g., corn and hay) in Japan, we would need to expand farmland by more than 50% (Nakajima, 2023), but it is not plausible.
- Moreover, the price of imported feed (grain) has been rising by around 60% compared to that before Covid-19 due to various reasons (MAFF, 2023).

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Consumer perception towards alt protein

NISHIMURA & Asahi



The reason why you DON'T want to eat alt protein, 2021



The reason why you eat plant-based alt protein , 2021



Source: Agriculture & Livestock Industries Corporation, 2021 and Cross Marketing, 2021

2. The current regulatory landscape of the alt protein industry in Japan (*)

(*) In this presentation, the focus in terms of food safety is solely placed on whether/when <u>regulatory approval</u> would be necessary. It goes without saying that FBOs need to follow <u>ALL</u> legal/regulatory requirements applicable to them to lawfully conduct business in Japan.

(*) The laws and guidance documents, and their interpretation are subject to continual change. Information contained in this presentation is based on the facts available as of **June 11, 2023**.

Who and how regulates the Japanese food industry?



When is pre-market approval necessary?



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Generally, pre-market approval is NECESSARY if FBOs want to place products that are unauthorized "food additives" or "GM foods" on the market. Otherwise, NO pre-market approval is necessary. Therefore, the important questions are:

Q.1 Is your product categorized as GM food?

Q.2 Where your product is not GM food, then is your product categorized as "food" or "food additives"?

Alt protein derived from precision fermentation ("PF") technology and some types of "plant-based protein" are likely to be especially relevant with these questions.

When is pre-market approval necessary? (1)



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- What is the definition of GM food* in Japan?
 Any food that: * GM food additives are also regulated under the same framework..
 - I. (a) is a whole or a part of organisms derived from designated recombinant DNA techniques or (b) contains a whole or a part of (a); or
 - II. (c) is produced from microorganisms derived from designated recombinant DNA techniques or (d) contains (c).

Esp. relevant with products derived from PF technology.

- Pre-approval by MHLW is necessary. FBOs need to submit dossier to MHLW. MHLW asks FSC's opinion for risk assessment. Officially this pre-approval procedure will take around 1-year though 'stop-the-clock' is applicable.
- Where FBOs produce the type II food in Japan, such FBOs shall follow the manufacturing criteria.
- Compliance with the law based on the Cartagena Protocol on Biosafety is necessary (if applicable).

When is pre-market approval necessary? (2)



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• What is food?

All food and drinks (except for pharmaceutical products).

• What are food additives?

Any substances that are used by being <u>added</u>, <u>mixed</u>, <u>infiltrated</u> or <u>other</u> <u>methods</u> into food, in the process of <u>producing</u> food or for the purpose of <u>processing or preserving</u> food. If such substances are **NOT** listed in the authorized food additives catalogue, pre-market approval is necessary to be placed on market. Both any substances normally consumed as foods and natural flavourings **CAN** be used as food additives without pre-approval.

Case by case analysis is necessary: Product composition, proposed usage, use level and nutritional value among other things are relevant with identification of your product. Generally, whole foods (e.g., milk, meat and fish) are categorized as foods. New type protein extract/concentrate could fall under both categories.

When is pre-market approval necessary? (3)



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- <u>NO</u> regulatory framework requiring <u>pre-market approval</u> to place "novel foods" on the Japanese market.
- However, MHLW **may prohibit** FBOs from placing foods on the market if those foods :
- 1. have **NOT been generally used for human consumption**; or
- 2. have been generally used for human consumption but are **served in a significantly different way from normal usage**(1)

have concerns to cause adverse effects on human health (2)

(1) e.g., isolation/concentration/encapsulation, resulting in significant amount of consumption or different digestion pattern.

(2) Not only "likely" to cause adverse effects on human health but also include "uncertain" to cause adverse such effects.

The definition of "novel food" is NOT super clear. Some alt protein products, including cultivated meat would fall under category 1 or 2.



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- If your product is neither unauthorized GM food nor food additives...
- You still need to follow the process criteria and/or product criteria applied to your product category (if any), each established by the MHLW.
- Process criteria: Standard for producing, processing, using, cooking, or preserving food (additives).
- Product criteria: Standard for composition and specification of food (additives).
- For example, where you produce a plant-based food (alternative to meat, fish, dairy or egg) and intend to use certain food additives that are normally used for <u>conventional animal-based products</u>, whether such food additives are authorized to be used for <u>plant-based food</u> could be a big issue. Normally, such food additive is only authorized to be used in conventional meat (milk, egg or fish) products.

- Food information <u>MISLEADS</u> consumers if such information claims your product is substantially better than:
- I. actual its quality, standard or any other particular in related to the content of such product; or
- II. competitors' products falsely.
- Recently, Q&A in related to food labeling of plant-based food was published. Basically, the terminology connected with conventional animal products (e.g., meat, milk, butter, egg and burger) is <u>not prohibited</u> to be used for plant-based protein products **IF** the fact that such products do <u>NOT contain conventional</u> <u>animal sources</u> and/or <u>plant-based ingredients are used therein</u> is clearly mentioned in the labeling to avoid for misleading general consumers.
- There are NO specific guidance documents or Q&As in related to food labeling issues of other types of alt protein products (such as PF and cell-based meat).



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Japan: Paving Its Way to a Regulatory Environment to Promote the Alternative Protein Industry

Megumi Avigail Yoshitomi, JACA



Currently 51 **companies and academia** participate in our organization to discuss such as cultivated food's safety requirements, labeling rules, protection of the rights of cell donors (Wagyu farmers etc.), and how and what kind of information should be provided to consumers, in an effort to shape the industry in a highly transparent manner.





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Cultivated food development companies and labs in Japan

• At least five companies are focusing on developing cultivated food-related technologies by cooperations with labs and external companies



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 At least five companies are focusing on developing cultivated food-related technologies by cooperations with labs and external companies





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| Law firms | | | | | |
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Stakeholders of the Cellular Agriculture field in Japan

Politicians Japan's Parliamentary Group for Cellular Agriculture



Ministries

- MHLW conducts sessions regarding Hazards and Risk analysis of cultivated food
- **MAFF** manages Public-Private Council for alt-protein promotion, including cell-ag (JACA is the admin of cell-ag group)
- METI allocated 300 billion yen in the second supplementary budget for FY2022 to support the production of a variety of bioproducts manufacturing, including cell-ag industry

Cabinet office

- Food Safety Commission of Japan's support on risk assessment research
- De-regulation office

Industry Association

- Japan Association for Cellular Agriculture (dedicated to cellular agriculture)
- Japan Bioindustry Association (dedicated to biotechnology promotion in general)
- Cellular Agriculture Institute of Commons (student-centered event organizer and article publisher)

Policy recommendations toward MHLW about the safety requirement of cultivated food

We need to

- Raise the level of understanding of food safety among members involved in the development of cultivated food ٠
- Build industry consensus on the concept of hazards and risks of cultivated foods ٠



Goal

safety



Market-entry for Alternative Protein Industry

David Ettinger

Partner

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June 15, 2023

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AsiaPac Could be the World Leader in Alt Proteins



The APAC Alternative Protein Industry Report 2022 - The Future is Asian - Published by Green Queen Media

| green queen media | technology development but, hopefully, the tic |
|----------------------------|---|
| <u>9</u> | will soon turn. Several governments are making |
| | regulatory strides and investing in alternativ |
| | proteins to meet national policy goals, bolster for |
| | security, mitigate climate impact, and strengthe |
| The APAC | their economies. If governments can instill the |
| | proper regulatory frameworks for the industr |
| Alternative Protein | Asia Pacific could well become a world leader |
| Alternative Frotein | alternative proteins. |
| Inductory Donort | |
| Industry Report | This report highlights the wins in the industry, an |
| · · · / | investigates these theories, providing invaluab |
| 2022 | insight from some of the sector's biggest hitter |
| | APAC's alternative protein acceleration may appear |

To date, government support for, and regulation of, alternative proteins has failed to keep pace with

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and ble ers. ear to have slowed, but in fact is undergoing a necessary refocus towards a brighter future.

<u>Good Food Institute</u> (GFI): Asia is one of the fastestgrowing regions on Earth for alternative proteins



 "Many countries across the region are eyeing Singapore's precedent-setting regulatory approval of cultivated meat sales as an example they could potentially replicate."



Singapore & U.S.: Approve cultured meat product

Australia, Israel, South Korea, India, China mainland: Existing regulatory framework

Hong Kong No pre-market approval requirements



Japan: Under development

Consider starting with Singapore, Australia, Hong Kong and Israel – These regions may be a more favorable launching ground for alternative proteins



JUST's cell-based chicken nuggets.

- Local government supporting the development of cultured meat
 - Food authorities of Singapore and Australia encourage presubmission consultation
 - Israel has recently taken a significant step forward in approving alternative proteins
 - Hong Kong CFS released an article discussing that cultivated meat must be fit for human consumption, truthful and not misleading labeling, etc.

Recent Developments regarding Cultured Meat in Asia-Pacific

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After Singapore approved the world's first cultured chicken produced by Eat Just, Inc. in December 2020, more and more companies announced that they have received approval of their alternative protein products in Singapore.

Solar Foods protein 'made from air' gets novel food nod in Singapore

By Flora Southey

26-Oct-2022 - Last updated on 26-Oct-2022 at 15:07 GMT



According to Food Frontier, the Singaporean alt protein market has 11 local and more than 17 international plant-based meat manufacturers, along with 11 companies operating in the food biotech space. Some cell ag companies working in Singapore include:

- Biomanufacturing company ESCO ASTER, the first and only firm yet to have received full regulatory approval from a government entity (the Singapore Food Agency), with ISO 22000 and FSSC 22000 certifications, to produce and sell cultivated meat with the highest safety standards.
- GOOD Meat, the first producer worldwide to receive regulatory approval to use serum-free cell growth media in cultivated products in Singapore. It produces and sells cultivated chicken in specialized restaurants. In December, the company announced the first butchery in the world to sell and serve cultivated meat.

Source: Vegconomist

Recent Developments regarding Cultured Meat in Asia-Pacific



- Israel considers "development of alternative protein" as a national goal
- Australia FSANZ starts to review cultured quail meat

Israel: Development of alternative proteins a 'national goal'

Representatives from the Israeli Prime Minister's Office visited two leading Israeli food-tech companies, and met with start-up CEOs, academics and investors in the field.



Prime Minister Office Director General Yossi Shelley and Prime Minister's Animal Rights Advisor Tal Gilboa (center) visiting Tnuva, March 30, 2023. Source: Government Press Office.

| Food Standa | rds Code | Food businesses | Consumer | Our science | About us | | | |
|---|--|---|----------|-------------|-------------------------------|--|--|--|
| Media centre | Statement on Cul | tured Quail as a Novel Food appl | ication | | | | | |
| Food Standards Code Statement on Cultured Quail as a Novel Food application | | | | | | | | |
| Food businesses | Date: 0/02/00 | | | | | | | |
| Consumer | Food Standards Australia New Zealand (FSANZ) has commenced its assessment of an application from Vow Group Pty Ltd seeking | | | | | | | |
| Our science | | | | | | | | |
| About us | Assessment of application A1269 - Cultured Quail as a Novel Food will include chemical, nutritional, microbiological and dietary | | | | | | | |
| Media centre | exposure assessments, detailed examination of the applicant's production process and a review of the food science to ensure that the product is safe to consume prior to it going on sale. | | | | | | | |
| | To help inform aspects of its assessment, FSANZ is commissioning research to better understand consumer attitudes to products produced by new technologies, including whether any specific labelling requirements are needed. | | | | | | | |
| | The assessment is expected to take around 12 months and will include two rounds of public consultation at dates to be advised. | | | | | | | |
| | If the product is approved by FSANZ, Australian and New Zealand food ministers will have 60 days to review FSANZ's decision. | | | | | | | |
| | Statements attributable to the FSANZ CEO, Dr Sandra Cuthbert | | | | | | | |
| | "The food sector is seeing rapid innovation and change in products and markets globally. FSANZ's primary role is to ensure a safe food supply so Australian and New Zealand consumers can be confident the foods they choose to buy are safe to eat. | | | | | | | |
| | | can have trust and confidence in rts have a strong track record of | | | velop world-leading standards | | | |
| | More inform | ation | | | | | | |
| | • A1269 | - Cultured Quail as a Novel Foo | d | | | | | |

Hong Kong



S Centre for Food Safety The Government of the Hong Kong Special Administrative Region

- The Center for Food Safety (CFS) of Hong Kong considers that cultured meat is a meat produced from animal cell culture techniques. It is intended to be consumed as an alternative to conventional meat products.
- No preapproval requirement for ordinary/novel foods in Hong Kong

<u>CFS's Advice to the Trade</u>

- Ensure products for sale are fit for human consumption
- Ensure information on food labels is truthful and not misleading
- Correctly describe food products and provide adequate information on food labels to allow informed choices

Alternative protein in other Asia-Pacific countries

- Local authority issued a ROADMAP to develop alternative proteins per category
- Not promulgated any new food regulations or standards for cultured meat

- Cultured meat is being taken seriously in China
- National Policy MARA 14th Five-Year Plan for National Agricultural and Rural Science and Technology Development (2021-2025)
- Cell-based ingredients are subject to the recognition system under Korea's Temporary Standards
- No guidelines concerning cultured meat at the current stage

South Korea





Japan

Local government is actively developing this area

Specific guidance to clear cultured meat at the current stage

China





South Korea

- South Korea proposed to establish a specific food standard regulating alternative protein foods
- MFDS in May 2023 announced that ingredients intended for use as food that are obtained through new technologies such as cell and microbial culture are subject to the recognition system of Temporary Standards
- Local enterprise are developing technology for potential commercialization of cultured meats.



Legislation development: South Korea launches public consultation on food standards for alternative protein products

By Pearly Neo 01-Feb-2023 - Last updated on 01-Feb-2023 at 03:44 GMT





Development of Cell-Based Meat in China



Keller& Heckman

Milestone: First meat developed from muscle stem cells -

• On November 18, 2019, Chinese scientists have produced 5 grams of meat cultured from animal muscle stem cells.

National Policy

- China's 14th Five-Year Plan for National Agricultural and Rural Science and Technology Development & China's 14th Five-Year Plan for Bioeconomy Development
 - Proposes the development of cultivated meat; explore and develop novel foods such as synthetic protein (published in May 2022)

Quick Observations for Alternative Proteins in AsiaPac



- Government
- Many food authorities in the region are still watching on the development of alt protein in other countries before making any regulatory moves

Consumers



 Many consumers yet to know new protein foods such as cultured meat; further consumer education appears to be necessary in terms of their future acceptance of these new foods

Industry

• Joint efforts by industry would help the government understand the new technologies used in alt protein industry and contribute to the rule-making process



KH Insights







Think early and plan for publication of non-sensitive information to gain consumer trust

Regulation

02 Closely monitor regulatory developments

Preconsultation

03 Regulatory consultation in advance is highly recommended



♦ Keller& Heckman

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