The Legislative Council

of the

Hong Kong Special Administrative Region

Delegation of the Panel on Food Safety and Environmental Hygiene

Report on the duty visit to
San Francisco of the United States to study the
regulatory framework governing food truck
operations in San Francisco and to understand the
regulatory system of the United States for
imported food products

9 to 13 March 2016

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1.1 Purpose of the report

1.1.1 A delegation of the Panel on Food Safety and Environmental Hygiene ("the Panel") of the Legislative Council visited San Francisco of the United States ("US") from 9 to 13 March 2016 to study the city's experience in regulating food truck operations and to understand US' regulatory control over imported food products. This report presents the main findings and observations of the delegation.

1.2 Background of the visit

- 1.2.1 In his 2015-2016 Budget Speech, the Financial Secretary requested relevant government departments to implement as early as possible the proposal to facilitate alfresco dining operation and to consider introducing food trucks to the mix of Hong Kong's existing food scene.
- 1.2.2 At the Panel meeting on 9 June 2015, the Panel agreed to conduct an overseas duty visit to New York and San Francisco of US in September 2015 to study the regulatory frameworks of the two cities governing food truck operations and to understand US' regulatory control over imported food products.
- 1.2.3 On 3 July 2015, the Panel obtained the House Committee's permission to undertake the oversea duty visit.
- 1.2.4 However, due to the unavailability of some receiving organizations in New York to meet with the delegation, with the agreement of delegation members, the duty visit originally scheduled for September 2015 was rescheduled to be conducted from 9 to 13 March 2016 to cover the city of San Francisco only.

1.3 Objectives of the visit

1.3.1 The objectives of the duty visit are:

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- to obtain first-hand information on the regulatory framework governing food truck operations in San Francisco and to understand the regulatory system of US for imported food products;
- (b) to study San Francisco's experience in governing food truck operations, including licensing requirements, mode of operation, food safety and environmental hygiene issues, the enforcement mechanism and trade facilitation initiatives;
- (c) to study the measures adopted by the relevant regulatory authorities in ensuring safety of imported food products, such as surveillance of imported food at the ports of entry; and
- (d) to exchange views with the relevant government organizations and parties on the operation of food trucks and the regulatory control of imported food products.

1.4 Membership of the delegation

1.4.1 The delegation comprised the following seven Members:

Hon Tommy CHEUNG Yu-yan, GBS, JP (Chairman of the Panel for the 2015-2016 session and leader of the delegation)

Hon Steven HO Chun-yin, BBS (Deputy Chairman of the Panel for the 2015-2016 session)

Hon Charles Peter MOK, JP (Non-Panel Member)

Dr Hon KWOK Ka-ki (Member of the Panel)

Hon SIN Chung-kai, SBS, JP (Member of the Panel)

Dr Hon Helena WONG Pik-wan (Member of the Panel)

Hon CHUNG Kwok-pan (Non-Panel Member)

1.4.2 Miss Josephine SO, Clerk to the Panel, and Ms Wendy LO, Senior Council Secretary, accompanied the delegation on the visit.

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1.5 Visit programme

1.5.1 The delegation visited San Francisco from 9 to 13 March 2016. The detailed visit programme and a list of the organizations and persons met by the delegation are in **Appendices I and II** respectively.

2.1 Food truck operations in San Francisco

Overview

- 2.1.1 The delegation understands that San Francisco currently has some 300 food trucks with permits to sell food. Its annual Street Food Festival, launched every August since 2009, attracts many popular food trucks to the event. In 2015, there were 75 food trucks participating in the seventh annual San Francisco Street Food Festival (an annual celebration of food and drink, showcasing different culinary arts and gourmet food) attended by 80 000 people.
- 2.1.2 The delegation has met with officials of San Francisco Department of Public Works, San Francisco Planning Department, and San Francisco Department of Public Health to understand the regulations governing food truck operation in San Francisco.



The delegation meets with officials of San Francisco Planning Department, San Francisco Department of Public Works and San Francisco Department of Public Health

Regulatory framework governing food truck operations in San Francisco

Definition of a mobile food facility

2.1.3 The delegation has learnt that a Mobile Food Facility ("MFF") refers to any vehicle or pushcart used in conjunction with a commissary or other permanent food facility upon which food is sold or distributed at retail. MFF does not include a "transporter" used to transport packaged food from a food facility or other approved source to the consumer.

Procedures for applying an MFF permit in San Francisco

- 2.1.4 The San Francisco Government introduced in 2011 the Mobile Food Facility Program ("MFF Program") to streamline the rules and regulations for mobile food vending, with the objectives of making it faster and easier for prospective operators of food trucks and other "mobile food facilities" to secure locations and get licensed. The MFF Program also aims to ensure a fairer competition between food trucks and bricks-and-mortar restaurants by regulating where food trucks can operate.
- 2.1.5 The delegation has noted that food truck operations in San Francisco are governed primarily by the California Retail Food Code, the San Francisco Public Works Code and the San Francisco Fire Code. The California Retail Food Code sets out the structural, equipment and operational requirements for all retail food facilities in California. The San Francisco Public Works Code enforced by the Department of Public Works regulates, among others, the trading locations and hours of mobile food facilities in San Francisco and the San Francisco Fire Code ensures that truck operators properly maintain and safely operate gas-fire appliances.

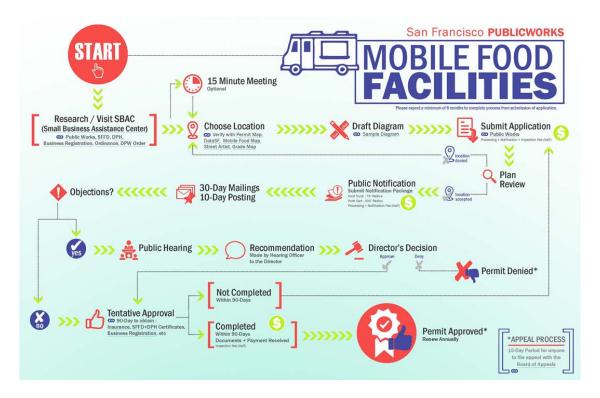
potable water is obtained.

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According to section 113751 of the California Retail Food Code, "commissary" refers to a food facility that services mobile food facilities, mobile support units, or vending machines where any of the following occur: (a) food, containers, or supplies are stored; (b) food is prepared or prepackaged for sale or service at other locations; (c) utensils are cleaned; and (d) liquid and solid wastes are disposed, or

- 2.1.6 The delegation has also noted that under the MFF Program, a prospective food truck operator planning to vend in public locations (e.g. public sidewalks and streets) in the City and County of San Francisco must obtain a permit from the Director of Public Works, accompanied by approval by the Director of Public Health and the Fire Marshal's Office. Every person desiring an MFF permit must first file an application with the Department of Public Works. In addition, he or she is required to inform businesses and residents within 75-foot radius of the proposed trading location through mailing and posting about his or her intention to operate a food truck there. Public hearing will be held if there is any protest against the approval or rejection of the application.
- 2.1.7 Following the hearing, the Director of Public Works will decide whether to approve or reject the application. Should the Director approve the application, the applicant concerned will be issued a 90-day tentative approval to obtain the necessary documents from the relevant government departments for the issue of final permit by the Department of Public Works. The documents required include:
 - (a) business registration certificate from the Office of the Treasurer and Tax Collector;
 - (b) certificate of sanitation from the Department of Public Health;
 - (c) permit from the San Francisco Fire Department for the use of gas-fire appliances; and
 - (d) health permit from the Department of Public Health.

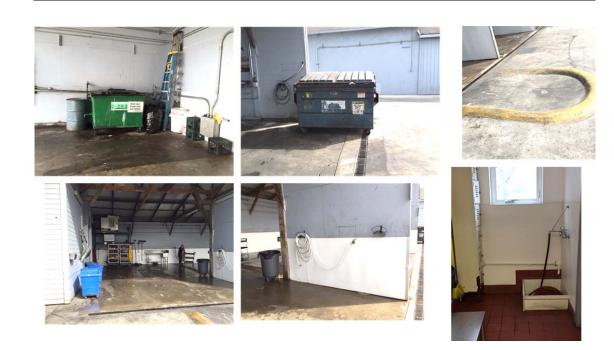
2.1.8 To obtain a health permit from the Department of Public Health, a prospective food truck operator has to fulfill a number of requirements including (a) operating in conjunction with an approved commissary; (b) meeting the specified construction and equipment requirements ²; (c) ensuring that employees can have access to approved restroom facility located within 200 feet travel distance from the trading location.



Interactive flowchart on procedures for applying an MFF permit in San Francisco (Source: SF Department of Public Works)

The requirements cover the installation of hand-wash sink, ware-washing sink, refrigerator, ventilation system, potable water tank and liquid waste tank.

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Photos on an approved commissary (Source: San Mateo Environmental Health Services Division)

Food safety and hygiene requirements

- 2.1.9 The delegation has been informed that food truck operators are also required to comply with the licensing requirements as prescribed in the California Retail Food Code, covering areas such as:
 - (a) sources of food;
 - (b) food storage and preparation;
 - (c) cleaning and maintenance of the truck and equipment;
 - (d) skills and knowledge of the employees;
 - (e) health and hygienic practices of the employees; and
 - (f) plumbing and waste disposal systems.



Delegation members visit mobile food trucks operating on 5M : 5th and Minna Street



Delegation members pay a visit to the SoMa StrEat Food Park

Permitted locations and hours of operation

The San Francisco Public Works Code sets out the location and 2.1.10 time requirements for operating food trucks. The delegation has learnt that food trucks are not allowed to operate in residential districts and within a 75-foot radius of any restaurant's primary entrance. In addition, they have to keep a specified distance from certain city facilities such as bus zones, fire hydrants, pay phones, pedestrian signal crossings and fire alarms. Food trucks are also obliged to follow the Good Neighbour Policy to ensure the maintenance of the quiet, safety and cleanliness of the approved trading location and its adjacent area. For example, food truck operators/employees are required to walk a 100-foot radius from their truck location within 30 minutes after close of business, and pick up and dispose of any trash left by patrons. Regarding business hours, food truck operators are allowed to operate between 6:00 am and 3:00 am the following day. All MFFs are limited to providing service and sales at one location for no more than three days per week. Such days shall be measured in 24-hour cycles so that they may begin on one day and extend to the following day so long as the subject cycle does not constitute more than 24 consecutive hours at a single location.



Delegation members visit mobile food trucks operating according to scheduled locations



Mobile food trucks operating on 5M: 5th and Minna Street

Enforcement

2.1.11 The delegation understands that all MFFs having a permit from the Director of Public Works and the approvals of the Director of Public Health and the Fire Marshal's Office and their commissaries are subject to surprise inspection at any time during operating hours. Inspections will be conducted regularly as well as at the time of permit renewal by the relevant authorities to ensure the compliance of food truck operators with the licensing requirements. The Department of Public Health inspects the food trucks on-site either once or twice a year, depending on the types of the food trucks. The health permit may be suspended or revoked if the operator concerned does not comply with the relevant health and safety regulations. The Department of Public Works also inspects the food trucks operating in public locations. The operator's permit may be suspended or revoked if he or she violates the relevant regulations or operates in a manner with negative impacts on public health, safety and/or convenience.



Delegation members taste traditional Hong Kong foods from the food truck "Hongry Kong"

2.2 Food truck operations in San Mateo

2.2.1 The delegation has received a briefing by officials of the Environmental Health Services Division, County of San Mateo on its MFF Program.



The delegation meets with representatives of the Environmental Health Services Division, San Mateo County Health Services

Overview

- 2.2.2 The delegation has been informed that the Environmental Health Services Division endeavours to keep food safe to eat through:
 - (a) inspecting food sold in markets, restaurants, schools, mobile catering facilities and special events;

- (b) educating the public and businesses about proper sanitation and food handling;
- (c) following-up on complaints and reports of food-borne illness; and
- (d) providing information on food establishment compliance via the internet.
- 2.2.3 In San Mateo County, there are at present a total of 205 mobile trucks. Of them, 10 are "limited food dessert trucks", 105 "gourmet trucks" and 75 "route trucks" (which are usually what are called traditional "taco trucks" that drive a daily route to constructions sites and office parks).

Types of mobile food facility permits available in San Mateo

- 2.2.4 The delegation has noted that there are four different categories of MFFs that may be permitted in San Mateo County:
 - (a) prepackaged cart permitted for the sale of pre-packaged foods only (e.g. ice cream cart, chips and soda cart);
 - (b) prepackaged truck permitted for the sale of whole uncut produce, or prepackaged ice cream;
 - (c) limited food preparation unit permitted for the sale of non-potentially hazardous foods that do not require preparation other than heating, baking, popping, portioning, bulk dispensing, assembly, or shaving of ice (e.g. steamed or boiled hot dogs, tamales in the original or inedible wrapper); and
 - (d) unlimited food preparation unit for non-permanent, traveling food establishments that engage in full food preparation (e.g. taco truck, gourmet food truck or coffee cart, etc).

2.2.5 In San Mateo County, all food facilities including MFFs must comply with all applicable state laws and San Mateo County ordinances/regulations and obtain a valid Environmental Health Permit in order to operate. Violators are subject to closure and penalty fees (i.e. a fine up to three times the cost of permit fee and/or other administrative actions³). MFFs are required to operate in conjunction with a commissary, mobile support unit or other facilities approved by the enforcement agency, and they have to be stored at or within a commissary or other location approved by the enforcement agency in order to have protection from unsanitary conditions.

Requirements and procedures for applying a permit

- 2.2.6 The delegation has also noted that to obtain a permit to operate in San Mateo County, a food truck operator needs to fill out an application form and get ready the following:
 - (a) owner's and MFF's information;
 - (b) a list of all foods that will be sold or the menu;
 - (c) a route schedule;
 - (d) commissary agreement form, with locations for overnight storage of vehicle;
 - (e) written operational procedure for food handling and preparation, cleaning and sanitizing of food contact surfaces and utensils;
 - (f) payment for permit fee;

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³ California Retail Food Code, Section 114387

- (g) insignia issued by the Department of Housing and Community Development⁴ ("HCD"); and
- (h) copy of food safety certification or enrollment in valid food safety class.⁵



Photos on an approved commissary (Source: San Mateo Environmental Health Services Division)

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Each MFF that is either a special purpose commercial modular coach or a commercial modular coach shall be certified by HCD. HCD adopts rules and regulations to protect the health and safety of people from dangers inherent in the use of substandard and unsafe structural, fire safety, plumbing, heat-producing, and electrical systems, equipment and installations of all manufactured homes and mobile homes.

Owner or manager is required to attend an 8-hour training course for food safety and pass a food safety certification examination. Employees or food handlers are required to attend a training course and pass the relevant examination that provides basic, introductory instruction on food safety knowledge.

- 2.2.7 After all necessary documentations are provided and reviewed, inspection will be scheduled to ensure compliance. While all equipment should be ready to be tested at time of inspection, the inspection will focus on employee's knowledge/health and hygiene, hand-washing sinks, food and equipment temperature, food sources, water supply, and other cooking or refrigeration units.
- 2.2.8 The delegation has been informed that the enforcement agency conducts more frequent inspections on commissaries. Inspections on a commissary will be conducted at least three times a year to ensure compliance, having regard to the large number of food trucks it may serve.



The delegation presents a souvenir to the representatives of officials of the Environmental Health Services Division, County of San Mateo

2.3 Network of mobile food markets founded by Off the Grid

- 2.3.1 Off the Grid, founded by Mr Matt Cohen in 2010, has introduced a fairly new phenomenon with the idea of grouping street food vendors together to create an experience that would allow neighbors to connect with friends and families to reconnect with each other. Working with a diverse group of hundreds of food and beverage vendors, Off the Grid currently operates more than 50 weekly markets around the San Francisco Bay Area and at least seven markets throughout the San Mateo County.
- 2.3.2 The delegation has met with Mr Matt Cohen to understand his successful experience in setting up mobile food markets and to learn about the challenges faced by vendors.



The delegation meets with Mr Matt Cohen, Founder of Off the Grid





Mobile food trucks operate in Off the Grid's weekly market

- 2.3.3 The delegation has noted that basically, Off the Grid is a design company that organizes street fairs in under-utilized public spaces such as parks, street closures, private properties and federal land for vendors to showcase their gourmet food under their brands and business names. Its core business is to help vendors to start/run their business in a sustainable manner by providing them with expertise advice and through-train support services from business planning, organizing, marketing, licence application, management and operations to documentation etc. The delegation has also noted that Off the Grid charges vendors for the services it provides calculated at a prescribed percentage (around 10% to 12%) of the gross revenue from the operations of the vendors each year. For special events, Off the Grid offers a variety of food at each market and changes the combination of vendors so that each event is unique. Off the Grid also provides marketing, curation, management and operations expertise for each event.
- 2.3.4 The delegation finds that Off the Grid believes in supporting small businesses. 64% of its vendor businesses are minority owned, and 65% of the vendors are first time business owners. Through partnering with Off the Grid, 30% of the vendors have been able to add at least one additional truck to their fleet since working with Off the Grid, and 60% of the vendors also plan to add at least one truck to their fleet in the coming years.
- 2.3.5 As a trade facilitation initiative, Off the Grid has developed a mobile application "Off the Grid Markets" to facilitate customers in tracking their favourite food trucks and getting live updates and announcements about upcoming street food markets and available vendors in their vicinity.



The delegation presents a souvenir to Mr Matt Cohen, Founder of Off the Grid.

3.1 Federal agencies and their roles

- 3.1.1 Numerous federal, state and local agencies share responsibilities in regulating the safety of food supply in US. Federal responsibility for food safety rests primarily with the Food and Drug Administration ("FDA"), which is part of the US Department of Health and Human Services, and the Food Safety and Inspection Service ("FSIS"), which is part of the US Department of Agriculture ("USDA").
- 3.1.2 The delegation has received briefings by representatives from FDA and USDA on their food safety policy and measures. Delegation members have also exchanged views with the official from the Customs and Border Protection ("CBP") on surveillance of imported food at ports of entry.



Delegation members receive briefings on work and measures of food safety surveillance by representatives from FDA, USDA and CBP

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3.1.3 The delegation has noted that FDA is responsible for, among other things, ensuring that all domestic and imported food products (except for most meats and poultry) are safe, sanitary, nutritious, wholesome, accurately labelled and up to the same safety standards that govern food products produced in US. FDA also oversees the safety of all seafood, fish, and shellfish products. FSIS on the other hand regulates most meat, poultry and processed egg products. Currently, FDA regulates about 80%-90% of the food supply in US and FSIS the remaining 10%-20%.

3.1.4 The delegation has been informed that other federal agencies also play a role. The Government Accountability Office has identified as many as 15 federal agencies, including FDA and FSIS, as collectively administering at least 30 laws related to food safety. State and local food safety authorities collaborate with federal agencies for inspection and other food safety functions. The text box below provides a comparison of FDA and USDA and other federal agencies' responsibilities for food safety and related food quality and other requirements.

<u>Agency</u>	Responsibility
Food and Drug Administration (FDA)	• Food (but not meat)
	Dietary supplements
	Bottled water
	Seafood
	Wild game ("exotic" meat)
	• Eggs in the shell
U.S. Department of Agriculture (USDA)	Grading of raw fruit and vegetables
	Meat and Poultry
	 Eggs, processing and grading
	 Certifying organic production
National Oceanic and Atmospheric Administration	 Grading of fish and seafood
Environmental Protection Agency (EPA)	Drinking water
	Pesticide residues
Customs and Border Protection (CBP)	• Front-line enforcement and referral
Department of Justice (DOJ)	• Law enforcement
Federal Trade Commission (FTC)	Advertising
Alcohol and Tobacco Tax and Trade Bureau (TTB)	Alcohol

A comparison of FDA and other federal agencies' responsibilities for food safety and related matters (Source: FDA)

3.2 Regulatory system administered by the Food and Drug Administration

3.2.1 The delegation has noted that FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act ("FFD&CA"), the Public Health Service Act, the Fair Packaging and Labeling Act and parts of the Egg Products Inspection Act which are designed to protect consumers' health and safety. These laws apply equally to domestic and imported products. In carrying out its responsibilities under these laws, FDA conducts inspections on establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by FSIS. FDA also inspects vehicles and other conveyances, such as boats, trains, and airplanes, in which foods are transported or held in interstate commerce.

FDA's Import Program

3.2.2 While the product requirements under relevant laws apply both to domestic and imported products, section 801 of FFD&CA allows for refusal of importation of FDA-regulated products for appearing to be adulterated or misbranded based on evidence, as it provides that "if it appears from the examination of such samples or otherwise that... (1) such article has been manufactured, processed, or packed under insanitary conditions... or (2) such article is forbidden or restricted in sale in the country in which it was produced... or (3) such article is adulterated, misbranded, or in violation of section 505 (New Drugs)... then such article shall be refused admission...".

Food Safety Modernization Act

3.2.3 The delegation has been advised that in order to better protect public health and prevent food-borne illness, the federal government reformed the food safety system in 2011 by passing the FDA Food Safety Modernization Act. The objective of the reform is to strengthen the food safety system by focusing more on preventing food safety problems rather than reacting to problems after they have occurred. Under the reform, FDA has implemented a series of preventive measures to enhance the safety control system for domestic and imported food products.

Multifaceted approach to safeguard the safety of imported food

3.2.4 The delegation has noted that to safeguard the safety of imported food, FDA employs a multifaceted approach that includes international collaboration, strengthened importers' accountability and targeted surveillance.

International collaboration

3.2.5 The delegation understands that FDA adopts a global strategy for more effective control of the safety of imported food products coming from sources around the world. Under the strategy, FDA has strengthened its international presence and co-ordination with foreign regulatory authorities by establishing offices in top exporting countries. These offices conduct and facilitate inspections in foreign sites, and provide information about the safety and quality of products exported to US to facilitate the making of admissibility decisions. In addition, FDA has agreements with more than 30 foreign counterpart agencies to share inspection reports and other non-public information that can help make better decisions about the safety of imported products.

Strengthened importers' accountability

- 3.2.6 The delegation has learnt that FDA has established the Foreign Supplier Verification Programme ("FSVP") to strengthen importers' accountability for the safety of their food products shipped to US. Under this programme, importers are required to verify that their foreign suppliers have risk-based preventive controls and the food products imported into US are produced in a manner that meets applicable US safety standards. If the importer obtains a certain food from a few different suppliers, a separate FSVP would be required for each of those suppliers. The supplier's performance is re-evaluated every three years or when new information comes to light about the supplier's performance or a potential hazard.
- 3.2.7 The delegation has further noted that apart from FSVP, FDA is planning to launch in 2018 the Voluntary Qualified Importer Programme

("VQIP") to expedite entry of imported food products into US from importers who achieve and maintain a high level of control over the safety and security of their supply chains. VQIP includes the approval for importation of food from a foreign supplier who has a current food facility certification issued by a third-party auditor/certification body accredited under FFD&CA and in accordance with FDA's third-party accreditation regulations. The delegation finds that VQIP will have the following merits:

- (a) FDA will expedite entry into US for all foods included in an approved VQIP application;
- (b) FDA will limit examination and/or sampling of VQIP food entries to "for cause" situations in which there is a potential threat to public health unless other situations arise;
- (c) field examination and/or sampling will be conducted at VQIP foods destination or another location chosen by the importer;
- (d) laboratory analysis will be expedited;
- (e) FDA will establish a VQIP Importers Help Desk dedicated to responding questions and concerns from VQIP importers; and
- (f) public posting on FDA's VQIP webpage of approved VQIP importers.

Targeted surveillance of imported products

3.2.8 The delegation has been advised that at present, all import entries have to go through CBP. With CBP's support, FDA requires food importers to provide prior notice for/information on each shipment to US, including information such as what these shipments contain and the countries to which the products have been refused entry. FDA makes use of the information so obtained to screen those food products that require field examination or sampling upon their arrival to US. Screened food products that are

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determined to be of low risk will be released at the ports of entry. For those with risk concern, FDA staff will further investigate to determine whether a field examination or sampling is required, more information has to be solicited, or the products should be released.

- 3.2.9 FDA's screening tool uses various sources of information to assess risk. The tools include FDA databases, surveillance results, a firm's previous compliance history, inherent risk of a product and previous history of importers, manufacturers and shippers.
- 3.2.10 The delegation has noted that FDA employs two-stage controls to ensure the safety and compliance of imported foods, both pre-arrival as well as after arrival at the ports of entry. Pre-arrival control measures include registration of food facilities, prior notice of shipments and screening the shipments that require inspection upon their arrival to US. Control measures used at the port-of-entry stage include field inspections and import alerts.
- 3.2.11 At present, all domestic and foreign facilities that manufacture, process, pack or keep food for human or animal consumption in US are required to register with FDA. Registration is renewed on a biennial basis. Food products imported from facilities that are not registered with FDA will be denied entry at the ports of entry.
- 3.2.12 All registered food facilities are also required to contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the relevant law. FDA will consider the following factors when identifying high-risk domestic and foreign facilities and allocating resources to conduct inspections:
 - (a) the known safety risks of the food manufactured, processed, packed or held at the facility;
 - (b) compliance history of the facility;
 - (c) the rigour and effectiveness of the hazard analysis of and the risk-based preventive controls taken by the facility; and

- (d) whether the food product or facility is certified to comply with the relevant food safety requirements.
- 3.2.13 Automated systems help FDA staff speed their screening of shipments while targeting FDA's resources on the riskiest products. The delegation has noted that FDA has introduced the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting ("PREDICT") information technology system, which uses data analytics from the entire life cycle of a product to better identify and target high-risk products for further investigation and inspection. The data analyzed include: (a) results of field examinations and sample analyses of previous entries; (b) results of foreign and domestic inspections on a facility; (c) ratings of inherent product risks; and (d) accuracy of product and facility coding/information provided by the importers.
- 3.2.14 The delegation has been informed that when necessary, FDA may issue import alerts (i.e. evidence-based notifications) to signal FDA staff at the field offices to pay special attention to a particular product or a range of products from a particular producer, shipper or importer which may pose safety concern. Once an import alert is issued, the concerned food products can be detained at the ports of entry without examination and refused admission into US unless the importer is able to demonstrate that the products are in compliance with US food safety requirements. FDA staff may consider the following actions:
 - (a) release;
 - (b) request documents or other information;
 - (c) conduct physical examination, label review and sample collection;
 - (d) send sample to FDA laboratory for analysis;
 - (e) release or detain product after analysis; and

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(f) detain – the food products will be detained if examination of the samples or other evidence indicates that they are not in compliance with the relevant food law. The importer has the right to provide evidence to refute the appearance of the violation. Based on the evidence, the detention will either stand (refusal of entry) or be overturned (release).



The delegation presents souvenirs to the representatives of FDA, USDA and CBP

3.3 Customs and Border Protection's cargo inspections

Protecting agriculture

- 3.3.1 The delegation has been informed that every year, millions of pounds of fresh fruits, vegetables, bulk grains (such as corn, soybeans, wheat, barley etc.), herbs, processed foodstuffs and other items enter US via commercial shipments from other countries. Although these items appear to be harmless, there could be hidden threats in those truckloads, trainloads and containers of fresh items, which could seriously threaten the country's agriculture, natural resources, environment and economy. CBP's agriculture specialists and officers at the ports of entry target, detect, intercept and thereby prevent the entry of these potential threats before they have a chance to do any harm.
- 3.3.2 Each year, CBP agriculture specialists intercept tens of thousands of "actionable pests" those identified through scientific risk assessment and study as being dangerous to the health and safety of US agricultural resources. CBP agriculture specialists inspect containers and trucks for smuggled agricultural products or packaging materials that might contain diseases, contaminants or invasive pests/species which could harm the agriculture and environment, examine wooden pallets that could hide the larvae of wood-boring insects poised to attack native trees or nursery stock, and ensure that imported fruits and vegetables are pest-free.
- 3.3.3 The delegation has noted that in the process of inspections, CBP agriculture specialists use specialized x-ray machines to detect organic materials. They also utilize agricultural canines specifically trained to sniff out meat and plant materials. When USDA transferred agricultural inspectors to CBP in 2003, approximately 75 canine teams were included. As of today, more than 116 CBP agriculture canine teams provide screening at the border crossings, pre-clearance locations, air passenger terminals, cruise terminals, cargo warehouses, and mail facilities that process international passengers and commodities.

3.4 Regulations over infant formula

3.4.1 Surveys conducted by the Administration have revealed that formula products and pre-packaged foods for infants and young children under the age of 36 months ("IYC foods") available in Hong Kong are mainly imported from places such as the European Union, Australia, New Zealand and US. The Administration conducted a public consultation exercise on its proposed regulatory framework on nutrition and health claims for formula products and IYC foods from January to April 2015. The delegation has taken the opportunity to meet with representatives of the Infant Nutrition Council of America ("INCA") to understand how formulated nutrition products for infants and young children are regulated in US.

<u>Definition of infant formula and regulatory requirements</u>

- 3.4.2 The delegation has been informed that persons responsible for the manufacture or distribution of infant formula that will be introduced into interstate commerce in US must comply with the provisions in FFD&CA and FDA's promulgated regulations. The latter, published in Title 21 of the Code of Federal Regulations ("CFR"), specify infant formula nutrient quality control procedures; records and reports; submission requirements; labelling requirements; terms and conditions under which certain infant formula may be exempted from some of the requirements; nutrient specifications requirements; and infant formula recalls.
- 3.4.3 The delegation has noted that "infant" is defined in CFR as "a person not more than 12 months old". "Infant formula" is defined as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk". It is regulated in US under the Infant Formula Act which governs safe production, nutritional sufficiency, notification, registration and records requirements, defines adulteration and imposes FDA's mandatory recall authority.

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- 3.4.4 Infant formulas must be manufactured in compliance with Current Good Manufacturing Practices ("cGMPs"). cGMP requirements specify production and in-process control system that covers all stages of process to ensure all requirements are met and are intended to prevent adulteration by limiting the potential for contamination by microorganisms, packaging and labelling issues and establishing traceability requirements.
- 3.4.5 The delegation has also noted that FDA does not define "toddler formula" which is commonly understood to mean products for young children over 12 months of age. Follow-on formulas and growing-up milks for young children older than one year are not considered as infant formulas in US because they are not intended to be used as a sole source of nutrition. As a result, they are regulated like all other food products intended for the general population and must comply with relevant cGMPs.
- 3.4.6 FFD&CA also requires persons responsible for the manufacture or distribution of infant formula to register with FDA and to make a submission to FDA for any new infant formula, which includes any infant formula that has had a major change in its formulation or processing, 90 days before any charitable or commercial distribution. After the first processing of a new infant formula, but before marketing, persons responsible for the manufacture or distribution of infant formula must submit to FDA a written verification which demonstrates that the formula, as actually produced, complies with the statutory requirements.

General labelling requirements

- 3.4.7 The delegation has learnt that all infant formulas sold in US must include the following information on labels:
 - (a) statement of identity;
 - (b) manufacturer's information;
 - (c) ingredient statement;
 - (d) net quantity of contents;

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- (e) allergen statement as defined under the Food Allergen Labeling and Consumer Protection Act;
- (f) a "Use by Date" which is set by manufacturer and must be based on shelf life test that demonstrates that the nutrient levels on the label will be met and that the product will be suitable for consumption;
- (g) nutrition information in specified order and units and in a tabular format:
- (h) nutrient minimum and maximum levels;
- (i) preparation and directions for use information; and
- (j) certain information about the health and safety of the infant, including "warning statement" and "doctor's statement".
- 3.4.8 The delegation has noted that while certain nutrient content claims are permitted on infant formula, FDA also permits the use of a qualified health claim regarding the relationship between the consumption of 100% whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis. The qualified health claim must use the specific language provided for in the petition response.

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The delegation meets with the representatives of INCA

4.1 Observations

4.1.1 Having received briefings and exchanged views with relevant parties/organizations, the delegation has the following observations.

Food truck operations

- 4.1.2 The experience of San Francisco and San Mateo in regulating food truck operations is a good reference for Hong Kong. The delegation notes that apart from federal and state laws, the governments of San Francisco and San Mateo adopt other specific rules and regulations to regulate food truck operations based on the local circumstances. Nevertheless, the underlying principles of the regulatory regimes are based upon convenience, operational flexibility and freedom which tend to increase the desire and motivation of food truck operators, and hence explaining the thriving of the market in the cities. In contrast, stringent entry barriers or operational rules will likely hinder market development.
- In Hong Kong, food truck is positioned as a tourism initiative with 4.1.3 a view to enriching the variety of culinary delicacies available to tourists and local people. The Commerce and Economic Development Bureau has been, in collaboration with the Food and Health Bureau, the Food and Environmental Hygiene Department, the Transport Department and other relevant departments, devising the policy and practice for the Food Truck Pilot Scheme ("Pilot Scheme") including matters relating to vehicle specifications and requirements, licensing requirements, mode of operation, food safety and environmental hygiene. Under the Pilot Scheme, there will be eight designated venues/locations for food truck operation. operation venue/location will provide two parking spaces. Therefore, there will be 16 food trucks altogether operating at the eight locations on a Apart from the eight designated venues/locations, the rotation basis. Administration will line up food trucks to provide services at designated large-scale tourism events.
- 4.1.4 The delegation is of the view that Hong Kong should learn from the experience of San Francisco and San Mateo to avoid the food truck proposal being monopolized by large consortia and corporations with strong

finances, putting small operators and young entrepreneurs at a disadvantage. The Administration should consider introducing different types of licenses to allow room for small-scale food truck operations.

- 4.1.5 As Hong Kong is a densely populated city lacking in space for large trucks to park for business, the delegation appreciates the Administration's proposal to set a limit on the number of food trucks operating under the Pilot Scheme at its teething stage and the permitted locations for doing business. Delegation members, however, are of the view that in the long run, the Administration should lift the above restrictions. They do not see a need for an arbitrary upper limit on the number of licensees. The Administration should leave it to the market force to determine the optimal number of food trucks operating in Hong Kong as well as the locations where business activities are conducted.
- 4.1.6 The delegation is impressed by San Francisco's and San Mateo's "business in conjunction with an approved commissary" system, as it can help ensure that the food offered by the food trucks meets the hygiene and safety standards and, in effect, help the food trucks survive. Drawing reference from their experience, the Administration should set strict requirement on the processing and preparation of food sold on food trucks and consider whether the "operation in conjunction with a licensed commissary/back-up kitchen" concept should be adopted in Hong Kong.
- 4.1.7 The delegation understands that food trucks in San Francisco and San Mateo travel to different locations to operate and measures/technologies (such as mobile phone applications) have been adopted to update customers of their trading locations. The delegation considers that the Administration should implement similar trade facilitation measures to foster the development of food trucks in Hong Kong.

Control over imported food products

4.1.8 It is observed that US attaches great importance to safeguarding the safety of imported food products. FDA and CBP work collaboratively in ensuring that only safe food enters the country and a large amount of imported food is examined or inspected every year. The delegation is very

much impressed by the multifaceted approach which FDA employs for safeguarding the safety of imported food. The PREDICT system (a tool for screening all lines of imported product electronically submitted to FDA via CBP's interface) is particularly useful, as complete and accurate data transmitted allows FDA to more efficiently and effectively make admissibility decisions by holding higher risk products for review and examination while allowing lower risk products to enter domestic commerce without FDA's further review.

- 4.1.9 The delegation notes that FDA advocates for stronger food safety systems globally including, among others, through fostering international partnership and cooperation with counterpart foreign government agencies and international organizations to share inspection reports and certain kinds of non-public information that can help make better decisions about the safety of imported products.
- 4.1.10 Delegation members consider that the experience of US in import control would provide very useful reference to Hong Kong. The multifaceted approach has facilitated early and appropriate decisions to be taken on the release or withholding of a shipment, and early actions on suspension or detention of similar imports as necessary in future.

Regulation of nutrition and health claims on formula products

4.1.11 The delegation notes that FDA does not define "toddler formula" which is commonly understood to mean products for young children over 12 months of age and hence its regulation on nutrition and health claims on formula products does not cover such products. Besides, certain nutrient content claims and health claims are permitted on their infant formulae. While there are controversies in Hong Kong over the Administration's proposed regulatory framework on nutrition and health claims on formula products and IYC foods, some delegation members are of the view that in finalizing its proposed framework governing nutrition and health claims on formula products, the Administration should keep it on par with prevailing international standards and balance the views received from various stakeholders.

4.2 Conclusions

4.2.1 The delegation considers the duty visit to San Francisco fruitful and enlightening. Through on-site visits and discussions with relevant government officials/organization representatives, delegation members have obtained a deeper understanding of the operations of food truck in San Francisco and San Mateo. This will facilitate their future discussion with the Administration on the Pilot Scheme. In addition, delegation members know more about the regulatory control of imported food products in US during this visit.

Acknowledgements

The delegation wishes to thank all the distinguished individuals, including the officials of San Francisco Planning Department, San Francisco Department of Public Works, San Francisco Department of Public Health, San Mateo Environmental Health Services Division, US Food and Drug Administration and US Customs and Border Protection, Mr Matt Cohen of Off the Grid as well as the representatives from Infant Nutrition Council of America with whom they met during the visit. The delegation is most grateful to them for their detailed briefings and the useful exchanges of views and information with delegation members.

The delegation is also grateful to US Consulate General in the Hong Kong Special Administrative Region and the Hong Kong Economic and Trade Office in San Francisco. The former has rendered great assistance in putting together the visit programme and the latter in logistics arrangements. Last but not least, the delegation expresses sincere thanks to staff of the Legislative Council Secretariat for their dedicated support and hard work.

ACRONYMS AND ABBREVIATIONS

CBP Customs and Border Protection

CFR Code of Federal Regulations

FDA Food and Drug Administration

FFD&CA Federal Food, Drug, and Cosmetic Act

FSIS Food Safety and Inspection Service

FSVP Foreign Supplier Verification Programme

cGMPs Current Good Manufacturing Practices

HCD Department of Housing and Community Development

INCA Infant Nutrition Council of America

IYC foods Pre-packaged foods for infants and young children

under the age of 36 months

MFF Mobile Food Facility

MFF Program Mobile Food Facility Program

the Panel Panel on Food Safety and Environmental Hygiene

Pilot Scheme Food Truck Pilot Scheme

PREDICT Predictive Risk-based Evaluation for Dynamic Import

Compliance Targeting

US the United States

USDA United States Department of Agriculture

VQIP Voluntary Qualified Importer Programme

APPENDICES

Appendix I: Visit programme

8 March 2016 (Tuesday)	Arrive at San Francisco	
	Meeting with officials of Environmental Health Services Division, San Mateo County Health Services	
	Visit to mobile food truck vendors	
9 March 2016 (Wednesday)	Meeting with Mr Matt Cohen, Founder of "Off the Grid Services"	
	Meeting with officials of San Francisco Planning Department, San Francisco Department of Public Works and San Francisco Department of Public Health	
	Visit to food truck "Hongry Kong"	
10 March 2016 (Thursday)	Meeting with officials of the US Food and Drug Administration, US Department of Agriculture and the US Customs and Border Protection	
	Meeting with representatives of the Infant Nutrition Council of America	
11 March 2016	Visit to SoMa StrEat Food Park	
(Friday)	Visit to the Hong Kong Economic and Trade Office in San Francisco	
	Depart for Hong Kong	
13 March 2016 (Sunday)	Arrive at Hong Kong	

Appendix II: List of organizations and persons met by the delegation

9 March 2016 (Wednesday)

Environmental Health Services Division, San Mateo County Health System

Mr Sheldon M. Lew, Food and Pool Program Supervisor

Ms Kameisha Nichols, Food and Pool Program Supervisor

Ms Ngai Wong, Environmental Health Specialist

Ms Joanne Jarin, Specialist, Mobile Food Program

Off the Grid Services

Mr Matt Cohen, Founder

San Francisco Department of Public Works

Mr Rahul Shah

San Francisco Department of Public Health

Mr Robert DeMarr, Environmental Health Inspector

San Francisco Planning Department

Mr Daniel A. Sider, Senior Advisor for Special Projects

10 March 2016 (Thursday)

US Customs and Border Protection

Ms Therese M. Randazzo, CBP Attaché

Mr Dickins Chun, Chief Inspector

US Food & Drug Administration, San Francisco District

Ms Cynthia L. Ford, Supervisory Investigator

US Department of Agriculture

Ms M Melinda Meador, Director of Agriculture Trade Office

APPENDICES

Hong Kong Economic & Trade Office in San Francisco

Ms Subrina CHOW, Director Mr C.T. WONG, Deputy Director

11 March 2016 (Friday)

Infant Nutrition Council of America

Mr James D. Richards, Associate Director, Global Regulatory and Nutrition Science

Mr Jason Grove, Senior Director, Global Government Affairs

Mr Clarence Chung, Head of Strategic Planning and Market Research, Greater China Region

Ms May Chung, Country Business Manager

REFERENCES

Materials/Publications

	Provided by	Materials/Publications
1.	San Mateo County Environment Health Services	Powerpoint materials on "Mobile Food Facilities Program"
2.	San Mateo County Environment Health Services	California Retail Food Code (excerpt from the California Health and Safety Code)
3.	US Food and Drug Administration	Powerpoint materials on the overview and works of US Food and Drug Administration
4.	US Customs and Border Protection	Powerpoint materials on "Agriculture Cargo Inspections at Oakland Maritime"
5.	Infant Nutrition Council of America	Powerpoint materials on overview of INCA, regulations relating to infant formula products and infant formula labeling requirements
6.	Research Office Information Services Division Legislative Council Secretariat	Fact sheet entitled "Food truck operations in San Francisco" (FSC13/15-16)
7.	Research Office Information Services Division Legislative Council Secretariat	Fact sheet entitled "Regulation of imported food in Hong Kong" (FSC14/15-16)

REFERENCES

	Provided by	Materials/Publications
8.	Research Office Information Services Division Legislative Council Secretariat	Fact sheet entitled "Regulation of imported food by the US Food and Drug Administration" (FSC15/15-16)

Websites

	Departments	Website
1.	Tourism Commission Commerce and Economic Development Bureau, the Government of the Hong Kong Special Administrative Region	http://www.tourism.gov.hk
2.	San Mateo County Health Services	http://smchealth.org/
3.	Off the Grid Services	http://offthegrid.com/about-3
4.	San Francisco Planning Department	http://sf-planning.org/
5.	San Francisco Department of Public Works	http://sfdpw.org/
6.	San Francisco Department of Public Health	http://www6.sfgov.org/index.aspx?page =135
7.	US Food and Drug Administration	http://www.fda.gov/
8.	US Customs and Border Protection	http://www.cbp.gov/

REFERENCES

Ī		Departments	Website
	9.	The Infant Nutrition Council of America	http://www.infantnutritioncouncil.com/
	10.	Hong Kong Economic and Trade Office in San Francisco	http://www.hketosf.gov.hk/sf/index.htm