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Prepared By: Caroline Yuen

Approved By: Alicia Hernandez

Report Highlights:

Hong Kong did not have any policy changes on regulating genetically engineered (GE) products in the past year.

Executive Summary:

The United States has strong interests in Hong Kong with respect to agricultural and food exports. In 2019, Hong Kong was the 9th-largest market for U.S. agricultural and food exports by value and the 6th-largest for consumer-oriented food products, with US\$3.2 billion in exports.

The Hong Kong government (HKG) has not imposed any regulatory barriers on microbial biotechnology and derived products used as food or food ingredients. Impossible Burger with its ingredient "leghemoglobin" is allowed in Hong Kong.

The HKG has previously indicated an intention to launch a public consultation on a mandatory premarket safety assessment scheme for biotech events, but no action has transpired in the past year. Occasional calls by consumer groups and certain Legislative Council members for mandatory labeling of Genetically Engineered (GE) foods have not moved the government to further action. Instead, importers are encouraged to comply with voluntary <u>guidelines</u> introduced in 2006. Post does not expect any new developments for labeling requirements with respect to GE food products in the upcoming year.

HKG officials reiterated that they are closely monitoring the international development and regulation of GE food products.

While few, if any, U.S. exports of living modified organisms (LMO) to Hong Kong occur, 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 LMOs intended for release into the environment must obtain approval prior to import into Hong Kong.

Regarding domestic production, Hong Kong has minimal GE crop production, which consists primarily of GE papayas grown for self-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 space.

There are no near-term changes expected in Hong Kong's policy on biotechnology and GE foods.

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CHAPTER 1: PLANT BIOTECHNOLOGY

Part A: Production and Trade

A) 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. While the Hong Kong government does not have substantial targeted funding subsidizing product development, it does not have regulatory barriers discouraging development of GE products either.

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 <u>State Key Laboratory of Agrobiotechnology</u>.

In April 2018, this State Key Laboratory of Agrobiotechnology was awarded RMB 1 million (US\$156,800) for research on plant hormones in the context of soybean and Arabidopsis thaliana with the ultimate objective to boost crops grown under harsh and dry environments. This was the first cross-border Chinese funding to support local scientific research. The sum was slightly larger than recent HKG funding for the life sciences, whose maximum has been HK\$1.2 million (US\$152,800) per project lasting up to three years.

However, the Chinese funding ended at the end of 2019, and no new funding was awarded in 2020.

The <u>Centre for Soybean Research</u> 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 soybean by whole-genome sequencing. (see <u>Nature Communications 5:4340</u>.) 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 reached 12,000 hectares in 2019 and are expected to increase to 24,200 hectares by the end of 2020. The <u>Gansu Academy of Agricultural Sciences</u> (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.

The Hong Kong professor in charge of this project explained that the soybean seeds in question are not GE. Instead they are the end products which have been subjected to a marker-assisted selection processes.

In the past decade, the Chinese University of Hong Kong cooperated on two GE rice projects with research institutions in China. The first project, with the National China Hybrid Rice Research and Development Center (link in Chinese), was aimed at improving the quantity of super hybrid rice by utilizing biotechnology to enhance photosynthesis. The second project was with several academic institutions in China to improve the lysine content of rice. With the retirement of the professor, the Hong Kong participation in this project ended. It is understood that the Chinese partners continue research on this project.

Finally, researchers from the University of Hong Kong, in collaboration with the Institut de Biologie Moleculaire des Plantes of France, have successfully generated tomatoes with enhanced antioxidant properties by genetic engineering. In November 2017, researchers announced a new strategy to simultaneously enhance health-promoting vitamin E six-fold and doubled both provitamin A and lycopene contents in tomatoes, significantly boosting antioxidant properties. The project has been restricted to laboratories in Hong Kong. There are no field trials carried out in Hong Kong because of the lack of space and because the University has yet to establish a field trial cooperation agreement with China. Further details are available at this link.

B) COMMERCIAL PRODUCTION

Hong Kong has no commercial production of GE crops nor does it 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. However, the AFCD has not received any application 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 are 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 2019, Canada soybean imports held 84 percent market share (\$13

million), followed by China and the United States with 13 percent (\$1.9 million) and four percent (\$535,358) market share, respectively.

Survey Reflecting Importation and Production of GE Crops

The Agriculture, Fisheries and Conservation Department (AFCD) of the HKG 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. The collected samples, however, only include foods that are under the regulatory portfolio of AFCD. Processed products are not covered by the survey as they are not under the oversight of AFCD.

In 2020, the AFCD tested 700 samples from a variety of imported and local produce, animal feed, soybean, seeds, flowers, and fish for the presence of GE ingredients. Of the 700 samples tested, 227 samples (32 percent) reflected GE ingredients, with papaya accounting for 98 percent of all GE samples. The GE papayas were reportedly sourced from China, the United States (Hawaii), and Hong Kong.

Apart from papayas, other GE samples included rice fish, and zebra fish. Survey results are summarized in Table 1.

Table 1: Survey for GE Products

	No. of Tested	No. of GE Positive	Species of Samples with
	Samples	Samples	Positive Result
Animal Feed	11	0	
Flower and Fish	38	4	Zebra fish, Rice fish
Imported Fruit	78	40	Papaya
Imported Vegetable	65	0	
Local Produce	387	183	Papaya
Other Imported Food and Feed	23	0	
Seeds	98	0	
Total	700	227	Papaya, Zebra Fish, Rice fish

Source: Hong Kong Agriculture, Fisheries and Conservation Department -GMO Survey Result 2019-2020

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 neither provides nor receives 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.

Part B: Policy

A) REGULATORY FRAMEWORK

The Food and Health Bureau (FHB) 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 falls under the portfolio of AFCD within FHB.

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 for GE events. However, this project has not been a priority for the government, and no further activity has taken place. 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.

Ordinance and Regulation Implementing the Cartagena Protocol on Biosafety

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 LMOs 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. (Note: "GMO" in the Ordinance refers to living modified organisms.) AFCD maintains an LMO online register which keeps non-confidential information received pertaining to the LMO approval applications. As of September 2020, the AFCD online register webpage does not show any application entries.

Under the law, documentation requirements are prescribed for all shipments containing LMOs. 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 LMOs:

a) LMOs intended for direct consumption as food, feed, or for processing; (LMOs-FFP)

- b) LMOs intended for contained use; and
- c) LMOs intended for release into the environment.

No specific requirement regarding the form of documentation accompanying LMO shipments is supplied. 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 the LMO 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 LMO 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 an LMO to be released or maintain the life of an LMO 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 an LMO that is intended for release into the environment.

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 self-consumption with little commercial value. The HKG position is that the exempted LMO poses a low risk to the local biodiversity because, based on 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

Prior approval is required for the production and importation of LMOs 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 2020).

C) STACKED OR PYRAMIDED EVENT APPROVALS

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 or deliberations on regulating innovative biotechnologies exist.

F) COEXISTENCE

No rules in place or proposed on coexistence.

G) LABELING

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. Instead, 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 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 <u>Section 61 – False Labeling and Advertisement of Food or Drugs</u> 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 700, do not include any processed food products outside the regulatory scope of AFCD. The results of the 2020 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.

I) 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 LMOs are imported or exported in a lot together with other living organisms;
- b) The LMOs are unintentionally mixed with those other living organisms; and
- c) The percentage of the amount of the LMOs 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 LMOs-FFP;
- 2. 0 percent for LMOs intended for contained use; and
- 3. 0 percent for LMOs 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.

There has been no impact on 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 China 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

Some Hong Kong consumer organizations and a few Legislative Council (Legco) members continue to advocate for mandatory labeling of GE foods based on consumers' "right to know", not food safety necessarily, most recently during a July 2017 Legco Panel meeting. Anti-technology groups also express doubts about whether voluntary labeling is effectively implemented by the trade.

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 consumers and the industry alike. 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. Additionally, HKG officials have indicated the effective implementation of the Pre-market Safety Assessment Scheme should take priority over mandatory labeling as it will provide the legal basis for preventing unauthorized GE food products from entering the Hong Kong market.

In short, there are relatively few voices asking for mandatory labeling of GE food products in Hong Kong in the recent years.

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) 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 rice fish.

E) TRADE BARRIERS

None

Part E: Policy

A) REGULATORY FRAMEWORK

The Food and Health Bureau (FHB) 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 FHB.

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 LMOs that are to be released into the environment. As of September 2020, the Registry remained empty.

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

B) APPROVALS

Prior approval is required for the production and importation of LMOs 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 2020).

C) INNOVATIVE BIOTECHNOLOGIES

None

D) LABELLING AND TRACEABILITY

None

E) INTELLECTUAL PROPERTY RIGHTS (IPR)

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

F) INTERNATIONAL TREATIES AND FORUMS

Hong Kong participates in the World Organization for Animal Health (OIE) within the People's Republic of China 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.

G) RELATED ISSUES

None

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 believes 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 mention of policy/legislation urgency 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 PRODCUTION

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-up opportunities that lead to a Hong Kong tycoon's investment in Impossible Foods. This venture capital company was also engaged in the funding of Perfect Day, an animal-free dairy protein company based in the United States.

B) EXPORTS

None

C) IMPORTS

Impossible Burgers with leghemoglobin as an ingredient are allowed 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 LMOs are subject to the same food regulations as conventional food. LMOs 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:

Not applicable, as long as the product in question is not an LMO.

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 LMOs, they are subject to the same regulations as conventional food items.

D) MONITORING AND TESTING

In connection with plant and animals, the Agriculture, Fisheries and Conservation Department conducts an annual survey for the presence of GE produce 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

Plant-based products, including Impossible Burgers, are gradually establishing a foothold in Hong Kong's food market. In general, the public likely does not associate such products with biotechnology.

Attachments:

No Attachments