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Report Highlights:

Hong Kong's biotech situation has not changed over the past year. Hong Kong has no GE animal production with crop production limited to GE papayas for self-consumption. Hong Kong imports GE products and encourages voluntary, not mandatory, labeling of genetically engineered (GE) products according to 2006 guidelines. GE development in Hong Kong is limited to research with all field trials conducted in conjunction with universities in mainland China.

SECTION I: EXECUTIVE SUMMARY

Hong Kong, with \$3.8 billion in U.S. exports, was the 6th largest market for U.S. agricultural and food exports, by value, in 2015, and fourth largest for consumer-oriented products.

Although the Hong Kong Government (HKG) has previously indicated an intention to launch a public consultation on a mandatory pre-market safety assessment scheme for biotech events, no further action has transpired. 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 guidelines introduced in 2006. Post does not expect any new developments for labeling requirements with respect to GE food products in the upcoming year.

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

Regarding domestic production, Hong Kong has minimal GE crop production and would consist primarily of GE papayas grown for self-consumption. There is no animal cloning in Hong Kong.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

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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. For example, the Chinese University of Hong Kong cooperates on two GE rice projects with research institutions in China. The first project, with the National China Hybrid Rice Research and Development Center, is aimed at improving the quantity of super hybrid rice by utilizing biotechnology to enhance photosynthesis. The project is still at the research stage requiring technical enhancement. According to the professor in charge of the research, 50 percent of rice produced in China is a hybrid type with the use of transgenic plant production methods that produces 30 percent higher yield than conventional rice. The second project is with several academic institutions in China to improve the lysine content of rice. The project has moved to the stage of "food safety assessment" but remains far from commercialization.

Furthermore, the University of Hong Kong School of Biological Sciences has developed a new strategy to promote plant growth and seed yield in a model Arabidopsis thaliana plant, hence increasing CO2 absorption from the atmosphere and boosting food production. With this technology, researchers have identified a plant-growth promoting gene, designated as "Purple acid phosphatase 2" (AtPAP2) from the model plant Arabidopsis thaliana. The engineered plants can grow faster and produce 38 percent to 57 percent more seeds. The researcher reported these findings at two international conferences: in May 2015 at the 9th International Conference for Plant Mitochondrial Biology in Poland and in September 2015 at the 2nd FEBS Plant Organellar Signaling Workshop in Croatia. Several patent applications are pending but the technology has yet to be transformed into applications. Details of this project can be found 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 production of GE crops, prior approval from the Agriculture, Fisheries, and Conservation Department (AFCD) is required before any GE crops may be planted. Currently, the AFCD's online public register for the production of GE crops reflects no production of GE crops in Hong Kong.

c) EXPORTS:

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

d) IMPORTS:

Soybean imports are almost exclusively non-GE varieties as they are destined for human, not animal, products are used as an ingredient in a processed product for export. Canadian Special Quality White

Hilum (SQWH) grade soybeans are reportedly popular among Hong Kong buyers, however, importers claim that, while SQWH soybeans are non-GE, there is no identity preservation. In 2015, Canada soybean imports held 91 percent market share (\$24 million), followed by China and the U.S. with 7 percent (\$1.8 million) and 0.75 percent (\$197,529)¹ market share, respectively.

Survey Reflecting Importation and Production of GE Crops

The Hong Kong Government's Agriculture, Fisheries and Conservation Department (AFCD) tested 520 samples from a variety of imported fruits, vegetables, animal feed, soybean, seeds, ornamental flowers and fish during 2015 and 2016 for the presence of GE ingredients. Of the 520 samples tested, 81samples (16%) reflected GE ingredients, with papaya accounting for 72 %. Among these, 24 came from a pool of 43 local papaya samples (56%) and 34 from a pool of 50 imported papaya samples. The imported GE papayas were reportedly sourced from China, the U.S. and Thailand. Papaya samples originating from Fiji, Malaysia, Australia and the Philippines did not contain GE ingredients. Of 25 aquarium fish tested, including Rice fish and Zebra fish, 23 tested GE positive.

The table below depicts the summary of the survey result

	No. of Tested Samples	No. of Positive Samples	Species of Samples with Positive Result
	Samples	±	Fositive Result
Imported Fruit	77	34	Papaya
Imported Vegetables	68	0	
Animal Feed	11	0	
Imported Food	30		
Seeds	99	0	
Local Produce	182	24	Papaya
Ornamental Flowers and	53	23	Zebra Fish, Rice Fish
Aquarium Fish			
Total	520	81	Papaya, Rice Fish, Zebra
			Fish

Source: Hong Kong Agriculture, Fisheries and Conservation Department

e) Food Aid

Hong Kong neither provides nor receives food aid.

f) Trade Barriers:

Currently, Hong Kong does not have any biotechnology-related trade barriers adversely affecting U.S. exports.

PART B: POLICY

a) REGULATORY FRAMEWORK

The Food and Health Bureau (FHB) determines the policy direction of GE food regulation. The Food

¹ Global Trade Atlas – Hong Kong Census & Statistics Department

and Environmental Hygiene Department (FEHD) is the Bureau's department for food safety, which administers programs through its Center for Food Safety (CFS). Administration of policies relating to agricultural production falls under the portfolio of the Agriculture, Fisheries and Conservation Department (AFCD) within FHB.

Pre-Market Safety Assessment Scheme

The Hong Kong government 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. In 2016, the government reiterated its intention for a public consultation before deciding on the details of the pre-market safety assessment scheme and its implementation timetable. Nevertheless, there is no indication that the HKG is prepared to launch any consultation in the upcoming year.

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 events 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 premarket safety assessment scheme become effective.

Ordinance and Regulation Implementing the Cartagena Protocol on Biosafety

To implement measures pursuant to China's membership to 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. The Ordinance stipulates that the production and importation of LMOs to Hong Kong (except for exemptions provided by the Exemption Notice – to be discussed later) with the intention to be released into the environment requires prior approval from the Agriculture, Fisheries and Conservation Department. (Note: "GMO" in the Ordinance refers to living modified organisms.) The AFCD maintains a LMO online register which keeps non-confidential information received pertaining to the LMO approval applications. As of November 2016, 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 or other documents required or utilized by existing

documentation systems, or 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). The 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 genetically engineered papaya and any LMO that is contained in a veterinary vaccine (live recombinant veterinary vaccines) from the application of an Ordinance's provision that a person must not knowingly cause a LMO to be released or maintain the life of a 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 a LMO that is intended for release into the environment.

The Government decided to exempt 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 Government 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. As such, the release of GE papaya to the environment is unlikely to pose a risk to local biodiversity. Due to the species barrier, 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 for 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 which are intended to be released into the environment (except for the exemption mentioned above.) All applications are provided at the <u>AFCD link</u>. As of November 2016, the AFCD online registry webpage does not show any applications.

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.

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 released guidelines for voluntary labeling of GE foods in response to public calls for consumer information to make appropriate choices. In 2008, the HKG announced, based on an evaluation of the voluntary labeling scheme, that there was no need for a mandatory labeling law in Hong Kong and that there currently is no international consensus on mandatory labeling. Instead, the Government chose to closely monitor international developments on this issue and to promote the voluntary guidelines to the trade for more widespread adoption.

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

- The labeling of GE food will comply with existing food legislation.
- The threshold level applied in the guidelines for labeling purpose is 5 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 is not recommended.

As the guidelines are voluntary, U.S. food exports should not be affected. However, note that the Hong Kong Government does not encourage negative labeling where no GE counterpart of the respective product exists. Also, the HKG does not encourage negative labeling using very definite terms such as:

- GMO free,
- Free from GM ingredients, etc

For products with negative labeling, the government may take the initiative to test the products against 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 5 percent of GM content) and to have documentation to substantiate such declaration. For more details, please refer to <u>GAIN Report HK#6026</u>.

h) MONITORING AND TESTING:

The Agriculture, Fisheries, and Conservation Department conduct an annual survey for the presence of various imported and locally grown crops available from local markets and farms in Hong Kong. The randomly collected samples, which totaled around 500, included the majority of local and imported sources available at the markets, however, did not include any processed food products which are outside the regulatory scope of AFCD. The results of the 2015-2016 survey were provided earlier in this report under Chapter 1, Part A, D: Imports.

As the 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 GE.

i) LOW LEVEL PRESENCE (LLP) POLICY:

According to the voluntary labeling guidelines of GE food products, the threshold level applied for labeling purpose is 5 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. 1.5% for LMOs-FFP:
- 2. 0% for LMOs intended for contained use; and
- 3. 0% for LMOs intended for release into the environment.

j) ADDITIONAL REGULATORY REQUIREMENTS: None

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

Hong Kong has intellectual property legislation covering <u>Patents</u>, <u>Registered Designs Laws</u>, <u>Copyright</u>, <u>Trade Descriptions</u>; <u>Layout-Design (Topography) of Integrated Circuits</u> and <u>Plant Varieties Protection</u> but Hong Kong currently has no commercial plantings of GE crops.

1) 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.

m) INTERNATIONAL TREATIES/FORA:

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), World Organization for Animal Health (OIE) and Asia Pacific Plant Protection Commission is not as an individual member but as part of the China delegation.

Hong Kong, being a Special Administrative Region of China, may not necessarily be 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:

Hong Kong's 'green' groups, 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, with the latest being the call by a legislator in a Legislative Council Panel meeting in April 2016 for mandatory labeling. Concerned groups also express doubts about whether voluntary labeling is effectively implemented by the trade.

In 2013, the Hong Kong Consumer Council² renewed its call for mandatory labeling for GE food in light of a survey showing that the industry does not comply with the existing voluntary guidelines. There are products containing GE ingredients exceeding threshold level (5%) that do not carry any positive labeling as recommended by the guidelines. Also, some samples were found with misleading negative GE labels when the ingredients had no commercialized GE counterparts. The guidelines consider the negative labels under these circumstances as misleading and do not recommend their use. Samples were found carrying negative labeling but failed to provide any documentation

² A statutory organization promoting and protecting consumer interests

substantiation.

In 2013, given the survey findings with respect to the lack of positive labeling and some misleading/unsubstantiated cases of negative labeling, the Hong Kong Consumer Council reiterated its call for mandatory GE labeling so that the trade is required to provide consumers with information to make choices.

Furthermore, the Consumer Council cited samples of negative labeling on products that contained small traces of GE ingredients. However, these samples were in compliance with the Guidelines as the GE ingredients were found under the threshold limit of 5 percent. Given the possibility of adventitious mixing of GE and non-GE crops, the Consumer Council therefore suggested the trade avoid using negative labeling and lower the threshold level of 5 percent.

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. Hong Kong retailers have said they would not import any products that carry a GE label.

b) MARKET ACCEPTANCE/STUDIES:

Hong Kong consumers are generally not concerned about foods containing GE ingredients but rather prices, food safety and nutritional values of larger concern.

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 PRODDUCTION:

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 Agriculture, Fisheries and Conservation Department (AFCD) within FHB.

With the implementation of Genetically Modified Organisms (Control of Release) Ordinance, importation of live transgenic animals, which 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 has to be made on import documents.

The Hong Kong government maintains a Genetically Modified Organisms Registry which lists all the importation of living modified organisms that are to be released into the environment.

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) INNOVATIVE BIOTECHNOLOGIES:

None

c) LABELING AND TRACEABILITY:

None

d) INTELLECTUAL PROPERTY RIGHTS (IPR):

Hong Kong is not considering any legislation to address intellectual property rights for animal biotechnologies.

e) INTERNATIONAL TREATIES/FOR A:

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.

f) 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/ GE as opposed to a ban.

b) MARKET ACCEPTABCE/STUDIES:

There is no mention of policy/legislation urgency on the importation of cloned animals because the public assumes that this is not yet an immediate issue.			