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Approved By:
William Verzani
Prepared By:
Caroline Yuen

Report Highlights:

Hong Kong's biotech situation has not changed over the past year. Although officials are occasionally urged by influential legislators and consumer advocacy groups to adopt a mandatory biotech labeling policy, the Hong Kong Government has indicated that mandatory labeling is currently not a legislative priority.

SECTION I. EXECUTIVE SUMMARY

Hong Kong, with $4 billion in U.S. exports, was the 6th largest market for U.S. agricultural and food exports (by value), and the fourth largest for consumer-oriented food products in 2016.

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 near future.

At a trade forum in 2017, HKG officials reiterated that they are closely monitoring international developments on the regulation of GE food products, particularly the U.S. regulatory framework on voluntary labeling of GE foods.

While of minimal impact due to few, if any, U.S. exports of living modified organisms (LMO) to Hong Kong, HKG 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 local environment must obtain HKG approval prior to import.

Regarding domestic production, Hong Kong has minimal GE crop production and consists primarily of GE papayas grown for private household consumption. There is no animal cloning or genetic engineering in Hong Kong.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

TABLE OF CONTENTS

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. The Chinese University of Hong Kong is a key partner with research institutions in China for the development of plant biotechnology.

The Chinese University of Hong Kong's Center for Soybean Research has collaborated with soybean breeders and researchers in China to develop stress tolerant soybeans. This research group successfully identified a novel salt tolerant gene in wild soybeans by whole-genome sequencing and employed this discovery to breed and screen for soybean cultivars that have been field tested with satisfactory results. In 2016, two soybean cultivars with salt and drought tolerance properties were approved by Gansu Province in China for cultivation by farmers there. The initial acreage in 2016 was about 70 hectares, which is expected to increase in years to come since the farmers are allowed to keep the seeds for propagation. These soybeans were used for both food and feed. One of the soybean cultivars has good potential to develop into food processing raw material while the other has good potential to be utilized in high altitude regions (>2100m).

The Chinese University of Hong Kong also cooperates on two GE rice projects with research institutions in China. The first project, which is still at the research stage, is with the National China Hybrid Rice Research and Development Center and is focused on improving the yield of super hybrid rice by enhancing photosynthesis. The second project is with several academic institutions in China to improve the lysine content of rice. While this second rice project has moved to the "food safety assessment" stage, it reportedly remains far from commercialization.

Additionally, the University of Hong Kong's School of Biological Sciences has reportedly successfully researched a new method of promoting plant growth and seed yield in a model Arabidopsis thaliana plant. According to the researchers, the engineered plants can grow faster and produce 38 to 57 percent more seeds. Details and conclusions of this research were reported at the 9th International Conference for Plant Mitochondrial Biology in Poland in May 2015 and at the 2nd FEBS Plant Organellar Signaling Workshop in Croatia in September 2015. Several patent applications are pending and the technology has yet to be transformed into applications.

HKG estimates that Hong Kong has around 250 biotechnology-related companies, largely pharmaceutical and traditional Chinese medicine oriented. These companies are engaged in different activities including research & development, manufacturing and marketing. To support biotechnology development, HKG has helped establish a Bio-Informatics Center located in the Hong Kong Science Park. The Center acts as a central data resource for the biotechnology community.

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 (apart from some GE papayas for home consumption), there are no domestic GE crop exports. For processed products, since Hong Kong's food import and export regulations do not distinguish between conventional and GE food products, it is possible that Hong Kong may export some food products that contain imported GE ingredients such as soy sauce and soy milk beverages.

d) IMPORTS:

The major soybean processors in Hong Kong frequently require non-GE soybeans because of market-driven factors. For example, many local processors export their final product to overseas markets that require GE-free ingredients. According to contacts, Canadian Special Quality White Hilum (SQWH) grade soybeans are popular among Hong Kong importers. In 2016, Canada soybean imports held 89 percent market share ($21million), followed by China and the United States with 7 percent ($1.6 million) and 4 percent ($812,776), respectively.

Survey Reflecting Importation and Production of GE Crops

In 2017, the AFCD tested 521 samples from a variety of imported and domestically produced fruits, vegetables, animal feed, soybean, seeds, ornamental flowers and fish for the presence of GE ingredients. Of the 521 samples tested, 161samples (31 percent) reflected GE ingredients, with papaya accounting for 89 percent of all GE positive findings. Among these GE papaya samples, 86 came from a pool of 135 local samples (64 percent) and 58 from a pool of 65 imported samples (89 percent). Overall, 72 percent of the tested papayas (including both locally produced and imported) were GE positive. This percentage is higher than the survey results in 2015 (47 percent) and 2016 (70 percent).

Apart from papayas, aquarium fish (including Rice fish and Zebra fish) was the only other product category tested GE positive in the survey.

The table below depicts the summary of the survey result

	No. of Tested Samples	No. of GE Positive Samples	Species of Samples with Positive Result
Animal Feed	10	0	
Flower and Fish	55	17	Rice fish, Zebra fish
Imported Fruit	79	58	Papaya
Imported Vegetable	59	0	
Local Produce	237	86	Papaya
Other Imported Food and Feed	23	0	
Seeds	58	0	
Total	521	161	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:

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

PART B: POLICY

a) REGULATORY FRAMEWORK:

The Hong Kong Food and Health Bureau (FHB) determines the policy direction of GE food regulation. The Food and Environmental Hygiene Department (FEHD) is the FHB'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 AFCD within FHB.

Pre-Market Safety Assessment Scheme

The Hong Kong government 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. Under the proposed framework, if a GE event had previously been evaluated under a foreign regulatory scheme, the applicant could provide approval certificates and safety evaluations for review by the CFS. Also, 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

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 a Genetically Modified Organisms (Documentation for Import and Export) Regulation in March 2011. This ordinance stipulates that the production and importation of LMOs in Hong Kong for release into the local environment, apart from items listed under the Exemption Notice (to be discussed later in this report), require prior approval from the AFCD. The AFCD maintains a LMO online register which keeps non-confidential information received pertaining to the LMO approval applications. As of October 2017, 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 emphasizes 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).

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 on June 23, 2012. The Notice exempts certain varieties of genetically engineered papaya and LMOs contained in certain veterinary vaccines (live recombinant veterinary vaccines) from the pre-arrival/pre-production AFCD approval requirement.

Specifically, HKG exempts local papaya growers from applying for approval to release GE crops into the environment as most locally produced papayas are backyard crops for self- consumption with little commercial value. The HKG's position is that the exempted LMO poses a low risk to the local biodiversity because 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. This exemption notice also caters to the need 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 this AFCD link (empty as of October 2017).

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 HKG 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 released guidelines for voluntary labeling of GE foods in response to public calls for consumer information to make informed 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 is currently no international consensus on mandatory labeling. Instead, the HKG 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. The guidelines, only applied to prepackaged foods, 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 GAIN Report HK#6026.

h) MONITORING AND TESTING:

The 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 normally total around 500 and do not include any processed food products which are outside the regulatory scope of AFCD. The results of the 2017 survey were provided earlier in this report.

As the Hong Kong food laws do not distinguish between conventional and GE food products, no action was taken by the AFCD regarding the 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 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. 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):

While Hong Kong currently has no commercial plantings of GE crops, Hong Kong has intellectual property legislation covering Patents, Registered Designs Laws, Copyrights, Trade Descriptions, Layout-Designs (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.

m) INTERNTIONAL 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), 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:

Some Hong Kong consumer organizations and a few Legislative Council (Legco) members continue to advocate for mandatory labeling of GE foods with the latest action being a call by a legislator in a Legislative Council Panel meeting in July 2017 for mandatory labeling.

In 2013, the Hong Kong Consumer Council[1] renewed its call for mandatory labeling for GE food in light of a survey showing that industry does not comply with the existing voluntary guidelines. According to the survey, there were products identified as containing GE ingredients in excess of the threshold level (5%) with no recommended positive labeling. Also, some samples were found with misleading negative GE labels when the ingredients had no commercialized GE counterparts.

According to multiple contacts, 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 response to the call for mandatory labeling has been to stress that there has been no international consensus on the labeling of GE food products. Government officials have indicated that

[1] *A statutory organization promoting and protecting consumer interests*

the safety of local foods including GE ingredients 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.

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.

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 FHB determines the policy direction of GE animals and products derived from these animals or their offspring. The FEHD is the FHB's department for food safety that administers its programs through their 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, 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 HKG 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 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.

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.

b) MARKET ACCEPTANCE/STUDIES:

There is no mention of policy/legislation urgency on the importation of cloned animals.