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Report Highlights:
There are no changes since the last report. There is no mandatory labeling regulation for Genetically Engineered (GE) products. The Hong Kong Government (HKG) continues to encourage the trade to follow the set of voluntary guidelines on labeling GE products that was published in 2006.

REPORT OUTLINE

Report Highlights:

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CHAPTER 2: ANIMAL BIOTECHNOLOGY
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Section I : Executive Summary

Hong Kong has not instituted any major changes to its biotech policy since the last report. Although the Hong Kong Government (HKG) indicated in 2013 that it expected to launch a public consultation on a mandatory pre-market safety assessment scheme for biotech events, no consultation has been launched.

Despite calls by consumer groups for mandatory labeling of Genetically Engineered (GE) foods, the HKG has ruled out such an initiative at the moment on the grounds that there is no international consensus. Instead, the government encourages the trade to comply with the voluntary guidelines which were introduced in 2006.

In September 2011, the HKG implemented a Genetically Modified Organisms (Control of Release) Ordinance and a Genetically Modified Organisms (Documentation for Import and Export) Regulation to comply with the Cartagena Protocol on Biosafety. The Ordinance and Regulation stipulate import documentation requirements for products containing living modified organisms (LMOS). Products containing LMOs intended to be released into the environment must request approvals prior to import. These requirements have not impacted U.S. agricultural and food exports to Hong Kong because there are minimal, if any, U.S. exports of LMOS to Hong Kong intended for release into the environment.

Table 1. Hong Kong: U.S. Agricultural Exports to Hong Kong in 2014

Products	**US$ million**	**% of U.S. total exports**	**Ranking**
All Agricultural, Fish & Forestry	4,294	2.58	6
HS1005 Corn (Maize)	6.5	0.06	44
Soybeans	0.6	-	41
Sub-total	7.1		

All Consumer-Oriented food products	3,840	5.61	4

Source: Global Trade Atlas – U.S. Department of Commerce, Bureau of Census

Section II: Plant and Animal Biotechnology

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a) Product Development:

The Chinese University of Hong Kong is cooperating with research institutions in China on two GE rice research projects. The first project is with the National China Hybrid Rice Research and Development Center to improve 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. The yield is 30 percent higher 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.

For all GE product development projects, work in Hong Kong is limited to laboratory research with field trials in China.

b) Commercial Production:

Hong Kong has no commercial production of biotechnology crops, nor does it conduct field trials. However, there is some backyard production of papayas, which could be of GE origin – further details provided under Part B Policy: Exemptions to GM Ordinance.

c) Exports:

Hong Kong does not export any GE crops.

d) Imports:

Soybeans: The few soybean users in Hong Kong require non-GE soybeans because of market-driven factors; for example, their processed products are exported to overseas markets demanding GE free ingredients. Buyers generally have a perception that all U.S. soybeans are of GE origin. Some users of soybeans for processing reported that Canadian Special Quality White Hilum (SQWH) grade soybeans are popular among Hong Kong buyers. However, importers claim that while SQWH soybeans are non-GE there is no identity preservation. In 2014, Canada accounted for 90 percent ($25 million) of Hong Kong's soybean market while the U.S. had a share of 1.2 percent ($338,555)[1].

Survey Reflecting Importation and Production of GE crops

During 2013-2014, the Agriculture, Fisheries and Conservation Department (AFCD) conducted a survey of 976 crop samples from markets and farms to assess the presence of GE ingredients in crop supplies, of which 281samples (29%) were found with GE ingredients. The percentage of GE products

[1] Global Trade Atlas – Hong Kong Census & Statistics Department

found in this survey was higher than that of last year (20%). Of these 281samples, papaya accounted for 265 samples (94 %) of all GE positive samples. Of these 265 GE papaya samples, 245 came from a pool of 529 local papaya samples (46%) and 20 from a pool of 40 imported papaya samples (50%). A total of 569 papaya samples were tested, of which 265 samples tested GE positive (47%). The imported GE papayas were claimed to be sourced from Fiji, China, the U.S. and Thailand. Also, 2 samples of papaya seeds were found of GE origin among a total of 75 seed samples of various species including beetroot, alfalfa, broccoli, melon, etc.

No other imported fruit types or local produce were found with GE traits. The remaining 14 GE samples were aquarium fish. The survey did not include processed foods.

The table below depicts the summary of the survey result

	No. of Tested Samples	No. of Positive Samples	Species of Samples with Positive Result
Imported Fruit	62	20	Papaya
Imported Vegetables	94	0	
Other Imported Food & Feed	64	0	
Seeds	75	2	Papaya
Local Produce	652	245	Papaya
Ornamental Flowers and Aquarium Fish	29	14	Zebra Fish, Rice Fish
Total	976	281	Papaya, Rice Fish, Zebra Fish

Source : Hong Kong Agriculture, Fisheries and Conservation Department

e) Food Aid Recipient Countries:
Hong Kong is not a food aid recipient.

Part B: Policy

a) Regulatory Framework:
The Food and Health Bureau (FHB) determines the policy direction of GE foods. The Food and Environmental Hygiene Department (FEHD) is the Bureau's department for food safety, which administers its 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 HKG indicated in 2013 that it would launch a public consultation on a mandatory pre-market safety assessment scheme for GE events. However, consultation has not been launched because other regulatory issues have taken priority. According to the proposed regulatory framework, a GE developer must register a GE event prior to the importation of a food product containing that GE event. A designated website would list the Hong Kong approved GE events. Food manufacturers and importers would be responsible for ensuring that their products contain only approved GE ingredients. If the GE

events have been evaluated by other regulatory agencies, the applicants should provide approval certificates and evaluation findings for evaluation 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.

Although the HKG position is that the application burden would fall on GE event developers, the trade feels vulnerable that the future law could make them accountable if their products are found to contain GE ingredients which have been derived from GE events not registered in Hong Kong.

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. The HKG introduced the law to implement measures set forth under the Cartagena Protocol on Biosafey. China has been a party to the Convention on Biological Diversity and the Protocol since 1993 and 2005 respectively. These are now extended to Hong Kong with the implementation of the new law.

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 August 2015, the AFCD online register webpage does not show any application entries.

Under the law, there are prescribed documentation requirements 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.

There is no specific requirement regarding the form of documentation accompanying LMO shipments. 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 that should 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 an Ordinance 's provision that a person must not knowingly import a LMO that is intended for release into the environment.

The HKG 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. Furthermore, the HKG explained that the exempted LMO will pose a low risk to the local biodiversity because, based on a risk assessment conducted by the HKG, papaya is an exotic species and does not have 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 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 AFCD link. As of June 2015, the AFCD online register webpage does not show any applications.

c) Field Testing:
There are no field tests currently conducted in Hong Kong.

d) Stacked Events Approvals:
No regulations pertain to stacked events approvals.

e) Additional Requirements:
None

f) Coexistence:
None

g) Labeling:

Labeling of GE Food Products - Voluntary Labeling Approach

There is no legislation for mandatory labeling for GE foods or feeds. The Center for Food Safety released guidelines for voluntary labeling of GE foods in 2006 to answer the public's call for consumers' right to make informed choices. In 2008, the HKG announced that there is no need for a mandatory labeling law in Hong Kong based on an evaluation exercise of the voluntary labeling scheme. The HKG decided not to adopt a mandatory scheme because currently there is no international consensus on mandatory labeling and instead toclosely monitor international development 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 are advisory in nature and do not have any legal effect. Adoption is entirely voluntary and is not binding. The guidelines apply to prepackaged food.

The guidelines are based on the following four principals:

- The labeling of biotech 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, it should be noted that the HKG does not encourage negative labeling where no GE counterparts 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) Trade Barriers:
None

i) Intellectual Property Rights :
Not applicable because Hong Kong does not commercially plant GE crops.
However, Hong Kong has intellectual property legislation covering Patents, Registered Designs Laws, Copyright, Trade Descriptions; Layout-Design (Topography) of Integrated Circuits and Plant Varieties Protection.

j) Cartagena Protocol Ratification:
China ratified the Cartagena Protocol on Biosafety in 2005. It was 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 are provided earlier under the paragraph "Regulatory Framework".

There has been no impact on trade.

k) International Treaties/Fora:
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.

Under Article 153 of the Basic Law, the views of Hong Kong must be sought before international agreements to which China is a party are extended to Hong Kong.

l) Related Issues:
None

m) Monitoring and Testing:
The Agriculture, Fisheries and Conservation Department (AFCD) – a regulatory agency for plants and animals - conducts an annual survey monitoring the importation and production of GE crops. Details are included under Part A, d) Imports.

The Center for Food Safety, a food safety regulatory agency, does not actively test for GE products.

n) Low-Level Presence Policy:
According to the voluntary labeling guidelines of GE food products, the threshold level applied for labeling purpose is 5 percent, in respect to individual food ingredients. Details of the labeling guidelines was discussed earlier under 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.

Part C: Marketing

a) Market Acceptance:
On the whole, Hong Kong consumers are not concerned about foods containing GE ingredients. There have not been any strong actions in the general public urging the HKG to adopt mandatory labeling for GE foods in recent years. Prices, food safety and nutritional values are of bigger concern in general. However, local food processors would specify the use of non-GE soybeans particularly if their products are exported overseas.

b) 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 consumer's "right to know." Food safety or science is not their key argument. They also express doubts about whether the existing voluntary labeling is effectively implemented by the trade.

In 2013, the Hong Kong Consumer Council[2] 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 carrying misleading negative GE labels when the ingredients do not have any 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 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 urge for mandatory labeling so that the trade is required to provide adequate information to consumers 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 still 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

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

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 the choices of consumers, reduce variety of food supplies to Hong Kong and add a burden to consumers and the industry alike. Hong Kong's retailers have said they would not import any products that carried a GE label. They believe that consumers will not choose GE products when there are other choices available.

c) Market Studies:
None

Part D: Capacity Building and Outreach

a) Activities:
Hong Kong government officials regularly attend APEC High Level Policy Dialogue for Agricultural Biotechnology (HLPDAB).

Educating HKG officials, educators, stakeholders and media on the science-based principles and consumer benefits of biotechnology is the most effective way to maintain voluntary GE labeling. Thus, ATO Hong Kong organized a biotech outreach program on August 24 and 25, 2015 with relevant stakeholders in Hong Kong and Macau.

ATO Hong Kong invited Dr. Alison Van Eenennaam, Cooperative Extension Specialist, Department of Animal Science, University of California, Davis, and the 2014 Borlaug CAST (Council for Agriculture Science and Technology) Communication Award winner, to conduct a series of outreach activities addressing different key audience who influence the major GE labeling decision makers in Hong Kong and Macau. The program included a meeting with key government officials who are in charge of food safety and labeling and two rounds of seminars, reaching approximately 70 participants. Included in the audience were Hong Kong and Macau government officials working on food regulations and Cartagena Protocol; nutritionists, dietitians, key retailers, traders, importers, food manufactures, consultants and academia. Dr. Van Eenennaam told the audience, from a scientific point of view, how cost prohibitive and impracticable it is to adopt mandatory labeling given that livestock worldwide has been fed with GE crops for decades as well as the integration of GE ingredients in the global processed food supply chain. Through the presentation, the audience was educated on the merits and scientific development of GE foods.

b) Strategies and Needs:
Close monitoring of the government's approach to implementing its upcoming pre-market safety assessment scheme is required.

Chapter 2: Animal Biotechnology

Part E: Production and Trade

a) Biotechnology Product Development:
There is no genetic engineering and cloning being done on Hong Kong's limited animal farms.

b) Commercial Production:
None

c) Exports:
None

d) Imports:
Importation of transgenic animals is limited to two types of aquarium fish: zebra fish and rice fish. They are imported at a very insignificant amount as pet fish.

Part F: Policy

a) Regulation:
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 Register which lists all the importation of living modified organisms that are to be released into the environment. The Register does not show the importation of any cloned animals which 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) Labeling and Traceability:
None

c) Trade Barriers:
None

d) Intellectual Property Rights (IPR):
Hong Kong is not considering any legislation to address intellectual property rights for animal biotechnologies.

e) International Treaties/Fora:
Hong Kong participates in World Organization for Animal Health (OIE) as part of the China delegation.

Part G: Marketing

a) Market Acceptance:
Certain legislative Council members, media and consumers group continue to press the HKG to look into the issue if products of cloned animals are exported to 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 as opposed to banning them.

b) Public/Private Opinions:
There is no mention of policy/legislation urgency on the importation of cloned animals because the public assumes that the latter is not yet an immediate issue.

c) Market Studies:
None

Part H: Capacity Building and Outreach:

a) Activities:
None

b) Strategies and Needs:
Not applicable for the moment