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Report Highlights:

In the past year, Hong Kong did not have any policy changes to regulations pertaining to genetically engineered (GE) products, while monitoring the development of synthetic biology. Hong Kong does not maintain specific regulations for GE products, which are subject to the same food regulations of conventional foods. However, Hong Kong does maintain production and import controls on living modified organisms. Hong Kong does not impose barriers on microbial biotech ingredients/foods. In 2021, Hong Kong launched its first vegan lab-developed ice cream, containing Perfect Day's non-dairy protein derived from a GE microbe. Impossible Foods, which contains soy leghemoglobin (also produced from a GE microbe), has also enjoyed access to the Hong Kong market for many years. In addition, a Hong Kong company is developing lab-grown non-genetically engineered seafood products, with planned commercialization by the end of 2023.

Executive Summary:

Hong Kong has been a major market for U.S. agricultural and related products for decades, ranking 15th in 2021, with an export value of \$2 billion. Although the value of U.S. exports declined about 12 percent, the decrease was not due to any regulatory barriers related to biotechnology. Supply chain issues, a strong U.S. currency, and increased direct exports to mainland China account for the overall decrease in U.S. agricultural exports. High-value, consumer-ready food products continue to present the majority of U.S. agricultural exports to Hong Kong amounting to \$1.6 billion. Hong Kong was the sixth largest U.S. export destination for these products in 2021. Last year, the United States exported \$10 million worth of corn, \$197,000 worth of soybeans and \$12 million in cotton to Hong Kong. Post has not heard of any market access problems related to biotechnology issues.

The Hong Kong government (HKG) does not pose any trade barriers to genetically engineered (GE) products. It also has not imposed any regulatory barriers on microbial biotechnology and derived products used as food or food ingredients. Impossible Burger with its ingredient “leghemoglobin” and Perfect Day’s non-dairy protein, both proteins produced and purified from GE microbes, are allowed in Hong Kong.

The HKG has previously indicated an intention to launch a public consultation on a mandatory pre-market safety assessment scheme (PMSAS) for biotech events, but no action has emerged in the past years. However, in September 2021, the Hong Kong government submitted a paper to the Legislative Council concluding that Hong Kong does not need to launch PMSAS because biotech events of GE products commercially produced and sold internationally have generally passed safety assessments in other countries and regions with a PMSAS in place for years.

Occasional calls by consumer groups and certain Legislative Council members for mandatory labeling of GE foods have not moved the government to further action. Instead, importers are encouraged to comply with voluntary [guidelines](#) introduced in 2006. Post does not expect any new developments for labeling requirements with respect to GE food products in the upcoming year. In addition, HKG officials reiterated that they are closely monitoring the international development and regulation of GE food products.

The United States does not export living modified organisms to Hong Kong. Hong Kong has implemented a Genetically Modified Organisms (Control of Release) Ordinance and a Genetically Modified Organisms (Documentation for Import and Export) Regulation in compliance with the Cartagena Protocol on Biosafety. Any product containing “Genetically Modified Organisms” (GMOs) intended for release into the environment must obtain approval prior to import into Hong Kong. Since the implementation of this regulation, there have not been any applications for release of “GMO” into the environment.

The HKG is monitoring the international development of synthetic biology in the context of the Ordinance. In the future, the government may modify the definition of “GMO” under the Ordinance to be in line with any changes of the Cartagena Protocol.

Regarding domestic production, Hong Kong has minimal GE crop production, which consists primarily of GE papayas grown for domestic consumption. There is no animal cloning in Hong Kong.

Biotechnology in Hong Kong is limited to research carried out by academic institutions. There are no field trials in Hong Kong because of the lack of available land.

Post does not anticipate any changes in Hong Kong’s policy on biotechnology and GE foods in the near term.

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CHAPTER 1: PLANT BIOTECHNOLOGY

Part A: Production and Trade

A) RESEARCH AND PRODUCT DEVELOPMENT

For all GE product development projects, work in Hong Kong is limited to laboratory research with field trials conducted in China. There is only one university in Hong Kong that has successfully partnered with Chinese academic institutions to conduct field trials in China. Hong Kong does not maintain any regulatory barriers discouraging development of GE products.

The Chinese University of Hong Kong houses a Partner State Key Laboratory of Agrobiotechnology research center approved by the Chinese government, that partners with research institutions in China for the development of plant biotechnology. In 2018, the Ministry of Science and Technology (MOST) of China approved renaming it as the [State Key Laboratory of Agrobiotechnology \(SKL\)](#). The [Centre for Soybean Research](#) is established under the Chinese University of Hong Kong. It partners with soybean breeders and researchers in China to develop stress-tolerant soybeans. The Centre successfully identified a novel salt tolerance gene in wild soybeans through whole-genome sequencing (see [Nature Communications 5:4340](#).) A few soybean cultivars have been field tested with satisfactory results. In 2017, two types of soybean seeds with salt and drought tolerant properties were approved by the Chinese government for cultivation by farmers in the Gansu Province.

Currently, there are three types of soybean seeds adopted for commercial cultivation in Gansu. The accumulated sowing acres increased steadily, reaching 12,000 hectares in 2019 and 40,000 in 2021. The [Gansu Academy of Agricultural Sciences](#) (link in Chinese) is the key partner with the Centre for this soybean project. It is understood that the Centre for Soybean Research has not applied for patents and has allowed Gansu Academy to have free use of the research results. According to the center, the soybean seeds in question are not GE. Instead, these are the end products which have been subjected to a marker-assisted selection process.

It is understood that the Center continues its research on stress tolerance of soybeans. The Center is also looking for anti-lodging and high biomass characters for new soybean development.

B) COMMERCIAL PRODUCTION

Hong Kong has no commercial production of GE crops and does not conduct field trials. Although Hong Kong does not ban the production of GE crops, prior approval from the Agriculture, Fisheries, and Conservation Department (AFCD) is required before any GE crops may be planted. The AFCD has not received any applications for the planting of GE crops. Therefore, the AFCD's online public register for the production of GE crops reflects no production of GE crops in Hong Kong. (The planting of GE papayas is exempted from obtaining prior approval from the AFCD. For details, please refer to Part B: Policy –Exemptions to Genetically Modified Ordinance.)

C) EXPORTS

As Hong Kong has no production of GE crops (except some GE papayas for personal consumption), Hong Kong does not have any domestic GE crop exports. For processed products, Hong Kong's food import and export regulations do not distinguish between conventional and GE food products. Therefore, it is possible that Hong Kong may export some food products that contain imported GE ingredients, such as soy sauce and soymilk beverages.

D) IMPORTS

The few major soybean users in Hong Kong generally require non-GE soybeans because of market-driven factors. For example, their processed products are exported to overseas markets demanding GE-free ingredients. Canadian Special Quality White Hilum (SQWH) grade soybeans are reportedly popular among Hong Kong buyers. In 2021, imports of Canadian soybean held 78 percent of the market (\$12 million). China held 19 percent of the market (\$3 million). The United States exported about \$53,000 worth soybean to Hong Kong, holding less than one percent of the market share.

Hong Kong's food import regulation does not differentiate GE products from conventional ones (except for living modified organisms discussed in Part B Policy). In addition, there is no mandatory labeling for GE food products. Therefore, there is no official record or data for food imports containing GE ingredients. A survey conducted by the Hong Kong government can serve as a reference of the presence of GE products in the market.

Survey Reflecting Importation and Production of GE Crops

The Agriculture, Fisheries and Conservation Department (AFCD) conducts annual surveys for the presence of GE products by drawing samples of various imported and locally-grown crops from local markets and farms in Hong Kong. However, the survey only includes foods that are under AFCD's regulatory portfolio. Processed products are not covered by the survey as they are not under the oversight of AFCD.

In 2022, AFCD tested 677 samples from a variety of imported and local produce, animal feed, soybean, seeds, flowers, and fish for the presence of GE ingredients. Of the 677 samples tested, 190 samples (28 percent) reflected GE ingredients, with papayas (including imported and locally grown papayas and seeds) accounting for 97 percent of all GE samples. The result was very similar to last year's survey. Last year, the GE rate of all samples were 30 percent and papayas accounted for the 99 percent. The GE papayas sampled this year were reportedly sourced from China, the United States (Hawaii), Malaysia, Thailand, Taiwan, and Hong Kong. The survey results showed that papayas imported from the Philippines were not of GE variety. Of all local produce, papaya is the only category indicated GE traces. Apart from papayas, other GE samples included tetra fish and zebra fish.

In fact, over the years, all GE samples were papaya, papaya seeds and ornamental fish. The 2022 survey results are summarized in Table 1.

Table 1: Survey for GE Products (2021-2022)

	No. of Tested Samples	No. of GE Positive Samples	Species of Samples with Positive Result
Animal Feed	9	0	
Flower and Fish	35	6	Zebra fish, Tetra fish
Imported Fruit	87	28	Papaya
Imported Vegetable	67	0	
Local Produce	363	156	Papaya
Other Imported Food and Feed	23	0	
Seeds	93	0	
Total	677	190	Papaya, Zebra Fish, Tera fish

Source: Hong Kong Agriculture, Fisheries and Conservation Department -GMO Survey Result 2021-2022

As Hong Kong food laws do not distinguish between conventional and GE food products, no action was taken by AFCD relative to sampled products identified as containing GE ingredients.

E) FOOD AID

Hong Kong does not provide nor receive food aid.

F) TRADE BARRIERS

Presently, Hong Kong does not have any biotechnology-related trade barriers adversely affecting U.S. exports. Post is closely monitoring for initiatives to launch mandatory labeling on GE products, which would impact U.S. agricultural and food exports to Hong Kong. However, post does not see any signs that the Hong Kong government is considering mandatory labeling on GE products.

Part B: Policy

A) REGULATORY FRAMEWORK

The Environment and Ecology Bureau determines the policy direction of GE food regulation. The Food and Environmental Hygiene Department (FEHD) is the Bureau's department for food safety, which administers programs through its Center for Food Safety (CFS). The administration of policies relating to agricultural production and import and export of animals and plants falls under the portfolio of AFCD within the Bureau.

Pre-Market Safety Assessment Scheme

The HKG first indicated in 2013 that it would launch a public consultation on a mandatory pre-market safety assessment scheme (PMSAS) for GE events. According to the proposed regulatory framework, a GE developer would be required to register a GE event prior to the importation of a food product containing that GE event. Food manufacturers and importers would be responsible for ensuring that imported products contain only approved GE ingredients. If a GE event has previously been evaluated

under a foreign regulatory scheme, then the applicant could provide approval certificates and safety evaluations for review by the CFS. A suitable transitional arrangement for GE food that is already on the market would be established should the pre-market safety assessment scheme become effective. However, this project had not been a priority for the government, and no further activity had taken place until recently. In September 2021, the HKG notified its latest position on PMSAS to the Legislative Council stating that Hong Kong does not need to launch the PMSAS because biotech events of GE products available in international trade have been approved by countries and regions with PMSAS. Thus, Hong Kong determined it does not need to duplicate efforts in evaluating such GE events.

Ordinance and Regulation Implementing the Cartagena Protocol on Biosafety

Legal Term	Laws and Regulations where term is used	Legal Definition
genetically modified organism and GMO	Genetically Modified Organisms (Control of Release) Ordinance Genetically Modified Organisms (Control of Release) Ordinance	means a living organism that possesses a novel combination of genetic materials obtained through the use of modern biotechnology
living organism	The Genetically Modified Organisms (Control of Release) (Exemption) Notice	means a biological entity capable of transferring or replicating genetic materials, including sterile organisms, viruses and viroids, but does not include a human being
modern biotechnology		means the application of in vitro nucleic acid techniques (including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles), or techniques involving the fusion of cells beyond the taxonomic family, that— (a) overcome natural physiological reproductive or recombination barriers; and (b) are not techniques used in traditional breeding and selection;

Hong Kong implemented a Genetically Modified Organisms (Control of Release) Ordinance and the Genetically Modified Organisms (Documentation for Import and Export) Regulation in March 2011 to implement measures pursuant to China’s membership to the Cartagena Protocol on Biosafety. The

Ordinance stipulates that the production and importation of “GMOs” to Hong Kong (except for exemptions provided by the Exemption Notice, discussed further below) that are intended to be released into the environment requires prior approval from AFCD. AFCD maintains a “GMO” online register which keeps non-confidential information received pertaining to the “GMO” approval applications. As of September 2022, the [AFCD online register webpage](#) does not show any application entries.

Under the law, documentation requirements are prescribed for all shipments containing “GMOs.” The HKG emphasized that the documentation requirements adhere strictly to the requirements stipulated by the Cartagena Protocol. According to the subsidiary regulation, documentation is required for the following categories of “GMOs:”

- a) “GMOs” intended for direct consumption as food, feed, or for processing; (FFP)
- b) “GMOs” intended for contained use; and
- c) “GMOs” intended for release into the environment.

The HKG does not maintain any specific requirement regarding the type of documentation accompanying “GMO” shipments. The use of a commercial invoice, other documents required or utilized by existing documentation systems, documentation as required by other local legislation, and/or administrative frameworks is acceptable as documentation to accompany “GMO” shipments. In addition to commercial invoices, other forms of documentation that are acceptable include import/export manifests; and licenses or certificates issued or required under other legislation (e.g. phytosanitary certificates). AFCD provides [guidelines on documentation requirements and documentation samples](#).

No adverse impact from these regulations has been reported by U.S. food and agricultural exporters to Hong Kong.

Exemptions to GM Ordinance

The Genetically Modified Organisms (Control of Release) (Exemption) Notice made under the Genetically Modified Organisms (Control of Release) Ordinance took effect June 23, 2012. The Notice exempts all varieties of GE papaya and any “GMO” that is contained in a veterinary vaccine (live recombinant veterinary vaccines) from the application of the Ordinance’s provision that a person must not knowingly cause a “GMO” to be released or maintain the life of a “GMO” in the environment.

The Notice also exempts two commercialized varieties of GE papaya (GE papaya with the unique identifier code of CUH-CP551-8 and GE papaya with the transformation event code of Huanong 1) and live recombinant veterinary vaccines from the application of the Ordinance’s provision that a person must not knowingly import a “GMO” that is intended for release into the environment.

There are anecdotes that the market has available unexempted GM papaya seeds, the unapproved Taiwan strains (i.e. the TW-lines), which are widely used in China because they are more disease-tolerant than the approved strains. Given that legal actions against seed vendors can be initiated only when there is proof suggesting that they have knowingly imported the unexempted GM papaya seeds, the Hong Kong government primarily takes educational rather than litigation measures to tackle the situation. Seed traders are reminded not to import seeds from unknown sources.

With the Exemption Notice, the HKG exempted local papaya growers from applying for approval to release GE crops into the environment. Most locally produced papayas are backyard crops for personal consumption with little commercial value. The HKG position is that the exempted “GMO” poses a low risk to the local biodiversity. According to a risk assessment conducted by the HKG, papaya is an exotic species with no close relatives in Hong Kong. The release of GE papaya to the environment is unlikely to pose a risk to local biodiversity. The inserted genes of GE papaya cannot pass on to local wild plants. The HKG conducted a second risk assessment in 2015 and the study yielded a similar result.

The exemption also caters to the need of the application of live recombinant veterinary vaccines in emergency situations such as an outbreak of a pandemic disease.

B) APPROVALS/AUTHORIZATIONS

Prior approval is required for the production and importation of “GMOs” that are intended to be released into the environment (except for the exemptions mentioned above.) All applications are provided at the [AFCD link](#) (empty as of September 2022).

C) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

No regulations pertain to stacked or pyramided event approvals.

D) FIELD TESTING

No field tests are currently conducted in Hong Kong.

E) INNOVATIVE BIOTECHNOLOGIES

No related regulations on regulating innovative biotechnologies exist. However, the Hong Kong government is monitoring the development for the definition and regulation of synthetic biology under the Conference of the Parties serving as the Meeting of the Parties (COP-MOP) to the Cartagena Protocol on Biosafety. The government’s position is that they will keep in view of decisions reached by COP-MOP on synthetic biology which might have an implication on Hong Kong’s implementation of the Genetically Modified Organisms (Control of Release) Ordinance (the Ordinance). In the meantime, Hong Kong follows the existing definition of “GMOs” in the Ordinance and will enforce the Ordinance if modified organisms of synthetic biology fall within the existing “GMO” definition in the Ordinance.

F) COEXISTENCE

No rules in place or proposed on coexistence.

G) LABELING AND TRACABILITY

Labeling of GE Food Products - Voluntary Labeling Approach

Mandatory labeling for GE foods or feeds is not required. In 2006, the Center for Food Safety (CFS) released guidelines for voluntary labeling of GE foods in response to public calls for consumer information. In 2008, the HKG announced there was no need for a mandatory labeling law in Hong Kong based on an evaluation of the voluntary labeling scheme and that there currently is no international consensus on mandatory labeling. The HKG reiterated its position not to adopt mandatory labeling in a paper submitted to the Legislative Council in 2021. The HKG chose to closely monitor international developments on this issue and promote the voluntary guidelines to the trade for more widespread adoption.

The guidelines were formulated by a working group established under CFS, with membership from various sectors including manufacturing, wholesale, retail, consumer groups, and government departments. The guidelines are only applied to prepackaged foods and are advisory in nature; they do not have legal effect. Adoption is voluntary and not binding. The guidelines are based on the following four principles:

- The labeling of GE food will comply with existing food legislation.
- The threshold level applied in the guidelines for labeling purposes is five percent, in respect to individual food ingredients.
- Additional declaration on the food label is recommended when significant modifications of the food, e.g. composition, nutrition value, level of anti-nutritional factors, natural toxicant, presence of allergen, intended use, introduction of an animal gene, etc., have taken place.
- Negative labeling, e.g. “GMO-free,” is not recommended and not encouraged where no GE counterpart of the respective product exists.

For products with negative labeling, the HKG may take the initiative to test the products for GE ingredients, and a zero tolerance will be adopted for testing purposes. If products are found to have misleading labeling, a retailer may be subject to prosecution under [Section 61 – False Labeling and Advertisement of Food or Drugs](#) of Chapter 132 Public Health and Municipal Services Ordinance.

If the trade chooses to apply negative labeling, the government advises to use less definite terms such as “sourced from non-GM sources” (which contains less than five percent of GM content) and to have documentation to substantiate such declaration. For more details, please refer to [GAIN Report HK#6026](#).

H) MONITORING AND TESTING

AFCD conducts an annual survey for the presence of GE ingredients in various imported and locally-grown crops available in local markets and farms in Hong Kong. The randomly collected samples, which totaled around 680, do not include any processed food products outside the regulatory scope of

AFCD. The results of the 2021-2022 survey are provided in Table 1 above. As Hong Kong food laws do not distinguish between conventional and GE food products, no action was taken by AFCD relative to sampled products identified as containing GE ingredients.

While the AFCD has oversight on agricultural production and the import and export of animals and plants, the Hong Kong Center for Food Safety (CSF) is the food safety regulatory authority. The CFS has in place a regular food surveillance program taking about 65,000 food samples annually for microbiological, chemical, and radiation level testings. This surveillance program does not cover the identification of GE ingredients in foods.

D) LOW LEVEL PRESENCE (LLP) POLICY

According to the voluntary labeling guidelines of GE food products, the threshold level applied for labeling purposes is five percent with respect to individual food ingredients. Details of the labeling guidelines may be found under Chapter 1, Part B, (G) Labeling.

In relation to the Genetically Modified Organisms (Control of Release) Ordinance and the Genetically Modified Organisms (Documentation for Import and Export) Regulation, the documentation requirements do not apply if:

- a) The “GMOs” are imported or exported in a lot together with other living organisms;
- b) The “GMOs” are unintentionally mixed with those other living organisms; and
- c) The percentage of the amount of the “GMOs” to the total amount of living organisms in the lot does not exceed the prescribed percentage.

The prescribed percentages are set as follows

- 1. 5 percent for “GMOs”-FFP;
- 2. 0 percent for “GMOs” intended for contained use; and
- 3. 0 percent for “GMOs” intended for release into the environment.

J) ADDITIONAL REGULATORY REQUIREMENTS

None

K) INTELLECTUAL PROPERTY RIGHTS (IPR)

While Hong Kong currently has no commercial plantings of GE crops, Hong Kong has intellectual property legislation covering patents, designs, copyright, trade descriptions; layout-design (topography) of integrated circuits and plant varieties protection.

L) CARTAGENA PROTOCOL RATIFICATION

China ratified the Cartagena Protocol on Biosafety in 2005, and its provisions were extended to Hong Kong on May 9, 2011, upon the implementation of the Genetically Modified Organisms (Control of Release) Ordinance and the Genetically Modified Organisms (Documentation for Import and Export)

Regulation. Details of the Ordinance and Regulation may be found under Chapter 1, Part B, A) Regulatory Framework. This development has not impacted trade.

Hong Kong does not send any delegates to the CPB bi-annual Conference of the Parties serving as the Meeting of the Parties (COP-MOP). Representatives from AFCD have attended previous COP-MOPs as members of the Chinese delegation.

M) INTERNATIONAL TREATIES AND FORUMS

Hong Kong does not actively participate in discussions related to GE plants within international organizations. Hong Kong is a member of the World Trade Organization (WTO), Asia-Pacific Economic Cooperation (APEC) and the Pacific Economic Cooperation Council (PECC). In addition, Hong Kong has observer status on the Trade Committee of the Organization for Economic Cooperation and Development (OECD). Hong Kong's participation in CODEX Alimentarius, the World Health Organization (WHO), the World Organization for Animal Health (OIE), and the Asia Pacific Plant Protection Commission is not as an individual member, but as part of the Chinese delegation.

Hong Kong, as a Special Administrative Region of China, is not necessarily subject to all international agreements under China's membership. Under Article 153 of the Basic Law, Hong Kong will be consulted prior to international agreements being extended to Hong Kong.

N) RELATED ISSUES

None

Part C: Marketing

A) PUBLIC/PRIVATE OPINIONS

In recent years, it appears that public calls for mandatory labeling of GE products have diminished. It is possible that the COVID-19 pandemic consumed most of the public's attention.

Before the pandemic, some Hong Kong consumer and green organizations continued to advocate for mandatory labeling of GE foods based on consumers' "right to know," not food safety necessarily, most recently during a July 2017 Legislative Council Panel meeting. Anti-technology groups also express doubts about whether voluntary labeling is effectively implemented by traders.

The food industry generally opposes mandatory labeling of GE foods on the grounds that it would limit consumer choice, reduce the variety of food supplies to Hong Kong, and add a burden to both consumers and the industry. Additionally, multiple Hong Kong retailers have indicated they would not import any products that carry a GE label.

The HKG's response to the call for mandatory labeling has been to stress that there has been no international consensus on labeling of GE food products. Government officials have indicated that the safety of foods including GE foods is monitored by the prevailing food surveillance program. In short,

in recent years, there have been relatively few voices asking for mandatory labeling of GE food products in Hong Kong.

B) MARKET ACCEPTANCE/STUDIES

Market analysts report that many Hong Kong consumers are generally not concerned about the existence of GE ingredients in local foods and are more focused on prices, food safety, and nutritional values. Organic food products are growing in popularity, but consumers do not necessarily understand that organic products may not contain GE ingredients.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Part D: Production and Trade

A) RESEARCH AND PRODUCT DEVELOPMENT

There is no genetic engineering or cloning in Hong Kong's limited livestock production.

B) COMMERCIAL PRODUCTION

None

C) EXPORTS

None

D) IMPORTS

Importation of transgenic animals is limited to insignificant levels of two types of aquarium fish: zebra fish and Tetra fish. The rice fish samples taken in AFCD's recent survey did not show any GE variety.

E) TRADE BARRIERS

None

Part E: Policy

A) REGULATORY FRAMEWORK

The Environment and Ecology Bureau determines the policy direction of GE animals and products derived from these animals or their offspring. The Food and Environmental Hygiene Department (FEHD) is the Bureau's department for food safety that administers its programs through its Center for Food Safety (CFS). Administration of policies relating to GE animals and/or livestock clones falls under the portfolio of the AFCD within the Bureau.

Genetically Modified Organisms (Control of Release) Ordinance

Legal Term	Laws and Regulations where term is used	Legal Definition
genetically modified organism and GMO	Genetically Modified Organisms (Control of Release) Ordinance	means a living organism that possesses a novel combination of genetic materials obtained through the use of modern biotechnology
living organism	Genetically Modified Organisms (Control of Release) Ordinance	means a biological entity capable of transferring or replicating genetic materials, including sterile organisms, viruses and viroids, but does not include a human being
modern biotechnology		means the application of in vitro nucleic acid techniques (including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles), or techniques involving the fusion of cells beyond the taxonomic family, that— (a) overcome natural physiological reproductive or recombination barriers; and (b) are not techniques used in traditional breeding and selection;

With the implementation of Genetically Modified Organisms (Control of Release) Ordinance, the importation of live transgenic animals that are to be released into the environment, must obtain prior approval from the AFCD. If imported for contained use, prior approval is not required, though a declaration must be made on import documents.

The HKG maintains a Genetically Modified Organisms Registry which lists all imports of “GMOs” that are to be released into the environment. As of September 2022, the Registry remained empty.

The HKG does not have any specific regulation on food products derived from cloned animals. Regarding cloning animal technology, the HKG has no current plans to conduct a risk assessment.

B) APPROVALS/AUTHORIZATIONS

Prior approval is required for the production and importation of “GMOs” that are intended to be released into the environment (except for the exemption mentioned above.) All applications are provided at the [AFCD link](#) (empty as of September 2022).

C) INNOVATIVE BIOTECHNOLOGIES

The Hong Kong government is monitoring the development of synthetic biology under COP-MOP and probably will adhere to its rulings relating to the definition and regulation, if any, in the context of the enforcement of the Genetically Modified Organisms (Control of Release) Ordinance.

D) LABELLING AND TRACEABILITY

None

E) ADDITIONAL REGULATORY REQUIREMENTS

NONE

F) INTELLECTUAL PROPERTY RIGHTS (IPR)

The HKG has not shown any signs that it is considering legislation to address intellectual property rights for animal biotechnologies.

G) INTERNATIONAL TREATIES AND FORUMS

Hong Kong participates in the World Organization for Animal Health (OIE) as part of the Chinese delegation. Hong Kong does not actively participate in discussions related to animal biotechnology within international organizations.

Hong Kong was chosen to be the venue for the Second International Summit on Human Genome Editing which was held in November 2018. The three-day summit was co-hosted by the Academy of Sciences Hong Kong, the Royal Society of London, the U.S. National Academy of Sciences, and the U.S. National Academy of Medicine. The Summit aimed to continue the global dialogue on human genome editing in relation to questions and concerns pertaining to science, application, ethics, and governance of human genome editing.

H) RELATED ISSUES

Founded in 2018, Avant Meats is a company in Hong Kong developing cultivated meat for food, skin care and cosmetics using its proprietary technology that produces protein directly from fish cells in a laboratory. The company partnered with the Bioprocessing Technology Institute within Singapore’s Agency for Science, Technology and Research (A*STAR), hoping that the partnership will help scale up Avant’s process for generating food-grade and cost-effective cell-cultured fish. Avant is aiming at production for commercialization by late 2023. Avant’s product offerings include cultivated fish filet

that caters to the international mass market and cultivated fish maw, an Asian premium ingredient. Avant also holds a patent for applying its technology for producing pure marine peptide, a skincare product active ingredient.

Part F: Marketing

A) PUBLIC/PRIVATE OPINIONS

Few discussions of GE animals and cloned animals or products from cloned animals take place in Hong Kong. The HKG may be sensitive to political pressure on this issue. Post anticipates that any new requirement would likely target labeling the food products as cloned or GE, as opposed to a ban.

B) MARKET ACCEPTANCE/STUDIES

There is no apparent urgency or calls to develop policy/legislation on the importation of cloned animals because the public assumes that this is not an immediate issue.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

Part G: Production and Trade

A) COMMERCIAL PRODUCTION

While no commercial production exists in Hong Kong, there is a venture capital firm based in Hong Kong, Horizons Ventures Ltd, identifying technology-focused start-ups opportunities which lead to a Hong Kong tycoon's investment in Impossible Foods. The company was also engaged in the funding exercise of Perfect Day, an animal-free dairy protein company based in the United States.

B) EXPORTS

None

C) IMPORTS

Impossible Burgers with leghemoglobin derived from a GE microbe as an ingredient are allowed in Hong Kong.

In January 2021, a local company successfully partnered with Perfect Day and launched a range of ice creams that uses Perfect Day's whey protein derived from a GE microbe. According to Perfect Day, the non-animal protein is produced by microbial fermentation of a fungal strain containing the gene sequence of bovine whey protein. The GE whey protein is identical to the protein found in cow's milk on a molecular level.

More information can be found on ATO's [report](#): Microbial Food Ingredients Encounter No Regulatory Barriers in Hong Kong.

D) TRADE BARRIERS

None

Part H: Policy

A) REGULATORY FRAMEWORK

Currently, Hong Kong does not have specific food regulations for microbial food ingredients. Microbial food ingredients that are not “GMOs” are subject to the same food regulations as conventional food. (The Hong Kong Government defines GMO as a living organism that possesses a novel combination of genetic materials obtained through the use of modern biotechnology.) “GMOs” are subject to the regulatory framework as described in Part B above. Post is not aware of any HKG plans to stipulate new regulations targeting microbial food ingredients.

B) APPROVALS/AUTHORIZATIONS:

Not applicable, as long as the product in question is not a “GMO”.

C) LABELING AND TRACEABILITY

There are no signs that the HKG is mapping out policies to regulate the traceability and labeling of microbial biotech-derived food ingredients. If food ingredients are not “GMOs” as defined in Hong Kong’s Genetically Modified Organisms (Control of Release) Ordinance, they are subject to the same regulations as conventional food items.

The ice cream products in Hong Kong using Perfect Day’s whey protein are marketed as dairy-free products and Impossible Foods highlights the plant-based nature of its products. There is no mentioning of any food ingredients being biotech driven in their promotional publications/labels.

D) MONITORING AND TESTING

In connection with plants and animals, the Agriculture, Fisheries and Conservation Department conducts an annual survey for the presence of GE products in the market (please refer above to Part B, Section H). The Food and Environmental Hygiene Department, which is the food safety regulatory agency, releases any food-related monitoring results. Post is not aware of any monitoring or testing of microbial-derived foods by the Hong Kong government.

E) ADDITIONAL REGULATORY REQUIREMENTS

Not applicable

F) INTELLECTUAL PROPERTY RIGHTS

Please refer above to Part B, Section K.

G) RELATED ISSUES

None

Part I: Marketing

A) PUBLIC/PRIVATE OPINIONS

Post has not seen widespread discussion of microbial biotechnology in the media, though plant-based foods are slowly gaining popularity in the market. There is not much association of plant-based protein with biotechnology.

B) MARKET ACCEPTANCE/STUDIES

While the public may not be familiar with the concept of microbial biotechnology, Hong Kong is picking up the trend of healthy lifestyle with the growing popularity of organic, vegetarian, and vegan foods. This healthy eating trend was further fueled by the COVID-19 pandemic. In recent years, Hong Kong has witnessed the emergence of meatless meats. Hong Kong was the first overseas market that Impossible Foods launched its plant-based beef alternative in April 2018. In general, the public likely does not associate such products with biotechnology.

In April 2018, *HKEX* launched a new listing regime (Chapter 18A)³ to allow pre-revenue biotech companies and new economy companies with non-standard share structures to raise capital in Hong Kong. This policy facilitates financing for biotech companies and strengthens Hong Kong's position as a leading funding hub for biotechnology.

Attachments:

No Attachments