



1. Introduction

1.1 The Subcommittee on Issues Relating to Animal Welfare and Cruelty to Animals will discuss the safety of pet food products at its meeting to be held on 25 April 2016. To facilitate Members' deliberation on the subject matter, this information note studies the regulatory regimes established by the European Union ("EU"), the United States ("US"), Japan and Singapore governing the safety of pet food products sold in their respective markets.

2. Overview of regulatory regimes in Hong Kong and overseas places studied

2.1 Unlike the overseas places studied, Hong Kong has no dedicated legislation regulating the safety of pet food products sold in the territory.¹ This is notwithstanding the surge in the number of dogs and cats kept as pets² and the ensuing increased demand for pet food products over the years. Currently, pet food products are regulated by general legislation, e.g. the Trade Descriptions Ordinance (Cap. 362) which prohibits any person from applying false or misleading trade descriptions, including descriptions as to composition and place of origin, to goods in the course of trade or business.

2.2 In contrast to Hong Kong, the EU and Japan have enacted specific laws on pet food, and the US has put in place a single regulatory regime governing food for both human and animal consumption. Singapore, though with a relatively smaller pet food market, has implemented specific regulatory measures to safeguard pet food safety. The respective regulatory

¹ According to the Government, pre-packaged pet food products sold in Hong Kong were mainly imported from the US, the EU member states, Canada, Thailand and the Mainland.

² According to the latest available figures from the Census and Statistics Department, the number of dogs and cats kept as pets surged from 297 100 in 2005 to 415 100 in 2010.

frameworks of the above overseas places are detailed in the following paragraphs, and their salient features are compared in the **Appendix**.

3. Regulatory regime in the European Union

3.1 In 2014, about 135 million dogs and cats were kept as pets in the EU and the annual sales of pet food products (including those for dogs and cats) amounted to about 9 million tonnes.³ The regulation of pet food products is covered under the EU's regulatory regime for animal feed, which aims at ensuring that feedstuffs do not present any danger to human or animal health, or to the environment.

3.2 Under the EU's regulatory regime for animal feed, pet food business operators engaging in the production, processing, storage and distribution of pet food products must register with the competent authority. They are also required to apply for approval when producing compound feedstuffs containing additives.

3.3 In addition, pet food business operators are subject to a set of hygiene and quality control requirements with regard to facilities and equipment, personnel, production, hazard analysis and control, storage and transport, record-keeping, complaint handling and product recall. There are also other requirements such as: (a) using only additives that are included in the EU Register of authorized feed additives for pet food production;⁴ (b) meeting the standards on allowable limits for specified undesirable substances in animal feed; and (c) complying with the product labelling requirements.

3.4 On imported pet food products, the EU has implemented stringent import control measures for products containing an animal origin ingredient since they may pose a risk of spreading animal diseases. These measures include: (a) requiring importers to source products from approved establishments in the country of origin, make consignment notification, and accompany the consignment by a veterinary certificate; and (b) conducting inspections at the port of entry.

³ See European Pet Food Industry Federation (2016).

⁴ Feed additives may not be put on the EU market unless authorization has been given following a scientific evaluation demonstrating that the additives concerned have no harmful effects on human and animal health, and on the environment.

3.5 In the EU, enforcement of the relevant legislation governing animal feed is vested in the individual member states. During 2013 and 2014, 75 notifications of serious health risks detected in pet food products were recorded by the EU's Rapid Alert System for Food and Feed ("RASFF"). RASFF functions as a network connecting food and feed competent authorities in the EU in the exchange of information about measures undertaken in response to serious risks detected in relation to food and feed.⁵

4. Regulatory regime in the United States

4.1 In 2013, the total number of dogs and cats kept as pets was estimated at 145 million in the US and the annual sales of dog and cat pet food products totalled some 8.3 million tonnes.⁶ The United States Food and Drug Administration ("FDA") is responsible for regulating animal feed (including pet food) under the same federal regulatory regime governing human food. Similar to food intended for human consumption, FDA requires pet food to be safe to eat, produced under sanitary conditions and properly labelled. At the state level, many states have also implemented their own animal feed regulatory programmes governing, among other things, licensing of manufacturers and labelling of pet food products under the respective state laws and rules.⁷

4.2 Under the federal regulatory regime, all domestic and foreign business operators that manufacture, process, pack or hold food for human or animal consumption in the US are required to register with FDA. FDA also requires that only additives that are "generally recognized as safe"⁸, pre-approved by FDA or defined by the Association of American Feed Control Officials ("AAFCO")⁹ for its intended use can be used in the production of pet

⁵ The various types of notifications made under the system include: (a) alert notifications that require rapid action; (b) border rejection notifications; and (c) information notifications. See European Commission (2014b & 2015).

⁶ See Pet Food Institute (2016).

⁷ FDA regulates animal feed products that are involved in interstate commerce, including imported products. State governments regulate animal feed products that are distributed within their jurisdiction.

⁸ A food additive may be established as "generally recognized as safe" if the substance is generally available and there is a consensus among qualified experts about the safety of the substance for its intended use.

⁹ AAFCO, a non-government advisory body comprising officials of the responsible local, state and federal regulatory agencies, develops model laws and regulations for the manufacture, distribution and sale of animal feed and ingredients.

food.¹⁰ In addition, FDA also establishes the action levels for poisonous or deleterious substances in human food and animal feed. Action levels represent limits at or above which FDA will take legal action to remove the affected products from the market.

4.3 FDA and many state governments have also imposed labelling requirements on pet food products to ensure safe and effective use of the products. While the federal regulations address basic labelling requirements such as proper identification of the product and listing of the ingredients, the state regulations may cover nutritional and usage aspects of the products such as guaranteed analysis¹¹ and feeding directions.¹²

4.4 As to import control arrangements, FDA requires importers of human and animal food (including pet food products) to submit prior notification of their shipments for the subsequent screening of the shipments and targeted inspection of higher risk products at the port of entry. Besides, importers of pet food products containing specified animal origin ingredients may be required to apply for a permit from the United States Department of Agriculture.

4.5 FDA is empowered to conduct inspections of the facilities of registered pet food business operators and suspend their registration if the pet food products produced or handled pose a threat of serious health consequences. FDA may also detain or request a recall of domestic/imported pet food products that pose health risks. In the 2014 and 2015 fiscal years, FDA issued about 219 warning letters to registered business operators that had violated relevant animal products regulations, and recorded 99 recall events¹³ involving 431 animal products including pet food products.¹⁴

¹⁰ Additives defined by AAFCO to be appropriate for use in animal feed are un-approved additives. However, the use of these additives will not be subject to any government regulatory action as long as the labelling is consistent with the accepted intended use and safety of using the additives is not challenged by new data.

¹¹ A guaranteed analysis lists the percentage of each of the nutrients in a pet food product. Many states in the US require pet food products to guarantee the minimum percentages of crude protein and crude fat, and the maximum percentages of crude fibre and moisture.

¹² The state labelling regulations are developed based on the model regulations developed by AAFCO to ensure uniformity across states.

¹³ According to FDA, product recalls are voluntary in most cases when the business operator discovers a product issue on its own or after FDA has raised concerns about the product.

¹⁴ See United States Food and Drug Administration (2016a).

4.6 To better protect public health and prevent foodborne illness, the federal government reformed the food safety system for both human and animal food in 2011. The FDA Food Safety Modernization Act, which was passed in January 2011, sets out reform measures including (a) requiring pet food business operators to implement a food safety system and a specified set of manufacturing standards i.e. the Current Good Manufacturing Practices for animal food¹⁵ to strengthen the preventive control of hazards, and (b) enhancing the safety of imported ingredients and products through the Foreign Supplier Verification Programme.¹⁶

5. Regulatory regime in Japan

5.1 In Japan, the total number of dogs and cats kept as pets amounted to about 19.8 million in 2015. The annual sales of pet food products was estimated at 597 000 tonnes in 2014.¹⁷ The Japanese government planned for creating a dedicated regulatory regime for pet food products in 2007, amid growing concern over pet food safety consequential to several recall exercises in the US and Japan.¹⁸ Subsequently, the Law for Ensuring the Safety of Pet Food was enacted in 2008 and came into force in 2009, governing the safety of locally produced and imported dog and cat pet food.

5.2 According to the Law for Ensuring the Safety of Pet Food, manufacturers and importers of dog and cat pet food products are required to notify the Ministry of Agriculture, Forestry and Fisheries ("MAFF") and the Ministry of the Environment ("MOE") of the names of their representatives and of the names and addresses of their plants and warehouses, before they start the business. The law also requires manufacturers, importers and distributors of pet food products to keep production and/or sales records of the products manufactured, imported or distributed by them.

¹⁵ The set of standards covers various aspects of animal food manufacturing including personnel, plant and grounds, sanitation, water supply and plumbing, equipment and utensils, plant operations, and holding and distribution.

¹⁶ Under the Foreign Supplier Verification Programme, importers are required to ensure imported ingredients or food products are produced in compliance with the US laws and regulations. They are required to conduct risk-based verification activities such as engaging qualified auditors to conduct on-site auditing of foreign suppliers, and conducting sample tests on products.

¹⁷ See Japan Pet Food Association (2016).

¹⁸ The US has been one of the major countries of origin of imported pet food products sold in Japan. Early in 2007, approximately 2 200 dog and 1 950 cats in the US developed kidney failures and died after eating pet food contaminated with melamine and related compounds, and more than 150 brands of pet food products were voluntary recalled by a number of companies. In June 2007, a dog food product, identical to the one which was subject to a recall in the US, was found to have been imported into Japan and was then subject to a voluntary recall. See Sugiura, K. et al. (2009).

5.3 In addition, all pet food business operators involved in the manufacture, import and sale of dog and cat pet food products are obliged to observe the standards established by MAFF and MOE on (a) the production methods to prevent contamination with microbes and harmful substances; (b) maximum limits of harmful substances in products such as certain additives, pesticides and heavy metals; and (c) product labelling.¹⁹ MAFF further imposes import control requirements for specified products with animal origin ingredients. Consignments of such products are required to be accompanied by a health certificate from the veterinary administration of the exporting country.

5.4 With regard to their enforcement work, MAFF and MOE are empowered to request pet food business operators to submit reports about their operations. These two Ministries or the Food and Agricultural Materials Inspection Center ("FAMIC")²⁰ may also conduct on-site inspection of the business operators' facilities, and FAMIC may conduct sample tests on pet food products as well. Apart from on-site inspection, MAFF and MOE may order the business operators to recall, and prohibit the import and/or sale of pet food products that fail to meet the prescribed standards. Any persons violating the specified legislative provisions may be subject to a fine and/or imprisonment. According to FAMIC, a total of 289 on-site inspections were conducted between 2014 and 2015, and no non-compliance case was observed.²¹

6. Regulatory regime in Singapore

6.1 In contrast with other overseas places studied, Singapore has a much smaller pet population and pet food market. The number of dogs and cats kept as pets was estimated to be 156 000 in 2010. The annual sales of dog and cat pet food products amounted to 8 730 tonnes in 2012.²² Nonetheless, the Singapore government has established the Agri-Food and Veterinary Authority ("AVA") as the responsible regulatory authority of human and animal

¹⁹ In addition to the mandatory labelling requirements, the pet food trade in Japan has also implemented a voluntary labelling code specifying additional labelling requirements.

²⁰ FAMIC is an incorporated administrative agency responsible for, among others, ensuring the quality and safety of animal feed, feed additives, fertilizers and agricultural chemicals by conducting on-site inspections of business operators' facilities, and sample testing of the materials and products.

²¹ See Food and Agricultural Materials Inspection Center (2016).

²² See Agriculture and Agri-Food Canada (2013).

food in Singapore. Specifically, AVA administers a licensing scheme for local manufacturers and importers of animal feed and imposes control on imported pet food products.

6.2 According to its Feeding Stuffs Act, all business operators engaging in the manufacture, processing, import and/or sale of pet food products in Singapore are required to apply for a licence from AVA. The licensing conditions include: (a) ensuring that the pet food products are wholesome and safe for feeding and do not contain specified prohibited substances such as certain drugs and additives; (b) registering each type of manufactured or imported product with AVA;²³ (c) keeping the business premises clean and tidy; (d) complying with the product labelling requirements; and (e) keeping relevant product records.

6.3 With regard to import control arrangements, AVA requires all importers to apply for an import permit for each consignment of imported pet food products. Consignments of pet food products with meat or meat products are subject to additional requirements. For example, all the shipments must be accompanied by a health certificate from the veterinary administration of the exporting country certifying that, among others, the exporting country is free from specified diseases such as Bovine Spongiform Encephalopathy. In addition, prior approval in respect of the manufacturing plant is required if the products are imported from countries other than Australia, New Zealand, Canada, the United Kingdom and the US.

6.4 Pet food business operators which violate the specified legislative provisions, such as selling pet food products that contain harmful ingredient for animals, may be subject to a fine and/or imprisonment. AVA may suspend or revoke the licence of a business operator without prior notice.

7. Conclusion

7.1 All the overseas places studied have introduced multi-pronged measures to safeguard the safety of locally produced and imported pet food products under their respective regulatory regimes. Regulatory measures commonly adopted by them include: (a) implementing a registration/licensing

²³ The licensee has to submit information such as the manufacturer and manufacturing process, quality control tests, ingredients used and guaranteed analysis of the pet food products for registration.

scheme for business operators involved in the manufacture, processing, import and/or sale of pet food products; (b) prescribing standards on allowable limits for specified harmful substances or prohibiting the presence of certain harmful substances in pet food products; (c) mandating product labelling requirements; and (d) imposing control on imported pet food products, particularly for products with animal origin ingredients or meat products.

7.2 With a relatively larger pet food market than Singapore, the EU, the US and Japan have further set out a set of hygiene and hazard control standards for pet food production. The EU and the US have also regulated additives to be used in pet food production by implementing a pre-approval mechanism under their regulatory regimes.

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Regulatory regime governing pet food in selected overseas places

	The European Union	The United States	Japan	Singapore
Background				
Number of dogs and cats kept as pets	• 135 million (2014).	• 145 million (2013).	• 19.8 million (2015).	• 156 000 (2010).
Annual sales of pet food products	• 9 million tonnes in 2014.	• 8.3 million tonnes (for dog and cat pet food) in 2013.	• 597 000 tonnes in 2014.	• 8 730 tonnes (for dog and cat pet food) in 2012.
Overview of regulatory regime				
Major regulatory authorities	• Responsible authorities of individual European Union ("EU") member states.	• United States Food and Drug Administration ("FDA"); United States Department of Agriculture ("USDA"); and relevant state authorities.	• Ministry of Agriculture, Forestry and Fisheries ("MAFF"); and Ministry of the Environment ("MOE").	• Agri-Food and Veterinary Authority ("AVA").
Relevant legislation	• Relevant EU regulations including those governing feed hygiene, marketing and use of feed products, and additives for use in animal nutrition.	• Federal Food, Drug, and Cosmetic Act; and relevant state laws and rules.	• Law for Ensuring the Safety of Pet Food.	• Feeding Stuffs Act and related subsidiary legislation.

Regulatory regime governing pet food in selected overseas places

	The European Union	The United States	Japan	Singapore
Regulatory measures				
Registration/licensing of pet food business operators	<ul style="list-style-type: none"> Pet food business operators are required to register with the competent authority, and those producing compound feedstuffs containing additives are required to apply for approval. 	<ul style="list-style-type: none"> All domestic and foreign business operators that manufacture, process, pack or hold pet food for consumption in the US are required to register with FDA. 	<ul style="list-style-type: none"> Pet food manufacturers and importers are required to notify MAFF and MOE of the names of their representatives and of the names and addresses of their plants and warehouses before starting their business. 	<ul style="list-style-type: none"> Pet food business operators are required to apply for a licence from AVA.
Specification of hygiene and hazard control standards	<ul style="list-style-type: none"> Pet food business operators are obliged to comply with a set of hygiene and quality control requirements. 	<ul style="list-style-type: none"> Pet food business operators are required to implement a food safety system and a specified set of manufacturing standards for animal food. 	<ul style="list-style-type: none"> Pet food business operators are required to comply with the prescribed standards on pet food production. 	<ul style="list-style-type: none"> No specific standards are required. However, licensees are required to keep their business premises clean and tidy.
Pre-approval of additives used in pet food production	<ul style="list-style-type: none"> Only authorized additives may be used. 	<ul style="list-style-type: none"> Only additives that are "generally recognized as safe", pre-approved by FDA or defined by the Association of American Feed Control Officials for its intended use can be used. 	<ul style="list-style-type: none"> No pre-approval requirement is imposed. But business operators have to ensure that the products do not contain certain additives at levels exceeding the allowable limits. 	<ul style="list-style-type: none"> No pre-approval requirement is imposed.

Regulatory regime governing pet food in selected overseas places

	The European Union	The United States	Japan	Singapore
Regulatory measures (cont'd)				
Specification of standards regarding undesirable substances in pet food products	<ul style="list-style-type: none"> Standards on allowable limits are set for specified undesirable substances. 	<ul style="list-style-type: none"> Action levels, representing limits at or above which FDA will take legal action to remove the affected products from the market, are set for specified harmful substances. 	<ul style="list-style-type: none"> Standards on allowable limits are set for specified harmful substances. 	<ul style="list-style-type: none"> Licensees are required to ensure that pet food products sold do not contain specified prohibited substances.
Labelling of pet food products	<ul style="list-style-type: none"> Mandatory labelling requirements include: <ol style="list-style-type: none"> product description; animal species that the product are intended for; name and address of pet food business operator; list of feed materials; list of additives (if certain categories of additives are used); analytical constituents; minimum storage life; and instructions for proper use. 	<ul style="list-style-type: none"> Labelling requirements imposed by FDA include: <ol style="list-style-type: none"> proper identification of the product; net weight of the product; manufacturer's name and address; and list of ingredients. Additional labelling requirements at the state level may include: <ol style="list-style-type: none"> guaranteed analysis; nutritional adequacy statement; calorie statement; and feeding directions. 	<ul style="list-style-type: none"> Dog and cat pet food products are required to be labelled with information on: <ol style="list-style-type: none"> name of product; best-before date; name and address of manufacturer, importer or distributor; country of origin; and ingredients. The pet food trade has also implemented a voluntary product labelling code. 	<ul style="list-style-type: none"> All pet food products are required to be labelled with information on: <ol style="list-style-type: none"> manufacturing and expiry date; name and address of importer; ingredients; and animal species that the product are intended for. Additional information requirements are set for products with meat or meat products such as: <ol style="list-style-type: none"> name and address of manufacturer; and guaranteed analysis.

Regulatory regime governing pet food in selected overseas places

	The European Union	The United States	Japan	Singapore
Regulatory measures (cont'd)				
Import control mechanisms	<ul style="list-style-type: none"> Imported pet food products containing animal origin ingredients are subject to import control requirements such as making consignment notification and accompanying the consignment by a veterinary certificate. 	<ul style="list-style-type: none"> FDA requires importers of pet food products to submit prior notification of their shipments. It also conducts inspections on higher risk products at the port of entry. Importers of pet food products containing specified animal origin ingredients may be required to apply for a permit from USDA. 	<ul style="list-style-type: none"> Importers are required to ensure that the imported products meet the prescribed pet food standards. Consignments of specified pet food products with animal origin ingredients are required to be accompanied by a health certificate. 	<ul style="list-style-type: none"> Importers are required to: <ol style="list-style-type: none"> apply for an import permit for each consignment of products; accompany each consignment of products containing meat or meat products by a health certificate; and seek prior approval in respect of the manufacturing plant for products containing meat or meat products imported from certain places.

Regulatory regime governing pet food in selected overseas places

	The European Union	The United States	Japan	Singapore
Enforcement				
Enforcement of the relevant legislation	<ul style="list-style-type: none"> Enforcement is vested in individual member states. 	<ul style="list-style-type: none"> FDA may conduct inspections of registered pet food business operators' facilities, and may suspend their registration if the products produced or handled pose a threat of serious health consequences. FDA may detain or request a recall of pet food products that pose health risks. 	<ul style="list-style-type: none"> MAFF, MOE and the Food and Agriculture Materials Inspection Center ("FAMIC") are entrusted with conducting on-site inspection of pet food business operators' facilities. MAFF and MOE may request pet food business operators to submit reports about their operations while FAMIC may conduct sample tests on pet food products. MAFF and MOE may also order the recall of, and prohibit the manufacture and sale of products that fail to meet the prescribed pet food standards. Any person who violates the specified legislative provisions may be subject to a fine and/or imprisonment. 	<ul style="list-style-type: none"> Pet food business operators failing to comply with the specified legislative provisions may be subject to a fine and/or imprisonment.

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