

Vietnam's current Decree 38/2012 of the Government guiding the implementation of the Law of Food Safety. Should Vietnam enact a new Decree, Post will issue a new FAIRS Narrative and Export Certificate Report incorporating any regulatory changes.

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Abbreviated terms for easy reference:

- MOH (Ministry of Health, Vietnam)
- VFA (Vietnam Food Administration, MOH)
- MARD (Ministry of Agriculture and Rural Development, Vietnam)
- DAH (Department of Animal Health, MARD)
- PPD (Plant Protection Department, MARD)
- DLP (Department of Livestock Production, MARD)
- NAFIQAD (National Agro-Forestry-Fishery Quality Assurance Department, MARD)
- NOIP (National Office of Intellectual Property of Vietnam, MOST)
- CFS (Certificate of Free Sale)
- FBOs (Food Business Operators)
- GDC (General Department of Customs)
- MOST (Ministry of Science and Technology)
- MOIT (Ministry of Industry and Trade)
- DOF (Directorate of Fisheries, MARD)
- FSL (Law on Food Safety)
- GOV (Government of Vietnam)
- WTO (World Trade Organization)

Section I: General Food Laws

Vietnam's National Assembly promulgated the Law on Food Safety 55/2010/QH12 on June 17, 2010 and which entered into force on July 1, 2011. The Law on Food Safety (FSL) provides organizations and individuals with rights and responsibilities to ensure food safety; conditions for food safety; food production and trading; food import and export; food advertisement and labeling; food testing; food risk analysis; prevention and dealing with food safety incidents; information, education, and communication on food safety; and state management of food safety.

According to the FSL, all imported food, food additives, substances used in food processing, and tools and materials used for packing and containing imported food shall be subject to state inspection for food safety, except in cases where the state inspection of food safety is exempt, in accordance with governmental provisions. Imported food is only granted customs clearance once inspection results show that the products in question meet import requirements. The Food Safety Law outlines three categories of food inspection: 1) Strict Inspection; 2) Ordinary Inspection; and 3) Simplified Inspection. Depending on the type of product, MOH, the Ministry of Agriculture and Rural Development (MARD), or the Ministry of Industry and Trade (MOIT) are responsible for the development of specific guidelines on food safety inspection.

Pursuant to the FSL, the Government of Vietnam (GVN) promulgated Decree 38/2012/ND-CP, dated April 25, 2012 detailing implementation of a number of articles of the Law on Food Safety. Decree 38 provides guidance to MARD, MOIT, and MOH on implementing provisions of the FSL, including: 1) Declaration of conformity to technical regulations or food safety Regulations; 2) Safety requirements for genetically engineered foods; 3) Granting, and withdrawing food safety certificates for establishments that meet food safety requirements; 4) State inspection on food safety for imported and exported foods; 5) Labeling of food products; and 6) the Delegation of responsibilities for the state management of food safety to the relevant Ministries including MOH, MARD, and MOIT. Please refer to GAIN report VM3032 for more information.

On March 3, 2017, MOH's Vietnam Food Administration (VFA) notified the amendment of Decree 38/2012 to the World Trade Organization (WTO) as G/SPS/N/VNM/88, which allowed for the exemption of food safety inspections and declarations of conformity for technical regulations for food ingredients imported for processing exports. At that time, Decree 38/2012 included only these changes and was expected to be released in April. However, on November 23, 2017, VFA published a new Decree that would replace Decree 38 in an attempt to streamline and clarify a number of roles and responsibilities of Vietnam's ministries in relation to food import regulations. The GVN has yet to finalize the amendment of Decree 38 (as of December 2017). FAS-Hanoi will continue to follow this issue, report on any developments, and issue a new FAIRS Narrative and Export Certificate report (if warranted).

In order to specify the responsibilities on food safety management among MOH, MARD and MOIT; the GVN issued Inter-Ministerial Circular 13/2014/TTLB-BYT-BNNPTNT-BCT on April 9, 2014

regarding guidelines for assignments and coordination of state management of food safety. This Circular entered into force on May 26, 2014. Importantly, Circular 13 provides the detailed lists of food products under MOH, MARD, and MOIT management in Appendix 1, 2, and 3, respectively, clarifies which Vietnamese Ministry is responsible for what set of food products, and applies to both domestically produced foods and imported food products.

The major distinction worth noting in Circular 13 is that any addition of a nutrient, mineral, or additive is enough for the GVN to consider the product a functional food and, as a result, for the food safety responsibility to shift from MARD and MOIT to MOH. For example, a fruit juice product is normally under the food safety jurisdiction of MOIT. However, if the fruit juice has an added vitamin and/or mineral ingredient, jurisdiction then shifts to MOH. The Circular specifies VFA; MARD's National Agro-Forestry and Fishery Quality Assurance Department (NAFIQAD); and MOIT's Science and Technology Department (STD) as the key government agencies responsible for the Circular's implementation. Please refer to GAIN report <u>VM4029</u> for more information.

In order to handle administrative violations in food production and trade, food import and export; the GVN issued Decree 178/2013/ND-CP, dated November 14, 2013. Depending on the nature of violations, a range of administrative fines and additional sanctions shall apply such as: withdrawal of Certificates of Establishment satisfying the Conditions for Food Safety; enforcement of a recall of imported products which are subject to mandatory inspection at border checkpoints but not examined by inspection bodies; and enforcement of re-export, destruction or changing the purpose of use of an imported irradiated food, functional food, or genetically engineered food which are not accompanied by a Certificate of Free Sale or Health Certificate. Please refer to GAIN report VM4030 for more information.

In addition, under Article 317 of the new Penal Code 100/2015/QH13 which will take effect from January 1, 2018, a certain number of violations, such as using banned substances in the manufacture, preparation, processing, preservation of food; or processing, providing, or selling food with the knowledge that it does not comply with technical or food safety regulations, will be considered a criminal offense. As a result, as of December 2017, MOH/VFA published a draft Decree which would replace Decree 178/2013 (link: http://www.vfa.gov.vn/du-thao-gop-y/nghi-dinh-quy-dinh-xu-phat-vi-pham-hanh-chinh-ve-an-toan-thuc-pham-du-thao-6.html). This draft currently imposes more severe penalties and additional sanctions for violations in food production and trade. FAS-Hanoi will continue to monitor this development and will publish a GAIN report if the GVN does approve and issue this new Decree.

Section II: Food Additives Regulations

MOH issued Circular 27/2012/TT-BYT titled the Guidance on the Management of Food Additives, dated November 30, 2012, to formalize food additive regulations contained in the FSL. Circular 27/2012 took effect on February 1, 2013.

On May 11, 2015, MOH issued Circular 8/2015/TT-BYT to amend and supplement food additive managing provisions regulated in Circular 27/2012/TT-BYT. Accordingly, seven new food additives have been added to the List of food additives allowed for use in Vietnam. The Appendix amending and supplementing the maximum levels of some food additives allowed in food which are specified in Appendix 2 of Circular 27/2012/TT-BYT is included in this Circular. Circular 8/2015/TT-BYT entered into force on July 1, 2015. Please refer to GAIN report VM5044 for more information.

In order to consolidate the amended provisions, MOH issued the Consolidation of Circulars on the Management of Food Additives 2/VBHN-BYT dated June 15, 2015. The Consolidation 2/ VBHN-BYT provides the full list of additives approved for use in Appendix 1 and their maximum use levels in food in Appendix 2. The Vietnamese version of this Consolidation is available at: https://thuvienphapluat.vn/van-ban/The-thao-Y-te/Van-ban-hop-nhat-02-VBHN-BYT-2015-hop-nhat-Thong-tu-huong-dan-viec-quan-ly-phu-gia-thuc-pham-280909.aspx

The list of Harmonized Schedule (HS) Codes for food additives and food processing aids was promulgated in conjunction with Circular 40/2016/TT-BYT dated November 4, 2016. The list is available at: <u>http://vasep.com.vn/Thu-Vien-Van-Ban/1132_46104/Thong-tu-so-402016TT-BYT-Danh-muc-thuc-pham-phu-gia-thuc-pham-chat-ho-tro-che-bien-thuc-pham-va-dung-cu-vat-lieu-bao-goi-chua-dung-thuc-pham-theo-ma-so-HS.htm</u>.

In September 2017, MOH/VFA has published a draft Circular on their website replacing Circular 27/2012 on food additives management and are inviting public comments <u>http://www.vfa.gov.vn/du-thao-gop-y/gop-y-du-thao-thong-tu-quy-dinh-ve-su-dung-va-quan-ly-phu-gia-thuc-</u>

<u>pham.html</u> (Vietnamese only). However, as of December 2017, MOH/VFA has not yet notified the WTO regarding this amendment. FAS-Hanoi will continue to follow this issue and report on any developments.

Section III: Pesticides and Other Contaminants

On May 15, 2014. MOH notified the World Trade Organization (WTO) of G/SPS/N/VNM/55, an amendment of MRLs in food, and finally issued Circular 50/2016/TT-BYT providing MRLs for pesticides in food on December 30, 2016 (<u>VM7026</u>). This Circular took effect from July 1, 2017, completely replacing Section 8 of MOH's Decision 46/2007/QD-BYT, dated December 19, 2007 regarding pesticides MRLs in food.

As stipulated in this Circular, the GVN has updated and supplemented MRLs for two hundred and five (205) compounds for a wide range of foods, including: fruits, vegetables, cereals, nuts, coffee, tea, and products, meat, fat, skin, and offal, eggs, milk & dairy products, dried food vegetable oils, and spices. MRLs for certain compounds (e.g., endosulfan, endrin, lindane), whose use has currently been banned by MARD (Circular 3/2016/TT-BNNPTNT), are still maintained in accordance with Codex standards.

Other food tolerance regulations promulgated by MOH include:

• The National Technical Regulation QCVN 8-1:2011 promulgating the tolerance of mycotoxin contamination in food. This regulation sets up the maximum limits of aflatoxin, ochratoxin A, and other mycotoxins in many types of food, for example: nuts, corn, rice, raw milk, milk powder, spices, food formula for babies, etc.

• The National Technical Regulation QCVN 8-2:2011 promulgating the tolerance of heavy metal contamination in food. This regulation establishes the safety limits for levels of contamination of arsenic, cadmium, lead, mercury, methyl mercury and zinc allowed in food.

• The National Technical Regulation QCVN 8-3:2012/BYT promulgating the tolerance of microbiological contamination in food. This regulation prescribes the limits of microbiological contamination in food for milk and dairy, eggs, and products from eggs, meat and products from meat, aquaculture products, nutrition products for children aged 0 to 36 months old, bottled natural water, bottled water and instant-use ice, cream, vegetables and fruits, and products from vegetables and fruits.

• MOH's Circular 24/2013/TT-BYT, dated August 14, 2013, promulgating the national technical regulation on the tolerance of veterinary medicine residue in food.

Circular 24/2014 is currently the only regulation in force on MRLs for veterinary drugs as MARD repealed Circular 29/2010/TT-BNNPTNT, dated May 5, 2010, promulgating the maximum limits for certain products of animal origin starting from July 17, 2017. On September 7, 2016, MOH/VFA notified the WTO of G/SPS/N/VNM/82, amending Circular 24/2013. This amendment proposed zero tolerance for a number of compounds in food, including ractopamine, trenbolone, and zeranol. In response, the USG and other countries requested Vietnam not deviate from Codex standards and urged MOH to maintain its current MRLs for ractopamine and other vetererinary drugs. On May 31, 2017, the United States and Vietnam announced a resolution of the veterinary drug MRLs issue in a Joint Statement issued by the U.S. President and the Vietnamese Prime Minister. As of December 2017, the USG continues to monitor this issue and will update developments accordingly.

Regarding the registration of pesticides, due to the Law on Plant Health, MARD's Department of Plant Protection (PPD) is the governing authority for the registration of crop pesticides for use in Vietnam. PPD is also the governing authority for the inspection of pesticide residue in imported food of plant origin and conducts entry port inspections for both food safety and plant quarantine.

Section IV: Packaging and Container Regulations

Pursuant to the FSL and the Law of Standards and Technical Regulations, MOH issued three national technical regulations on food safety and hygiene for packages, containers, and equipment directly in contact with food as follows:

- QCVN 12-1:2011/BYT on food safety and hygiene for synthetic resin packages, containers, and equipment in direct contact with food

- QCVN 12-2:2011/BYT on food safety and hygiene for rubber packages, containers, and equipment in direct contact with food

- QCVN 12-3:2011/BYT on food safety and hygiene for metallic packages, containers, and equipment in direct contact with food

According to the FSL, food packages, containers, and equipment in direct contact with food must register an Announcement on Conformity¹ with Technical Regulations and Food Safety Regulations with MOH before being circulated on the market. Decree 38/2012 and Circular 19/2012/TT-BYT dated November 9, 2012 providing guidelines on the Announcement on Conformity with Technical Regulations and Food Safety Regulations stipulate in detail the registration procedures of the Announcement of Technical Regulation Conformity for food as well as for food packages, containers, and equipment in direct contact with food.

Section V: Labelling Requirements

1. General requirements

Vietnamese law imposes strict requirements on the labelling of goods. On April 14, 2017, the GVN issued Decree 43/2017/ND-CP replacing Decree 89/2009 on goods labelling. Decree 43/2017 provided labelling requirements for all categories of food, beverages, and agricultural inputs circulated in Vietnam, both domestically produced and imported. This Decree went into effect from June 1, 2017 (see GAIN report <u>VM7031</u>).

Previously, the FSL provided specific requirements on the labelling timeline for the use of prepacked food and special provisions for functional food, food additives, irradiated food, and genetically engineered food.

Along with these legal documents, the Joint Circular 34/2014/TTLT-BYT-BNNPTNT-BCT issued by MOH, MOIT, and MARD on October 27, 2014 for Guiding the Goods Label for Various Foods, Food Additives, and Aids for Processing Packaged Foods remains effective. (see GAIN report <u>VM5005</u>).

Accordingly, labels must be in Vietnamese and cover all mandatory contents. Depending on the requirements of each type of food, the contents can be included in a foreign language but must match the Vietnamese description, with their font size no larger than the relevant ones in Vietnamese.

The mandatory labelling contents for food include: i) Name of goods, ii) Name and address of the enterprise responsible for the goods; iii) Origin of goods, and iv) Additional details in conformity with the nature of the goods prescribed in Appendix I of Decree 43/2017 and other relevant legal documents. This Decree provides flexible choices for the presentation of expiration dates that may be represented either as a "use by" date or "best before" date. However, the manufacture and expiration dates must be

¹Announcement of technical regulation conformity means announcement by an organization or individual of the conformity of objects of activities in the domain of technical regulation with relevant technical regulations (Clause 9 Article 3 of the Law on Standard and Technical Regulation).

written in the "date-month-year" format (according to the western calendar) and must also be noted in this order if those dates are presented in another order on the product.

Food imported for consumption and circulation in the Vietnamese market must be labelled in either of the following ways: 1) Labelling in Vietnamese, including the full mandatory labelling contents; or 2) Being attached to secondary labels which contain the Vietnamese translation from the mandatory information of the original label and to supplement other mandatory information according to the nature of the commodity as prescribed in Decree 43/2017. Secondary labels are exempted for food ingredients, food additives, and food processing aids imported for internal production only and not for resale in the market.

Decree 43 also provides a transitional provision regarding the goods that were labelled in accordance with the Government's Decree No. 89/2006. Accordingly, the goods that were labelled and produced, imported, circulated, or used before the effective date of Decree 43 shall continue to be circulated or used until their expiration date. Those labels and commercial packages affixed with goods labels in accordance with Decree 89/2006 that have been produced or printed before the effective date of Decree 43/2017 shall continue to be used for a period not exceeding two years from the effective date of Decree 43/2017.

2. Other specific labelling requirements

2.1. Labelling food additives

In addition to general labelling requirements stipulated in Joint Circular 34, food additives need to be labeled as follows:

- Class name and international code (if any) must be enclosed with name of the food additive.

- If two or more food additives are present in packaging, their names must be listed completely in the order of proportion by weight.

- The phrase "Use for food" (*Dùng cho thực phẩm* in Vietnamese) must be clearly written below the name of food additive using bold letters with a minimum height of 2 millimeters.

2.2. Labelling irradiated food

In the case of food manufactured, processed, or preserved using irradiation, in addition to the mandatory labeling contents, the phrase "irradiated food", or an international-recognized irradiation food symbol accepted by Vietnam must be printed on the label.

2.3. Labelling functional food

The key legislation regarding the labeling of functional food is the FSL and MOH's Circular 43/2014/TT-BYT, dated November 24, 2014 regulating the management of functional foods ("Circular 43"). Circular 43 entered into force on January 15, 2015.

Under Circular 43, functional foods are categorized into four sub-groups: i) supplementary food (*Thực phẩm bổ sung* in Vietnamese); ii) health supplement, food supplement, and dietary supplement

(collectively "*thực phẩm bảo vệ sức khỏe*"); iii) food for special medical purposes or medical food (*thực phẩm dinh durõng dùng cho mục đích y tế đặc biệt* or *thực phẩm dinh durõng y học*); and, iv) food for special dietary use (*thực phẩm dùng cho chế độ ăn đặc biệt*).

The labeling of these products must comply with the requirements applicable to foodstuffs. Along with complying with standard regulations, the labeling for functional food must meet the following requirements:

- The specific phrase for the relevant sub-group name must be recorded on the product label (supplemented food, health supplement, food for special medical purposes, and food for special dietary use). The nutrient contents (e.g., the quantity of vitamins, minerals, enzymes, fatty acids, amino acids, or biological substances) must be displayed on the label.

- For supplementary food, the label must include the following contents: the objective of use, product utility, dosage, and special precautions or side effects of the product (if any);

- For food for special medical purposes and/or for special dietary uses, the label contents must include: directions for use and special precautions (if any);

- For health supplements, food supplements, and dietary supplements, the statement "This product is not a medicine, nor effective to replace medicine" must be listed directly after the product's effects or with other recommendations (if any). This phrase must have a contrasting color to the background color of the label and the letters must be at least 1.2 millimeters in height (or at least 0.9 millimeters if one side of the package is smaller than 80 square centimeters). In cases where the product name is the same as one of the main active ingredients, the quantity of such ingredients must be displayed on the label.

2.4. Labelling genetically engineered food (GE food)

In addition to requiring mandatory labeling for most GE food, the FSL also requires the phrase "*thực phẩm biến đổi gen*" ("genetically engineered food") to be displayed on the product.

MARD and MOST issued Joint Circular 45/2015/TTLB-BNNPTNT-BKHCN (Joint Circular 45) dated November 23, 2015 guiding the Labeling of Prepacked Genetically Engineered Foods which details the labeling requirements applicable to food products containing GE organisms and products of GE organisms for sale in Vietnam. This Circular entered into force on January 8, 2016 (see GAIN report <u>VM5088</u> for more information). This Circular applies to pre-packed foods containing at least one GE ingredient that is at least five percent of the total ingredients of the product. In instances where Circular 45 is applicable, the Vietnamese phrase "*biến đổi gen*" (aka: "genetically engineered") must be printed next to the GE component on the ingredient listing of the Vietnamese-language secondary label that is affixed on a product.

The labeling of GE food products as stipulated in Joint Circular 45/2015 does not apply in the following cases: a) food carried by people on entry for personal use within the duty free limit; food in diplomatic bags; food temporarily imported for re-export; food in bonded warehouses; food used as samples for testing and research; and food used during exhibitions or trade shows; and b) materials/food

additives/food processing aids, and food packaging material imported for internal production that are not for sale in the market or for internal transportation among warehouses of an enterprise.

Of special note this year and starting on January 8, 2017, Joint Circular 45/2015 will require the supplemental printing of the phrase "*biến đổi gen*" on the label of food products circulated in the market. After that date, pre-packed GE food products subject to this Circular and lacking labels compliant with Circular 45/2015 will not be allowed to be produced, traded, or imported into Vietnam.

Section VI: Other Specific Standards

1. General guidance on the import of agricultural products:

MARD issued Circular 4/2015/TT-BNNPTNT on guidelines for the GVN's Decree 187/2013/ND-CP dated November 20, 2013 on guidance on the Law on Commerce for international trade in goods and commercial agency, trading, processing and transit of goods with foreign countries in the agriculture, forestry, and aquaculture fields.

This Circular provides an overview on the guidelines and procedures for the export and import of goods subject to management of the agriculture, forestry, and aquaculture fields, including:

1. Export of timber and timber products from domestic natural forests, and firewood or charcoal made from timber or firewood originating in domestic natural forests;

- 2. Export and import of endangered and precious species of wild fauna and flora;
- 3. Export and import of plant varieties;
- 4. Export and import of breeding animals;
- 5. Export and import of live aquatic animals used for food;

6. Import of drugs and materials for the manufacture of drugs, vaccines, biological preparations, microorganisms and chemicals used in veterinary or aquatic veterinary medicine (hereinafter referred to as "veterinary drugs");

7. Import of products and materials used in the manufacture of products for the treatment and improvement of the aquaculture environment;

8. Import of plant protection products and materials included in the List of plant articles subject to pest risk analysis before being imported into Vietnam;

9. Import of livestock, poultry, aquatic animal feeds;

10. Import of fertilizer;

11. Export and import of genetic resources of plants used for scientific and technical study and exchange;

12. Export and import of food originating from animals, plants, and aquatic animals.

The unofficial translation of Circular 4/2015 is available at:

http://hethongphapluatvietnam.com/circular-no-04-2015-tt-bnnptnt-dated-february-12-2015-on-guidelines-for-the-decree-no-187-2013-nd-cp-on-guidance-on-the-law-on-commerce-on-international-trade-in-goods-and-commercial-agency-trading-processing-and-transit-of.html

For complete information on the importation of agricultural products, importers and exporters should refer to the specific regulations set up for each type of product.

2. Importation of live aquatic animals for consumption:

Currently, live aquatic animals are eligible for import for human consumption if they are listed in the Appendix 5 of Circular 4/2015 - the List of live aquatic animals approved for import for human consumption.

When importers apply for an import permit for live aquatic animals that are not included in the List of live aquatic animals approved for import for human consumption, the Directorate of Fisheries (DOF) of MARD shall conduct a risk assessment (only for the initial import consignment) in order to consider granting the permit and approve the risk management plan of the imported live aquatic animals.

The application for the import permit for live aquatic animals for human consumption (one set), must include:

- An application form for an import permit.

- A copy of the Certificate of Business Registration or Certificate of Investment (for first applications);

- A copy or a drawing of the aquatic animals applying for the import permit enclosed with their trade names and scientific names;

- A description of the biological characteristics of the aquatic animals applying for the import permit;

- A certificate of origin of the aquatic animals applying for the import permit issued by the competent agency of the exporting country. If the application is to be shared with DOF in person, a copy of the certificate (compared against the original) is required; or, for applications sent by post, an actual certified hardcopy enclosed with one notarized Vietnamese translation will be required;

- A plan for the management and observation of live aquatic animals when they are imported, transported, stored, processed, and consumed (using the form issued together with Circular 4/2015)."

Within 12 working days of the receipt of sufficient documents, DOF shall conduct the risk assessment of live aquatic animals imported for food use as stipulated in Circular 11/2015/TT-BNNPTNT dated March 10, 2015 (see GAIN report VM5034). It should be noted that the risk assessment under Circular 11/2015 applies to any live aquatic animals which are not included in the following lists: List of live seafood species allowed to be imported for food use; the List of invasive exotic species; or the List of

exotic species in danger of invasion, and requires the organization or individual (importer) to apply for a Risk Assessment for the proposed imported live seafood species before import permits are issued.

Regarding the export of live lobsters to Vietnam, DOF issued Decision 540/QD-TCTS-TTKN, dated September 7, 2015, incorporating American lobsters (*Homarus americanus*) into the List of live aquatic animals as already having a risk assessment conducted. The Decision took effect on the date of signing and the Vietnamese version is available at: https://thuvienphapluat.vn/van-ban/Thuong-mai/Quyet-dinh-540-QD-TCTS-TTKN-tom-hum-nhap-khau-thuy-san-song-da-duoc-danh-gia-rui-ro-289629.aspx. This decision permits the importation of American lobsters (*Homarus americanus*) into Vietnam for food use, but importers of live *Homarus americanus* are still required to obtain an import permit from DOF under Circular 4/2015. In addition, DAH no longer requires U.S. suppliers of live aquatic animals to apply under Appendix 3 Circular 25 for export to Vietnam.

3. National technical regulations on food quality and safety

Currently, there are other specific national technical regulations for food products which set out standards and limits for various food products. The current regulations are outlined below:

No.	Regulation	Dated	Content	
1.	Circular 23/2012/TT-BYT	11/15/2012	Issuing the National Technical Regulation on nutritious cereal products for children aged from 6 to 36 months	
2.	Circular 22/2012/TT-BYT	11/25/2012	Issuing the National Technical Regulation on supplementation formula products for children aged from 6 to 36 months	
3.	Circular 21/2012/TT-BYT	11/15/2012	Issuing the National Technical Regulation on special medical- treatment products for children aged 0 to 12 months	
4.	Circular 20/2012/TT-BYT	11/15/2012	Issuing the National Technical Regulation on supplementation formula products for children aged 0 to 12 months	
5.	Circular 18/2011/TT-BYT	05/30/2011	Issuing the National Technical Regulations on micronutrient fortified food	
6.	Circular 17/2011/TT-BYT	05/17/2011	Stipulating the limits of radiation contamination in food	
7.	Circular 05/2011/TT-BYT	01/13/2011	Issuing the National Technical Regulations on micronutrient fortified food	
8.	Circular 04/2011/TT-BYT	01/13/2011	Issuing the National Technical Regulations on micronutrient fortified food	
9.	Circular	01/13/2011	Issuing the National Technical Regulations on micronutrient	

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	03/2011/TT-BYT		fortified food
10.	Circular 01/2011/TT-BYT	01/13/2011	Issuing the National Technical Regulations on Food Additives
11.	Circular 45/2010/TT-BYT	12/22/2010	Issuing the National Technical Regulations on alcoholic beverages
12.	Circular 44/2010/TT-BYT	12/27/2010	Issuing the National Technical Regulations on Food Additives
13.	Circular 41/2010/TT-BYT	12/18/2010	Issuing the National Technical Regulations on fermented dairy products
14.	Circular 35/2010/TT-BYT	06/02/2010	Issuing the National Technical Regulations on non- alcoholic beverages
15.	Circular 34/ 2010/TT-BYT	06/02/2010	Issuing the National Technical Regulations on natural mineral water and bottled water
16.	Circular 33/2010/TT-BYT	06/02/2010	Issuing the National Technical Regulations on dairy fat products
17.	Circular 32/2010/TT-BYT	06/02/2010	Issuing the National Technical Regulations on cheese products
18.	Circular 31/2010/TT-BYT	06/02/2010	Issuing the National Technical Regulations on powder milk
19.	Circular 30/2010/TT-BYT	06/02/2010	Issuing the National Technical Regulations on fluid milk products
20.	Circular 28/2010/TT-BYT	05/20/2010	Issuing the National Technical Regulations on food additives- Acidity regulators
21.	Circular 26/2010/TT-BYT	05/20/2010	Issuing the National Technical Regulations on food additives - Firming agents
22.	Circular 25/2010/TT-BYT	05/20/2010	Issuing the National Technical Regulations on food additives - Artificial sweeteners
23.	Circular 24/2010/TT-BYT	05/20/2010	Issuing the National Technical Regulations on food additives – Antifoaming agents
24.	Circular 23/2010/TT-BYT	05/20/2010	Issuing the National Technical Regulations on Food Additives – Antioxidant agents

25	Circular 22/2010/TT-BYT	05/20/2010	Issuing the National Technical Regulations on Food Additives – Color retention agents
26	Circular 21/2010/TT-BYT	05/20/2010	Issuing the National Technical Regulations on Food Additives- Anticaking agents
27	Decision 38/2008/QD- BYT	12/11/2008	Stipulating the maximum limits of Melamine cross- contamination in food
28	Decision 46/2007/QD- BYT	12/19/2007	Issuing the maximum limits of chemical and biological contaminants in food, Part 7-List of approved food processing aids and maximum limits of processing aids in food

4. Micronutrients and fortified food

According to the FSL, MOH is responsible for regulating micronutrients and foods fortified with micronutrients. Additionally, the GVN issued Decree 9/2016/ND-CP, dated January 28, 2016, specifying the roadmap in Vietnam for the mandatory fortification of certain food products and reassigning the responsibilities of the three key ministries in charge of managing food safety of vegetable oils, wheat flour, and edible salts fortified with micronutrients. This Decree entered into force on March 15, 2016.

Decree 9/2016 specifies the foods which must be fortified with the relevant micronutrients as follows:

- Edible salt and salt used for food processing must be fortified with iodine;

- Wheat flour used for food processing must be fortified with iron and zinc;

- Vegetable oils which contain one of the following ingredients: soy oil, palm oil, rapeseed oil, and peanut oil, must be fortified with vitamin A, except for vegetable oils used for food processing.

The timeline for fortification of micronutrients in foods is scheduled as follows:

- Fortification of iodine in salt is mandatory after 1 year from the date of entry into force of this Decree;

- Fortification of iron and zinc in wheat flour and fortification of vitamin A in vegetable oils are mandatory after 2 years from the date this Decree enters into force.

Regarding the responsibilities of food safety management, MOIT is now in charge of the import of wheat flour and vegetable oils fortified with micronutrients and MARD is responsible for salt fortified with micronutrients.

MOH also issued Circular 44/2015/TT-BYT, dated November 30, 2015, promulgating the List of micronutrients allowed for use in food products. The list includes two parts: Part 1- Vitamins and Their Sources and Part 2- Minerals and Their Sources. However, the allowed levels of these vitamins and minerals have not been provided. In regards to micronutrients that are not included in the list enclosed

with this Circular but which are listed by CODEX or allowed for use in the countries of production, VFA shall consider and propose that MOH amend and supplement this Circular. It should be noted that the Circular does not apply for nutritional formula products for children, such as infant formula and supplemental formula (see GAIN report VM6005).

Section VII: Facility and Product Registration

1. Facility Registration

1.1. Food Business Operators registration for export of foodstuffs of animal origin and seafood

MARD held a major reorganization during 2017, under which the Department of Animal Health (DAH) assumed responsibility for the registration of Appendix 3 applications for the export of food products of animal origin and seafood to Vietnam starting from July 18, 2017 (see GAIN report VM7036). Before MARD's reorganization, NAFIQAD had been in charge of reviewing Appendix 3 registration applications.

The registration for export of foodstuffs of animal origin and seafood to Vietnam continues to follow MARD's Circular 25/2010/TT-BNNPTNT, dated April 8, 2010, guiding the hygiene and safety control for imported products of animal origin. Accordingly, food business operators (FBOs) must be approved by DAH and included in the List of FBOs eligible for exporting foodstuffs of animal origin and seafood to Vietnam.

The products regulated by MARD's Circular 25/2010 include:

- Seafood products, excluding live aquatic animals for food use (DAH has stated that live aquatic animals are not subject to Circular 25/2010),

- Meats and meat products: beef, pork, poultry, ovine, caprine, ostrich, etc.

- Edible animal offal,
- Eggs and egg products,
- Raw milk,
- Honey, and

- Other products of animal origin fit for human consumption (i.e. fat, edible bird's nest...).

According to Circular 25/2010, registration documents must be submitted to DAH by the Competent Authorities of the exporting country including:

- List of FBOs registering to export products to Vietnam by the form in the enclosed Appendix 1 of Circular 25/2010;

- Information on the food hygiene and safety (FHS) control system and competencies of the FHS Competent Authorities of exporting countries through the form in the enclosed Appendix 2 of Circular $25/2010^2$;

- Summary of the food business operator's FHS conditions through the form in the enclosed Appendix 3 of Circular 25/2010.

Within 30 working days of receipt of the completed registration documents, DAH will review the registration document, inform the Competent Authorities of the exporting country of the reviewing result, and, if approved, include the FBO to the List of FBOs eligible for exporting foodstuffs of animal origin and seafood to Vietnam. DAH requires no fee for applications for the registration of exporting products of animal origin and seafood to Vietnam.

Currently, DAH has published the List of FBOs eligible for exporting foodstuffs of animal origin and seafood to Vietnam on their website. However, during recent months, USDA/FAS has become aware that, in certain cases, DAH has requested additional registration information which may fall outside the Circular 25 jurisdiction and may unnecessarily restrict the listing for export of both food of animal origin and seafood to Vietnam. Post continues to work closely with DAH to clarify the purpose of additional information and update stakeholders on any developments.

The List of FBOs eligible for exporting food of animal origin to Vietnam is available at:

http://cucthuy.gov.vn/Pages/danh-sach-cac-doanh-nghiep-cua-22-nuoc-du-dieu-kien-xuat-khau-thucpham-co-nguon-goc-dong-vat-tren-can-vao-viet-nam.aspx

The List of FBOs eligible for exporting seafood to Vietnam is available at:

http://cucthuy.gov.vn/Pages/danh-sach-thuy-san.aspx

Should U.S. exporters have any questions or need clarification concerning registration for export of products of animal origin and seafood to Vietnam, please contact: <u>aghanoi@fas.usda.gov</u> or <u>usda4circ25@gmail.com</u>.

2. Product Registration

2.1. Foodstuffs of animal origin

2.1.1. Pre-shipment

FBOs must specify all types of products of animal origin to be exported to Vietnam as prescribed in Point 3 of the Appendix 3 of Circular 25/2010. When publishing lists of FBOs approved to export products of animal origin to Vietnam, DAH will also specify the types of products approved for export to Vietnam.

2.1.2. Registration for quarantine and food safety inspection: see Section VIII, Point 3.2.

² Previously, the Appendix 2 document was provided to NAFIQAD by the U.S. Department of Agriculture in 2010 and, again in 2013 in the case of offal products. As NAFIQAD was in charge of reviewing the registration documents at that time, they accepted both of these Appendix 2s from the United States.

2.2. Processed Food

On March 3, 2017, Vietnam notified the WTO of its intent to amend Decree 38/2012 through G/SPS/N/VNM/88 in order to simplify the procedures on Declaration of Conformity to Technical Regulations and Food Safety Regulations which are currently applied for both import and domestic products. However, on November 28, 2017, the GVN indicated its intent to replace Decree 38 and, as of December 2017, this has yet to occur. Therefore, the procedures on Declaration of Conformity remains unchanged at this time.

2.2.1. Pre-shipment

- For registration, the FSL requires all processed food, food additives, substances used in food processing, tools and materials used for packing and containing food to register an Announcement on Conformity with Technical Regulations (applicable to food products for which there are already technical regulations) before importation. Decree 38/2012/ND-CP extends the scope of the Announcement on Conformity with Food Safety Regulations to food products for which product-specific technical regulations have not yet been promulgated. Usually, MOH/VFA accepts the Announcement on Conformity with Food Safety Regulations on contaminant tolerances, such as Circular 24/2013, QCVN 8-1:2011, QCVN 8-2:2011, QCVN 8-3:2011, etc., for products of which specific technical regulations have not yet been promulgated (see Section III for details). A notarized copy of the Announcement Conformity with Technical Regulations or Food Safety Regulations is required for the application for a food safety inspection at the Port of Entry. Normally, a Vietnamese importer/distributor will assist an exporter in completing this process and registering the product with VFA so that it can be imported.

- According to the Law on Food Safety, MOH is the only governmental ministry responsible for promulgating Technical Regulations and Food Safety Regulations on food tolerances. MOH issued Circular 19/2012, dated November 9, 2012, providing the guidelines on the Announcement on Conformity with Technical Regulations and Food Safety Regulations process (see GAIN report VM4010).

- VFA is assigned as the competent authority responsible for the receipt or recognition of the Announcement on Conformity with Technical Regulations and the Announcement on Conformity with Food Safety Regulations according to Circular 19/2012.

• For an announcement of conformity based on certification by the appropriate body, the application shall include:

- Announcement of conformity with regulated technical standards;

- Product specifications;

- Certificate of conformity issued by a third party (a notarized copy or a copy accompanied by the original for verification);

- Certificate of conformity to HACCP standards, ISO 22000, or equivalent where the organizations or individuals manufacturing the product(s) have a quality control system that has been certified to conform to HACCP standards, ISO 22000, or equivalent (a notarized copy or a copy accompanied by the original for verification).

• For an announcement of conformity based on an appropriate self-assessment by organizations and individuals that manufacture and trade foods (the first party), the application shall include:

- Announcement of conformity with regulated technical standards;
- Product specifications;

- Product testing results in the most recent 12 months, including the criteria required by relevant regulated technical standards; issued by the following agencies: a testing lab designated by an authorized government agency or a recognized independent testing lab (the original or a notarized copy); or a testing lab from the country of origin recognized by an authorized agency in Vietnam (the original, a notarized copy), or a consular legalized copy).

- Quality control plan;
- Periodic monitoring plan (the first party's authentication);
- Report of Conformity Assessment (the first party's authentication);

- Certificate of conformity to HACCP standards, ISO 22000, or equivalent where the organizations or individuals manufacturing the product(s) have a quality control system that has been certified to conform to HACCP standards, ISO 22000, or equivalent (a notarized copy, or a copy accompanied with the original for verification).

• For announcements of compliance with food safety regulations for imported products whose regulated technical standards have not yet been provided (except for functional foods, and foods enriched with micro-nutrients), the application shall include:

- Announcement of compliance with food safety regulations;
- Product specifications;

- Product testing results from the 12 most recent months, including the major quality criteria, and safety criteria; issued by the following agencies: a testing lab designated by an authorized government agency or a recognized independent testing lab (the original or a notarized copy); or a testing lab from the country of origin recognized by an authorized agency in Vietnam (the original, a notarized copy, or a consular legalized copy).

- Periodic monitoring plan (authenticated by the organization or individual);

- Sample of the product label as circulated in the country of origin and the supplementary label in Vietnamese (authenticated by the organization or individual).

- Sample of the finished product for goods that are imported into Vietnam for the first time for verification when the application is filed;

- Business registration certificate with a license in food business or a certificate of legal entity for food importers (copies authenticated by the organization or individual);

- Certificate of satisfaction of food safety requirements for the importers that are legally required to be certified to satisfy food safety requirements (copies authenticated by the organization or individual);

- Certificate of conformity to HACCP standards, ISO 22000, or equivalent where the organizations or individuals manufacturing the product(s) have a quality control system that has been certified to conform to HACCP standards, ISO 22000, or equivalent (a notarized copy, or a copy accompanied with the original for verification).

• For imported functional foods and imported foods enriched with micro-nutrients, the application shall include:

- Announcement of compliance with food safety regulations;
- Product specifications;

- Certificate of Free Sale, public health certificate, or equivalent certificate granted by an authorized government agency from the country of origin verifying that the product is safe and wholesome for consumers, and complies with food safety laws (the original, notarized copy, or a consular legalized copy);

- Product testing results from the 12 most recent months, including the major quality and safety criteria; issued by the following agencies: a testing lab designated by an authorized government agency or a recognized independent testing lab (the original or a notarized copy); or a testing lab from the country of origin recognized by an authorized agency in Vietnam (the original, a notarized copy, or a consular legalized copy).

- Periodic monitoring plan (authenticated by the organization or individual);

- Sample of the product label as circulated in the country of origin and the supplementary label in Vietnamese (authenticated by the organization or individual).

- Sample of the finished product for verification when the application is filed;

- Business registration certificate with a food business license or a certificate of legal entity for food importers (copies authenticated by the organization or individual);

- Certificate of satisfaction of food safety requirements for importers that are legally required to be certified to satisfy food safety requirements (copies authenticated by the organization or individual);

- Certificate of conformity to HACCP standards, ISO 22000, or equivalent where the organizations or individuals manufacturing the product(s) have a quality control system that has been certified to conform to HACCP standards, ISO 22000, or equivalent (a notarized copy or a copy accompanied with the original for verification);

- Scientific information and documents proving the effect(s) of each ingredient that helps accomplish the announced functions (copies authenticated by the organization or individual).

2.2.2. Registration for food safety inspection: see Section VIII, Point 1.

2.3. Genetically Engineered Plants for use as food and feed

2.3.1. Pre-shipment certification

The GVN issued Decree 69/2010/ND-CP dated June 21, 2010 on the Biosafety for Genetically Modified Organisms and Decree 108/2011/ND-CP in November 2011 revising Decree 69/2010. The decrees provide the legal framework for bio-safety management of GE organisms, genetic specimens, and products derived from genetic engineering.

According to these decrees, MARD is designated as the governing authority on regulating GE crop field trials and approving GE products use as animal feed and human food.

On January 24, 2014, MARD issued Circular 2/2014/TT-BNNPTNT promulgating the approval process of issuing and withdrawing certification for genetically engineered plants for use as food and feed (see GAIN report VM4020). The Circular provides the approval process of issuing and revoking the Certificate for GE Plants to be used as food and feed. The Circular entered into force on March 10, 2014.

On February 14, 2015, MARD issued Circular 6/2015 amending Clause 2, Article 18 of Circular 02/2014 regarding the approval process of issuing and withdrawing certification for GE plants for use as food and feed. At this time, MARD continues to receive new applications dossiers for food/feed approval.

2.3.2 Registration for food safety inspection: see Section VIII, Point 3.1.

2.4. Animal Feed

2.4.1. Pre-shipment

On April 4, 2017, the GVN issued Decree 39/2017/ND-CP replacing Decree 08/2010/ND-CP on animal feed management and revoking a number of articles under Decree 66/2016 (dated July 1, 2016) regulating requirements for the investment and trade for plant quarantine and plant protection, plant varieties; common wild livestock; animal husbandry, aquaculture, and foods. This Decree entered into force on May 20, 2017 (see GAIN report VM7030).

Decree 39/2017 applies to both animal and aquaculture feeds and provides the management principles for animal feeds containing antibiotics. Specifically, Decree 39/2017 provides some provisions on the use of antibiotics in animals feed as follows:

- Antibiotics are not permitted to be used in feeds for aquatic animals.

- Animal feeds containing specified approved antibiotics for growth promotion for livestock and poultry are permitted to be circulated until December 31, 2017 (see GAIN report <u>VM6038</u>).

- Antibiotics used in animal feeds for the treatment of livestock, poultry and disease prevention in young livestock, poultry must be in the allowed list of veterinary drugs permitted for circulation in Vietnam and under the prescription of veterinarians who are licensed in the treatment and prevention of diseases for animals according to the Law on Animal Health. Animal feeds containing antibiotics for

disease prevention for young livestock and poultry are allowed for circulation until the end of December 31, 2020.

According to Decree 39/2017, imported animal and aquaculture feeds must be registered for circulation with the Department of Livestock Production (DLP) or the Directorate of Fisheries (DOF) respectively. The registration dossier includes:

- A written request for registration of imported animal and aquaculture feeds to be circulated in Vietnam;

- Certificate of free sale or equivalent documents of imported animal and aquaculture feeds as granted by the competent state authorities of the country of origin;

- Copy of one of the following certificates: ISO, GMP, HACCP or relevant documents from the manufacturers;

- Product information provided by the manufacturers, including: composition, safety and quality standards of animal feeds, uses, and manual;

- Announcement of applicable standards of organizations and individuals registering imported animal and aquaculture feeds for circulation in Vietnam; product sub-label in Vietnamese language in accordance with current regulations;

- Test results on quality and product safety indicators issued by laboratories appointed by the competent authorities of exporting countries or laboratories recognized by the regional or international organizations of quality certification or appointed, accepted by MARD;

- Product labels (certified by suppliers or importers).

- All documents must be originals or certified true-copies accompanied by a Vietnamese translation, certified by the organizations or individuals registering for import. If the originals are not in English, the Vietnamese translation must be notarized.

Within 20 working days upon receipt of a valid dossier, a Vietnam competent authority shall evaluate the contents of the dossier and issue a decision on the certification of animal and aquaculture feeds permitted for circulation in Vietnam. In the cases of rejection, DLP or DOF is required to clearly state the reason in writing.

Furthermore, importation of types of animal feed for the purposes of assay, testing, processing for reexport under contracts registered with foreign parties, or for introduction at trade fairs or exhibitions are subject to DLP or DOF's approval.

2.4.2. Registration for quality inspection: see Section VIII, Point 4.

Section VIII: Other Certification and Testing Requirements

3. Food safety inspection regulated by MOH

According to the FSL and Decree 38/2012/ND-CP, MOH is responsible for the import inspection of food additives, food processing aids, bottled water, natural mineral water, functional food, food fortified with micronutrients, utensils and packaging materials in direct contact with food, and food containers. The details of the imported food products under MOH's jurisdiction are specified in Appendix 1 of Inter-Ministerial Circular 13/2014/TTLT-BYT-BNNPTNT-BCT (GAIN report <u>VM4029</u>).

Legal background

Although the principles and scheme of inspection for imported foods are set in the FSL, the inspection methodology is assigned to specialized ministries.

In 2015, MOH revised the regulation on food safety inspection of imported foods under its jurisdiction. The new regulation, Circular 52/2015/TT-BYT, revises the methods of food safety inspection and the application of those methods. This Circular took effect on February 23, 2016 (see GAIN report VM6009).

- According to Circular 52, the application dossier for food safety inspection upon entry includes:
- Registration form for the inspection of imported food;

- Notarized copy or copy with trader's ³ stamp enclosed with the original for comparison or copy with trader's stamp obtained from VFA's online registration system of the product's conformity announcement;

- Notice on approval of simplified inspection by VFA (if any);

- Power of attorney of the trader who is responsible for the food quality-authorizing organizations or individuals to conduct the food importation (if any);

- Copy of packing list; and
- Copy of bill of lading and invoice certified as "true" by trader.

• Levels of Inspection

In compliance with the inspection scheme stipulated in the FSL, Circular 52/2015 sets three levels of inspection including:

Normal Inspection

Normal inspection applies to 100 percent of the goods in an imported consignment (e.g. all products in the consignment, regardless of whether or not there are different products in the consignment, are subject to normal inspection), except for the cases as provided for simplified and tightened inspection.

³ In this Circular, "trader" is used to indicate the individual or enterprise that registers the conformity announcement of food with VFA; and are therefore responsible for food quality. Traders may be importers who can import the food directly or if they can authorize the importation to a different enterprise.

Normal methods of inspection means inspecting dossiers and taking representative samples for sensory inspection, inspection of labeling, packaging status and special preservation status (if any).

Simplified Inspection

Simplified inspection means inspection of dossiers only. In order to apply this inspection method, the importer is required to submit a written request to VFA. Within 5 working days from the date of receiving the importer's request, VFA shall issue a notice of approval or disapproval of the application for simplified inspection. The maximum duration of the simplified inspection is 12 months.

Simplified inspection is applied to goods in the following cases:

- Certified by the Competent Agencies of exporting countries having signed international agreements on mutual recognition in activities of quality and safe food inspection under which Vietnam is the member; having inspection results issued by the Competent Agency of the exporting country in compliance with Vietnamese regulations;

- Having satisfactorily met the import requirements after three consecutive inspections on various dates within 12 months in the course of normal inspection, at the same time, having satisfactorily met the requirements during examination or inspections⁴ (if any);

- Having satisfactory results during the periodical inspections within 12 months of having applied for the simplified method;

Tightened inspection

Tightened inspection applies to imported goods in one of the following cases:

- Goods failing to meet the import requirements during previous inspections.

- There is warning from the Ministry of Health or the competent authority in the foreign country or the manufacturer concerning the product in question.

In the course of a tightened inspection, the inspection agency shall conduct one of the following cases;

- Inspection of dossiers and taking adequate samples for testing the group of indicators in the announced dossiers for goods failing to meet [the requirements] during previous inspections;

- Inspection by normal methods and testing the warning indicators or requiring the provision of a certificate of analysis for the warning indicators of laboratories accredited and recognized by state competent agencies of exporting country for goods, which are warned by MOH or the competent agency of foreign countries or the manufacturer.

⁴ According to Circular 19 on the Conformity Announcement (CA), establishments (domestic producers, importers) shall conduct a post-announcement examination annually after the CA for a product is recognized. The frequency of the post-announcement examination is stipulated as follows: 1) Once a year for establishments having HACCP or ISO 22000 certificates; and 2) Twice a year for establishments lacking these certificates.

Tightened inspection changes to normal inspection if the inspection results in two consecutive consignments satisfying import requirements; or when VFA issues a written notice ending tightened inspection.

Although VFA, under MOH, is the governing authority for food safety, it does not directly conduct food safety inspections. Instead, VFA assigns other professional agencies, particularly state-owned agencies, to conduct food safety inspections. The list of the agencies assigned to conduct food safety inspection by MOH is provided in Appendix II of this report. MOH's decision on assignment of an inspection body is valid for a specified period, currently 5 years; therefore, importers should contact the agencies for details.

2. Food safety inspection regulated by MOIT

Food under the MOIT's jurisdiction with regard to inspection include: wine, beer, soft drinks, processed milk, vegetable oil, cereals/grains, starch, bread, jams, and candies.

MOIT inspection is governed under Circular 28/2013/TT-BCT, dated November 6, 2013, which entered into force on December 20, 2013. Generally, MOIT inspection is consistent with the principles and schemes set in the FSL. However, it provides four levels of inspection: intensive inspection, normal inspection, simplified inspection, and simplified inspection by a dossier evaluation only. The latter inspection method is simpler and more alleviated than simplified inspection (see GAIN report <u>VM4004</u>).

According to Circular 28/2013, the Department of Science and Technology (DST) under MOIT is the governing authority for the food safety control of food products under that ministry's management. However, like VFA, DST does not directly conduct food safety inspections and instead assigns other professional agencies, particularly state-owned agencies, to conduct these inspections. Most food safety inspection bodies assigned by MOH are also assigned by MOIT. Please refer to Appendix II of this report for the list of food safety inspections assigned by MOIT.

3. Quarantine and food safety inspections regulated by MARD

MARD is responsible for the import inspection of cereals, meat and meat products, aquaculture and aquatic products, vegetables, bulbs, fruits, eggs and egg products, fresh milk used as an input, bee's honey and honey products, genetically engineered foods, salt, and agricultural foods in accordance with the provisions of the Government.

3.1. Quarantine and Food Safety Inspections for Imported Goods of Plant Origin

3.1.1. Plant quarantine

Plant quarantine is governed by the Law 41/2013/QH13 on Plant Protection and Quarantine. This law entered into force on January 1, 2015.

In order to implement the Law on Plant Protection and Quarantine, MARD released Circular 30/2014/TT-BNNPTNT (dated September 5, 2014), Circular 33/2014 (dated October 10, 2014), and

Circular 35/2014/TT-BNNPTNT (dated October 31, 2014). Circular 35/2014 published the list of articles subject to plant quarantine and the list of articles subject to pest risk analysis before importation into Vietnam. This Circular outlines that articles subject to plant quarantine shall be quarantined at the Vietnamese port of entry in order to be granted customs clearance (see GAIN report <u>VM4057</u>). Circular 33/2014 provides guidance on quarantine procedures for import, export, and in-transit for consignments of plant origin. Circular 35/2014 circulated the list of quarantine pests (see GAIN report <u>VM4067</u>). All of these Circulars have been in force since January 1, 2015.

- List of food subject to quarantine includes:
- Tubers, fruits, seeds, flowers, leaves, trunks, branches, stumps, roots, skins of all kinds;
- Broken grains, bran, oil-cake, raw natural fibers, plant fiber;
- Flour, starch of plant origin (except knead dough and denatured starch);
- Tobacco stems, fibred tobacco, livestock feed, yeast, cotton, cotton waste, rice straw and stem, aquatic plants;
- Livestock feed of plant origin;
- Mushrooms of all kinds (except salted, frozen, canned, and fermented mushrooms).
- List of food subject to pest risk analysis includes:
- Fresh fruit of all kinds;
- Fresh bulbs of all kinds.

In order to specify the list of articles subject to quarantine promulgated in the Article 1 of the Circular 30/2014, MARD released Decision 2515/QD-BNN-BVTV, dated June 29, 2015, promulgating the List of Harmonized Schedule (HS) codes for the List of regulated articles subject to plant quarantine. Decision 2515/QD-BNN-BVTV provides a detailed 8-digit HS code List based on Vietnam's current Harmonized Schedule, covering all articles subject to plant quarantine which was promulgated with only a broader category listing in the Article 1 of the Circular 30 (GAIN report <u>VM5047</u>).

However, on January 1, 2018, MARD's Circular 24/2017 (dated November 15, 2017) replaced Decision 2515/QD-BNN-BVTV, stipulating HS codes for specialized import and export goods. Accordingly, Appendix 3 of Circular 24/2017 provides a revised List of HS 8-digit codes for products subject to plant quarantine. Post plans to issue a GAIN report which will clarify all changes related to this Circular.

MARD's PPD is the governing authority for plant quarantine and has a system consisting of nine Sub-Departments of Plant Quarantine Region named from I to IX and responsible for import-export quarantine located at some main border checkpoints. The list of these inspection bodies is specified in Appendix II of this report.

- The application dossier for plant quarantine includes:
- An application form for plant quarantine as prescribed.

- An original or notified copy of the Phyto-sanitary Certificate issued by competent authorities of exporting countries.

3.1.2. Food Safety Inspection

On October 19, 2017, MARD/PPD notified the WTO of its intention to amend Circular 12/2015 issuing Guidance on the Food Safety Inspection for Imported Goods of Plant Origin as G/SPS/N/VNM/92. This draft proposes to maintain three inspection methods for imported products, including normal inspection, tight inspection, and simplified inspection, but also provides more details on exemptions for inspection and import suspension. The draft also provides guidance on registration for exporting countries, which includes requirements on food safety management systems and monitoring programs for foods of plant origin, however as U.S. products are already registered, this is not (currently) a concern. On December 15, 2017, the U.S. Government provided comments for this draft which requested Vietnam to clarify proposed provisions of import inspection and import suspension to ensure these provisions will not disrupt trade of food of plant origin. FAS-Hanoi will continue to monitor this development and will publish a GAIN report on the final Circular if MARD does approve and issue this regulation.

On November 6, 2017, PPD also notified the WTO on the amendment of Circular 33/2014 as G/SPS/N/VNM/93. This Circular currently only proposes to integrate documents for the registration and certification of food safety import inspection and quarantine for food of plant origin. The amendment of Circular 33/2014 has no other changes in procedures for quarantine of plant products.

Currently, (as of December 31, 2017), food safety inspections for plant products are regulated by MARD's Circular 12/2015/TT-BNNPTNT dated March 16, 2015, issuing Guidance on the Food Safety Inspection for Imported Goods of Plant Origin. Circular 12/2015 came into force on May 5, 2015.

Circular 12/2015 sets up three levels of inspection for products under MARD's food safety jurisdiction, based on risk levels, records of food safety violations (if any) of imported consignments, and requirements in compliance with international treaties of which Vietnam is a partner, and includes: normal inspection, intensive inspection and simplified inspection (see GAIN report <u>VM5039</u>).

In addition, MARD provided a List of 8-digit HS codes for plant products subject to food safety import inspection in Appendix 5 of Circular 24/2017, which took effect on January 1, 2018.

• The application dossier for food safety inspection includes:

- Original application for registration for Food Safety Inspection (as specified in the Appendix 3 of Circular 12/2015);

- For imported goods containing genetically engineered products: Goods are listed in the List of genetically engineered products with a Certificate issued as regulated in MARD's Circular 2/2014/TT-BNNPTNT, dated January 24, 2014, stipulating the order, procedure of issuing and withdrawing Certification for Genetically Engineered Plants for use as food and feed;

- For imported irradiated-goods: Certificate of Free Sale (CFS) issued by the competent agency of exporting country as regulated in MARD's Circular 63/2010/TT-BNNPTNT dated, November 1, 2010, regarding the Regulation on CFS for import-export products under MARD's management.

• Levels of food safety inspection

According to Circular 12/2015, the Inspection Bodies for import-export quarantine under PPD are also responsible for food safety inspection at border checkpoints. Inspection procedures are as follows:

Document review: inspection bodies to review the registration documents (source of origin, history of compliance with the provisions on food safety of organization, individual, or food business operators; regulations regarding genetically engineered products and irradiated products and other relevant regulations);

Visual inspection (not applicable for temporary import for export consignments): Inspection bodies to inspect the status of the consignment, packaging, labelling upon arrival at entry gate; inspection of compliance of information declared and any unusual signs that might cause a food safety problem.

Taking samples for testing: Inspection bodies sample to test for food safety criteria at a registered location following the sampling methods prescribed in the Article 9, 10, and 11 of Circular 12, regarding Normal Inspection, Intensive Inspection and Simplified Inspection, respectively.

As of April 2017, NAFIQAD, PPD, and MARD's Department of Science and Technology have approved 35 laboratories to perform food safety testing. An updated list of approved laboratories is available on NAFIQAD's website: <u>http://www.nafiqad.gov.vn/danh-sanh-phong-kiem-nghiem-chat-luong-an-toan-thuc-pham-nong-lam-thuy-san-duoc-chi-dinh-con-hieu-luc-cap-nhat-thoi-diem-thang-62015_t221c308n125.</u>

3.2. Quarantine and Food Safety Inspection for Imported Goods of Animal Origin

3.2.1. Quarantine of terrestrial animal and products thereof

Legal background

On June 19, 2015, the Vietnam National Assembly ratified the Law on Animal Health which entered into force on July 1, 2016 and provides several new provisions on the quarantine and hygiene inspection for food of animal origin. The Law stipulates that MARD is responsible for issuing the List of terrestrial animals and food of animal origin subject to quarantine and the List of terrestrial animals and food of animal origin exempted from quarantine.

MARD issued Circular 25, dated June 30, 2016, providing for the quarantine of terrestrial animals and terrestrial animal products (see GAIN report number $\underline{VM6065}$). The List of animals and animal products subject to quarantine specified in Circular 25 is as follows:

ANIMALS	ANIMAL PRODUCTS	•	Formatted Table
	1. Meat, viscera, by-products and products [made]		
1. Cattle: Buffalos, cows, donkeys, horses,	1. Meat, viscera, by-products and products [made]		

	mules, goats, sheep, pigs, rabbits, dogs, cats and other domestic cattle species;	from meat, viscera, animal by-products stipulated in Section I of this List in the forms of fresh, smoked, dried, salted or frozen, and canned.
	 Poultry: chickens, ducks, geese, turkeys, ostriche Laboratory animals: guinea pigs, white mice, rabbits and other laboratory animal species; 	 Sausage, pate, ham, fat and other animal products in the form of simply-prepared or processed. Fresh milk, yogurt, butter, cheese, canned milk,
	4. Wild animals: elephants, tigers, leopards, bears, o	powdered milk, bread milk and dairy products.
	5. Other animal species: bees, silkworms, and other insects.	4. Fresh eggs, salted eggs, egg powder, and egg products.
		5. Breeding poultry eggs, silkworm eggs; embryos, and animal sperm.
		6. Meat meal, bone meal, blood meal, feather meal and other animal products in the forms of raw materials; animal and poultry feed, aquatic animal feed that contain ingredients derived from animals.
		7. Fish meal, fish oil, fish fat, shrimp powder, oyster powder and other aquatic animal products used as raw materials for processing cattle, poultry and aquaculture feed.
		8. Pharmaceutical materials originating from animals: snake venom, bee venom, pangolin scales, bear gall, animal extract, digestive enzymes and other pharmaceutical materials originating from animals.
		9. Animal skins in the forms: fresh, dried, and salted.
		10. Fur, skin, stuffed animals of animal species: tigers, leopards, civets, rabbits, otters and from other animal species.
		11. Cilia: hairs of horse tails, hairs of cow tails, pig hair, fleece, and hairs of other animal species.
		12. Feathers: chicken feathers, duck feathers, goose feathers, peacock feathers, and feathers of other bird species.
		13. Teeth, horns, nails, tusks, and animal bone.

14. Edible bird nests and products thereof.
15. Honey, royal jelly, beeswax.
16. Silkworm cocoons.
17. Pathological materials.
18. Other objects subject to quarantine of animals and animal products as required by the importing country or the provisions of the international treaties to which Vietnam has signed or acceded to.

MARD also issued Decision 4758/QĐ-BNN-TY, dated November 11, 2015, promulgating the List of HS Codes for animal and animal products subject to quarantine requirements during importation and customs clearance. Consecutively, DAH and Vietnam Customs issued Letter 2403/KD-TY dated December 3, 2015 and Letter 1569/GSQL-GQ1 dated December 9, 2015, respectively, which excluded imported tanned skin products from quarantine (under the HS Codes: 4104; 4105; 4106; 4107; 4112.00.00; 4113; and 4115 (see GAIN report VM6011)

However, on January 1, 2018, MARD's Circular 24/2017 (dated November 15, 2017) replaced Decision 2515/QD-BNN-BVTV, stipulating HS codes for specialized import and export goods. Accordingly, Appendix 22 of Circular 24/2017 provides a revised List of HS 8-digit codes for terrestrial animal and animal products subject to quarantine. Post plans to issue a GAIN report which will clarify all changes related to this Circular.

Registration and declaration for the quarantine of terrestrial animals and terrestrial animal products

Before importation, the shipment owner shall send DAH a registration dossier for animal quarantine which shall include: 1) an application for Animal Quarantine and, 2) additional documents if imported animals or animal products are subject to the management of other ministries. The registration dossier can be sent by mail or submitted directly to DAH. Within 5 working days after receiving the completed registration dossier, DAH will issue an official letter guiding the shipment owner and relevant veterinary agency conducting the animal quarantine. In cases where DAH does not accept a quarantine registration, DAH shall provide the consignment owner a written response indicating the reasons for rejection. After receiving DAH's notification of acceptance to conduct quarantine, the shipment owner shall send a declaration for animal quarantine from the shipment owner, the veterinary agency at the border gate shall implement quarantine as regulated under the Law on Animal Health (see GAIN report VM6065).

3.2.2. Quarantine of aquatic animal and products thereof

In accordance with the Law on Animal Health, MARD issued Circular 26 dated June 30, 2016, providing for the quarantine of aquatic animals and aquatic animal products. This Circular details

provisions for Clause 3, Article 53 of the Law on Animal Health regarding the List of aquatic animals and aquatic animal products subject to and exempted from quarantine; the List of aquatic animals and aquatic animal products subject to risk analysis before being imported into Vietnam; and the List of objects subject to quarantine of aquatic animals and aquatic animal products. This Circular also provides instructions for application dossiers and the contents of the quarantine of aquatic animals and aquatic animal products being imported, temporarily imported for re-export, temporarily exported for re-import, transferred from one border-gate to another border-gate, [taken in and out of] bonded warehouses, and transited through the territory of Vietnam (see GAIN report <u>VM6053</u>).

Aquatic animals and aquatic animal products subject to quarantine include:

Aquatic animals	Aquatic animal products	Formatted Table
1. Fish: species of scaled fish, catfish, and other fish species.	1. Embryos, eggs, sperm, and larvae of aquatic animal species.	
 Crustaceans: shrimp, crab and snow crab, and other species of crustacean living in water. Mollusks: squid, octopus, snails, mussels, clams, ark clams, oyster and other mollusk species living in water. 	 Aquatic animal products in the forms of fresh, simply-prepared, frozen, chilled (including aquatic animals died in the form of whole animal). Aquatic animal products which are salted or processed (dried, smoked). 	
4. Amphibians: frogs, hylidae, and other species of amphibians.	4. Products in the forms of processed, canned; fish oil.	
 Reptiles: turtles, trionychidae, hawksbill sea turtles, crocodiles, aquatic species of reptiles, and other species of amphibian reptiles. Coelenterata: jellyfish, hydra, and coral. 	 5. Fresh eggs, salted eggs, and products from aquatic animal eggs. 6. Aquatic animal skin, fur, fins, scales, shells in the forms of fresh, dried, salted. 	
 7. Echinoderm: sea cucumbers and sea urchins. 8. Sponges. 9. Mammals living in water: whales, seals, otters, and other species of mammals that live in water. 	7. Other aquatic animal products subject to quarantine as required by the importing country or the provisions of the international treaties to which Vietnam has signed or acceded to.	
10. Other aquatic animals.11. Other aquatic animals subject to quarantine as required by the importing country or the provisions of the international treaties to which Vietnam has signed or acceded to.		

Appendix 23 of MARD's Circular 24/2017.

Registration and declaration for quarantine of aquatic animals and aquatic animal products

DAH requires importers to apply for an "instruction of quarantine" prior to submitting dossiers for quarantine declaration to the border-gate animal agency.

Application dossiers for imported aquatic animals and aquatic animal products are stipulated as follows:

- For quarantine registration: (1) Application for DAH's instruction of quarantine; (2) Copy of quarantine certificate issued by the competent authority of the exporting country (for aquatic animals and aquatic animal products originating from countries and territories that do not have agreements on quarantine certificate with Vietnam); (3) Copy of CITES permit (if applicable); (4) Copy of Import Permit issued by the Directorate of Fisheries (for breeding aquatic animals not included in the List of breeding aquatic animals for food-use not included in the List of live aquatic animals for food- use permitted for import).

- For quarantine declaration: (1) Quarantine declaration application; (2) Copy bearing the certification by the enterprise or the original of quarantine certificate of the exporting country. In cases where a copy is enclosed [with the dossier] or the original quarantine certificate is not enclosed [with the dossier], the original certificate of the exporting country must be submitted at the time of the commodities inspection.

At the time of inspection, the border-gate animal quarantine agency shall take samples of imported aquatic animal products for testing microorganisms, physical and chemical indicators, and monitoring toxic residues (such as antibiotics, heavy metals, veterinary drugs, and pesticides) in accordance with the provisions of Appendix 4 promulgated in conjunction with Circular 26/2016. The border-gate animal quarantine agency shall issue a Quarantine Certificate for imported aquatic animal products meeting requirements within 5 working days from the commencement of quarantine.

3.2.3. Food Safety Inspection

On July 18, 2017, MARD charged DAH with sole responsibility for the Appendix 3 process for the registration of facilities wishing to export foodstuffs of animal origin and seafood to Vietnam, as a result DAH is now the only agency in charge of food safety inspections for imported food of animal origin (both terrestrial and aquatic animals).

Officially, the following MARD's Circulars regulate the inspection of imported food of animal origin:

- Circular 25/2010/TT-BNNPTNT guiding the food hygiene and safety control (FHS) for imported products of animal origin; and

- Circular 51/2010/TT-BNNPTNT amending and supplementing a number of Articles of Circular 25/2010/TT- BNNPTNT and Circular 6/2010/TT-BNNPTNT.

However, in regards to inspection procedures, as the reference regulations stipulated in Circular 25/2010 were replaced by Circular 25/2016 and Circular 26/2016 on the quarantine of terrestrial animals and aquatic animal products respectively, DAH currently conducts food safety inspections for imported terrestrial animal products and aquatic animal products in accordance with MARD's Circular 25/2016 (see GAIN report VM6065) and Circular 26/2016 (see GAIN report VM6053). According to these Circulars, each shipment of animal products shall be sampled for testing microorganisms, physical and chemical indicators, and monitoring toxic residues (such as antibiotics, heavy metals, veterinary drugs,

and pesticides) as stipulated in relevant technical regulations. If this shipment meets import requirements, it shall be granted a certificate of quarantine and food safety inspection by an inspection body.

The inspection bodies responsible for quarantine and food safety inspection for imported food of animal origin are the seven Animal Health Office Regions named from I to VII under DAH. The list of these inspection bodies is specified in Appendix II of this report.

4. Food safety monitoring

MARD issued Circular 8/2016, dated June 1, 2016, stipulating food safety monitoring for agricultural and fisheries products circulated and consumed in the domestic market. This Circular applies to foods under MARD's jurisdiction, including: cereal, meat and meat products, fisheries and fisheries products, fruits and vegetables, eggs and egg products, raw milk, etc. Sampling will be conducted at wholesale markets and distribution establishments (e.g. importers' warehouses) by the Sub-Departments of Agro-Forestry and Fisheries Quality Assurance (monitoring authorities) at the provincial-level. This Circular entered into force on July 15, 2016.

The legal bases for monitoring are food safety and national technical regulations. The testing indicators (e.g. MRLs for veterinary drugs and pesticides and microbiological criteria) shall be determined based on one or more of the following criteria:

- Products and indicators found to violate food safety regulations according to consumers' complaints and/or competent authorities' warnings.

- Products and indicators found failing to conform to food safety during inspections and examinations conducted in previous years.

- Products and indicators causing food poisonings.

- As per request of MARD and the Departments of Agriculture and Rural Development (at the provincial level).

In cases where the products are found to be unsafe, the establishment must trace and recall the products, investigate the cause of unsafety, take corrective actions, and report results to monitoring authorities at provincial level. If an establishment fails to submit an investigative report and take corrective actions in the required period of time, the competent authorities will conduct an unannounced inspection.

In cases where samples of imported products are found to be unsafe in the monitoring program, monitoring authorities at the provincial level shall report to competent authorities in charge of food safety under MARD (NAFIQAD, PPD, or DAH).

5. Quality Inspection of Animal Feed

For the quality inspection of imported animal feed, DLP is the governing authority for terrestrial animal feed and DOF is the governing authority for aquatic animal feed. However, these agencies do not directly conduct inspections but instead assign other professional agencies to conduct assessments.

According to Decree 39/2017, imported animal feed shall be exempted from a quality inspection in the following cases:

- Temporary importation of animal feed for re-exportation.
- Animal feed in transit, transported from one border-gate to another border-gate.
- Animal feed sent to bonded warehouses.
- Animal feed are samples for trade fairs and exhibitions.
- Animal feed are samples for analysis at laboratories.
- Animal feed are samples for trials.

Decree 39/2017 specified four methods for quality inspection of imported feed as follows:

Normal inspection: Inspection will be conducted through review of dossiers, visual inspection, and sampling for analysis of at least one safety and quality criteria as prescribed by the applicable standards or national technical regulations. For animal feeds containing antibiotics, all antimicrobials contained in products must be tested.

Time-limited reduced inspection (not applicable for animal and aquaculture feeds containing antibiotics): Inspection will be conducted by dossier review and visual inspection. The applicable period for reduced inspection is 12 months. Samples shall be taken in cases where goods are not consistent with their dossiers or exhibit any signals that may affect the safety or quality of products. This method is only applicable to imported consignments which are of the same kind, produced by the same producer, and imported by the same importers with certificates of quality inspection for three consecutive imported consignments under normal inspection within a period not exceeding the 12 preceding months;

Exemption from quality inspection during a limited time (not applicable for imported feed containing antibiotics): This method is applied for feed consignments which satisfy the following conditions: consignments are of the same kind, produced by the same producer, and imported by the same importers with certificates of quality inspection for five consecutive imported consignments under normal inspection or three consecutive imported consignments under a time-limited simplified inspection within a period not exceeding the 12 preceding months.

Tightened inspection: This inspection method will be conducted by dossier review, visual inspection, and sampling all consignments for testing of at least 50 percent of safety criteria as regulated by the national technical standard and at least 50 percent of quality criteria as regulated by the applied standards and other norms (if any) as requested in writing by the MARD authority.

Tightened inspection shall be applied to imported consignments in the following cases:

- A previous importation did not satisfy requirements of safety and quality as stipulated;

- Imported goods are in the list of animal and aquaculture feeds with high risks of food safety issued by MARD or having a country of origin with high safety risks for human, animals, and environment as determined by MARD;

- Having MARD's written request for a strict inspection when goods circulated in the market have been detected as not satisfying quality requirements or have been alerted by relevant domestic or foreign organizations and individuals as having risks to human, animals, or the environment.

Registration for quality inspection

Importers shall submit a registration dossier for quality import inspection to DLP which shall include:

- A written request for quality inspection as prescribed;

- Copies of the following documents certified by importers: purchasing contracts, packing list, invoice, certificate of analysis, product labels; applicable standards of importers;

- For animal feed containing antibiotics, a registration dossier must include reports on the importation and consumption status of previously imported consignments.

Registration dossiers must be submitted through the Vietnam National Single Window web portal starting from September 25, 2015 for terrestrial animal feed and from June 1, 2016 for aquatic animal feed (link: https://vnsw.gov.vn/profile/MinistriesDetail.aspx?id=19&item=82).

Section IX: Import Procedures

Vietnam's National Assembly promulgated the new Law on Customs 54/2014/QH13, which entered into force on January 1, 2015. Accordingly, goods which are live animals, plants, difficult to preserve, or deemed as other special goods shall be prioritized for customs inspection. Importers will conduct the customs declaration before the date that the commodities arrive at the border checkpoint or within 30 days from the date on which the commodities arrive at the border checkpoint. Post notes that this change signified a regulatory easing, compared with previous regulations, which only allowed declarers (importers or customs brokers) to make changes to the declaration form before the inspection of physical goods.

According to the Law on Customs, the customs declaration shall be made electronically and a paper declaration may only be made for the following exceptions:

- Imported and exported goods of border residents;
- Imported and exported goods are in excess of the limit of tax exemption applied to incoming and outgoing persons;
- Cargo is for the purpose of emergency assistance and humanitarian aid;

- Cargo are personal gifts, presents, properties;
- Cargo is equipment containing goods according to the temporary importation/re-exportation, temporary exportation/re-importation method.
- Cargo to be temporarily imported and re-exported or exported and re-imported and are carried by incoming and outgoing persons used for work in the pre-determined time.
- The customs electronic data processing system or electronic customs declaration system fail to carry out transactions which may be caused by the operational failure of one or both systems or caused by other reasons. In cases where the electronic data processing system fails to carry out the customs procedures, customs authorities shall be responsible for making an announcement at least 1 hour from the time when such failures take place.
- Other cargo, as stipulated by the Minister of Finance.

The Customs electronic data processing system shall receive, examine, register, and handle electronic customs declarations 24 hours a day and 7 days a week.

The GVN issued Decree 8/2015/ND-CP, dated January 21, 2015, promulgating the implementation of the Law on Customs in detail regarding customs procedures, customs supervision, and inspection. Decree 8/2015 entered into force on March 15, 2015.

In order to implement the new Law on Customs, the Ministry of Finance (MOF) issued several recent Circulars, including:

- Circular 14/2015/TT-BTC, dated January 30, 2015, providing guidelines on the classification of goods, testing for goods classification; quality and safety testing for imported and exported goods.

- Circular 103/2015/TT-BTC, dated July 1, 2015, issuing the list of imported and exported goods.

- Circular 38/2015/TT-BTC, dated March 25, 2015, on customs procedures, customs supervision, inspection, export tax, import tax, and tax administration applied to exported and imported goods. The unofficial translation of Circular 38/2015/TT-BTC is available at: http://vasep.com.vn/Uploads/image/Ta-Van-Ha/file/38 2015 TT-BTC 250315 CP EN.doc.

Regarding food and agricultural products, Article 28 of Circular 38/2015 regulates the customs inspection process which includes a review of export and import licenses and the results of inspection by specialized agencies, such as inspection bodies under MOH, MARD, and MOIT. As most imported food and agricultural products are subject to both food safety inspection and animal or plant quarantine inspection, customs authorities shall verify the import license (if any); inspection results or notice of exemption from inspection sent by the specialized agency (MOH, MARD, or MOIT) or directly submitted to customs authorities by the importers.

Article 32 of Circular 38/2015 regulates the storage requirements for imported goods which are subject to quarantine or food safety inspection as follows:

Goods subject to quarantine

Quarantine (plant or animal health inspection) shall be carried out at the checkpoint. In cases where the quarantine authority permits the goods to be moved to an inland quarantine location, as prescribed by

law, the customs authority shall consider permitting the owner to move the goods to the quarantine location according to the confirmation of the authority on the Certificate of Quarantine Registration or the Note of Provisional Plant Quarantine Results (for plant-derived goods) or the Goods Transport Note (for aquaculture products) or other documents issued by the quarantine authority.

Goods subject to quality inspection and food safety inspection

Inspections shall be carried out at the checkpoint; if goods are moved to another location for inspection as requested by the specialized agency or the declarant wishes to put their goods into storage, the declarant shall make a written request. The Director of the Sub-Department of Customs where the customs declaration is registered shall consider permitting goods to be put into storage at an inland clearance depot (ICD), bonded warehouse, tax-suspension warehouse, and concentrated inspection places for exported or imported goods under the supervision of customs authorities; specialized inspection places, or the declarant's warehouse/depot.

Goods subject to both quarantine and food safety inspection

Procedures for putting goods into storage are similar to those for imported goods subject to quarantine.

Handling the results of inspection by a specialized agency

If the inspection result indicates that goods satisfy import requirements, the Sub-Department of Customs at the checkpoint will determine customs clearance of the goods as prescribed.

Section X: Copyright and/or Trademark Law

Copyright and trademarks are protected under the Intellectual Property Law and related legislation. The relevant Vietnam trademark authority is MOST's National Office of Intellectual Property of Vietnam (NOIP).

1. Laws on Intellectual Property (IPL)

- Law 50/2005/QH11 of November 29, 2005, on Intellectual Property (the English translation is available at http://www.wipo.int/wipolex/en/details.jsp?id=5005). This law stipulates copyright, copyright-related rights; industrial property rights; rights in plant varieties and for the protection of these rights. This law entered into force on July 1, 2006.

- Law 36/2009/QH12 of June 19, 2009, amending and supplementing a Number of Articles of the Law on Intellectual Property (the English translation is available at http://www.wipo.int/wipolex/en/details.jsp?id=6566). This law entered into force on January 1, 2010.

2. Related regulations on trade mark registration

- Decree 103/2006/ND-CP of September 22, 2006, detailing and guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property. The Decree makes detailed provisions and guidelines for implementing certain articles of the 2005 Intellectual Property Law concerning industrial property rights, including rights to trademarks, geographical

indications, industrial designs, and patents. The Decree entered into force on October 21, 2006 (see details at: <u>http://www.wipo.int/wipolex/en/details.jsp?id=5011</u>).

- Circular 1/2007/TT-BKHCN of February 14, 2007, guiding the Implementation of the Government's Decree 103/2006/ND-CP of September 22, 2006 detailing and guiding the Implementation of a Number of Articles of the Law on Intellectual Property Regarding Industrial Property. The Circular makes detailed provisions on the procedures for registration of industrial property rights. The Circular entered into force on May 6, 2007 (see details at: http://www.wipo.int/wipolex/en/details.jsp?id=5013).

- MOST's Circular 18/2011/TT-BKHCN of July 22, 2011, amending and supplementing several provisions of Circular 1/2007/TTBKHCN of February 14, 2007 on procedures for the registration of industrial property rights (see details at: <u>http://www.wipo.int/wipolex/en/details.jsp?id=14703</u>).

- Decree 97/2010/ND-CP of September 21, 2010, of the Government on Sanctioning of Administrative Violations in Industrial Property. This Decree specifies administrative violation acts in industrial property, sanctioning forms and levels, remedies; procedures for filing written requests for handling of violations; competence and procedures for settling written requests for handling of violations; in industrial property. The Decree entered into force on November 9, 2010 (see details at: http://www.wipo.int/wipolex/en/details.jsp?id=14608).

3. Procedures for registration of marks

Procedures for registration of marks are stipulated in detail in Circular 1/2007. Registration applicants must submit the following to NOIP:

- Declaration for registration;

- Documents, specimen, and information disclosing the industrial property object sought to be registered; for a mark registration application, the mark specimen and list of goods and services bearing the mark;

- Fee and charge receipts.

Each application may request registration of a mark used for one or more goods or services. In cases where any of the above documents are absent, NOIP may refuse to accept the application.

For an application for registration of a collective mark or certification mark, in addition to the above documents, the application must also contain the following documents:

- Rules on the use of the collective/certification mark;

- Explanation of particular characteristics and quality of the product bearing the mark (if the to-be registered mark is a collective mark used for a product with unique characteristics or a mark for certification of the quality of a product or a mark for certification of geographical origin).

If there are doubts about the validity of information supplied in an application, NOIP may request the applicant to submit the following documents within one month in order to certify such information:

• Documents proving the status of the applicant:

- Business registration certificate, contract, or another document certifying the applicant's goods production or service provision activities;

- Agreement or written certification that a manufacturer does not use the mark and does not oppose the mark registration by a person conducting commercial activities for the manufacturer's product;

- Establishment decision or license, or organization charter certifying the function and competence to manage a collective mark or a mark of certification of the quality or geographical origin of goods or services;

- Agreement, business registration certificate or documents related to the mark registration by coproprietors;

• Documents certifying that the applicant enjoys the right of mark registration from another person as prescribed;

- Written agreement or consent of the mark proprietor certifying the right of mark registration in the name of a representative or agent.

• Documents certifying the status of the application owner's representative: the applicant's original power of attorney; documents certifying that the application owner's representative is the legal representative of the organization registering the mark or his/her mandated person; papers certifying that the applicant's mandated person satisfies the requirements for acting as the application owner's representative.

• Documents evidencing the right to use/register a mark containing special symbols, for:

- Names, emblems, flags or armorial bearings of domestic or international agencies and organizations or certification, control or warranty hallmarks of international organizations;

- Names of characters or figures in publicly known works under copyright protection or trade names, trade indications, origin indications, prizes, medals or particular signs of a type of product, which may cause confusion;

- Signs covered by the protection of industrial property rights of other persons;

- Documents proving the right of priority;
- Information necessary for verification or affirmation of contents specified in the regulation on use of a collective mark or a certification mark or in other documents of the application.

APPENDICES

Appendix I. Government Regulatory Agency Contacts MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

International Cooperation Department (ICD)

(MARD) 2 Ngoc Ha Street, Hanoi, Tel: 84.24.38459670; Fax: 84.24.37330752 Contact: Mr. Tran Kim Long, Director General, Email: <u>htqt@mard.gov.vn</u>

Plant Protection Department (PPD)

149 Ho Dac Di, Hanoi Tel: 84.24.38519451 Fax: 84.24.35330043 Website: <u>www.ppd.gov.vn</u> Contact: Mr. Hoang Trung, Director General, Email: <u>hoangtrung.bvtv@mard.gov.vn</u>

Department of Animal Health (DAH)

15/78 Phuong Mai-Dong Da Hanoi Tel: 84.24.38696788; Fax: 84.24.38691311 Website: <u>www.cucthuy.gov.vn</u> Contact: Mr. Pham Van Dong, Director General Email: <u>TY@mard.gov.vn</u>;

DAH/Animal Quarantine Division

Tel: 84.24.38687151; Fax: 84.24.38686339 Contact: Nguyen Hoang Tung, Deputy Head of Animal Inspection Division

Directorate of Fisheries (DOF)

10 Nguyen Cong Hoan, Hanoi Tel: 84.24.37245371 ; Fax : 84.24.37245120 Email : <u>tcts@mard.gov.vn</u>

Department of Livestock Production (DLP)

16 Thuy Khue, Tay Ho, Ha Noi Tel: 84.24.37345443; Fax: 84.24.37345444 Contact: Mr. Hoang Thanh Van, Director General Email: <u>cn@mard.gov.vn</u>

National Agro-Forestry and Fishery Quality Assurance Department (NAFIQAD)

10 Nguyen Cong Hoan, Hanoi; Tel: 84.24.8354 966; Fax: 84.24.8317221 Contact: Mr. Nguyen Nhu Tiep, Director General Email: <u>nafiqad@mard.gov.vn</u>;

MINISTRY OF HEALTH (MOH)

Vietnam Food Administration (VFA) 138A Giang Vo, Hanoi Tel: 84.24. 38464489-38463702; Fax: 84.24.38463739 Email: <u>vfa@vfa.gov.vn</u>; Website: <u>www.vfa.gov.vn</u>; Contact: Mr. Nguyen Thanh Phong, Director General; Ms. Tran Viet Nga, Deputy General Director.

MINISTRY OF TRADE AND INDUSTRY (MOIT)

Department of Science and Technology 54 Hai Ba Trung, Hoan Kiem, Ha Noi Tel: 84.24. 22 202 222 Fax: 84.24.22 202525 Website: <u>www.moit.gov.vn</u> Email: <u>VKHCN@moit.gov.vn</u> Contact: Mr. Nguyen Phu Cuong, Director General

MINISTRY OF SCIENCE AND TECHNOLOGY

National Office of Intellectual Property of Vietnam (NOIP) 386 Nguyen Trai, Thanh Xuan, Hanoi; Tel: 84.24.3858 3069, 84.24.3858 3425; Fax: 84.24.3858 8449, 84.24.3858 4002 Website: <u>www.noip.gov.vn</u>

MINISTRY OF FINANCE

General Department of Vietnam Customs Block E3 - Duong Dinh Nghe street, Yen Hoa, Cau Giay, Hanoi Website: <u>https://www.customs.gov.vn/home.aspx?language=en-US</u>

Appendix II. Other Import Specialist Contacts

List of inspection bodies assigned by MARD

PPD/Plant Quarantine Sub-Department of Region I

2 Tran Quang Khai, Hai Phong Tel: 84.225.3821839; Fax: 84.225.3842593 Email: <u>kdtv1hp@yahoo.com</u> Management area: Hai Phong, Thai Binh, Hung Yen, Hai Duong, Quang Ninh

PPD/Plant Quarantine Sub-Department of Region II

28 Mac Dinh Chi, District 1, Ho Chi Minh City Tel: 84.28.38.251.401; Fax: 84.28.38.293.266 Email: <u>kdtvv2hcm@vnn.vn</u> Management area: Ho Chi Minh City, Ninh Thuan, Binh Thuan, Lam Dong, Binh Duong, Binh Phuoc, Tay Ninh, Dong Nai, Long An, Tien Giang, Ben Tre, Dong Thap, Ba Ria Vung Tau

PPD/Plant Quarantine Sub-Department of Region III

146 Hoang Dieu, Da Nang Tel: 84.511.3821622; Fax: 84.511.3873099 Email: <u>kdtv3@vnn.vn</u> Management area: Da Nang, Quang Tri, Thua Thien Hue, Quang Nam, Quang Ngai

PPD/Plant Quarantine Sub-Department of Region IV

66 Le Hong Phong, Quy Nhơn, Binh Đinh Tel: 84.256.3822964; Fax: 84.256.3822964 Management area: Binh Dinh, Phu Yen, Khanh Hoa, Kon Tum, Gia Lai, Daklak, Dak Nong

PPD/Plant Quarantine Sub-Department of Region V

149 Ho Dac Di, Dong Da, Hanoi Tel: 84.24.35.331302; Fax: 84.24.35332118 Email: <u>cckdtv5@fpt.vn</u> Management area: Ha Noi, Bac Ninh, Bac Giang, Vinh Phuc, Phu Tho, Ha Tay, Ninh Binh, Nam Dinh, Ha Nam, Hoa Binh, Son La

PPD/Plant Quarantine Sub-Department of Region VI

28 Tran Phu, Vinh city, Nghe An; Tel: 84.238.3837796; Email: <u>cckdtvv6@hn.vnn.vn</u> Management area: Nghe An, Thanh Hoa, Ha Tinh, Quang Binh

PPD/Plant Quarantine Sub-Department of Region VII

98B Ngo Quyen, Dong Kinh ward, Lang Son Tel: 84.205.3875797; Fax: 84.205.3875797 Email: <u>chicuckdtv7@gmail.com</u> Management area: Lang Son, Cao Bang, Bac Kan, Thai Nguyen

PPD/Plant Quarantine Sub-Department of Region VIII

7 Nguyen Hue, TP Lao Cai Tel: 84.214.3830503 Management area: Lao Cai, Ha Giang, Tuyen Quang, Yen Bai, Lai Chau, Dien Bien

PPD/Plant Quarantine Sub-Department of Region IX

386B Cach Mang Thang 8, Can Tho Tel: 84.292.3826709; Fax : 84.292.3828408 Email: <u>kdtvv9@hcm.vnn.vn</u> Management area: Hau Giang, An Giang, Kien Giang, Ca Mau, Bac Lieu, Tra Vinh, Soc Trang, Vinh Long

National Agro-Forestry and Fishery Quality Assurance Department - Branch I in Hai Phong 51 Le Lai, Ngo Quyen, Hai Phong Tel: 84.225.3837124; Fax: 84.225.3837507

E.mail: <u>branch1.nafi@mard.gov.vn</u>

National Agro-Forestry and Fishery Quality Assurance Department - Branch II in Da Nang 167-175 Chuong Duong, Ngu Hanh Son district, Da Nang Tel: 84. 236.3836155-3836761; Fax: 84.236.3836154 E.mail: <u>branch2.nafi@mard.gov.vn</u>

National Agro-Forestry and Fishery Quality Assurance Department - Branch III in Nha Trang

779 Le Hong Phong, Nha Trang, Khanh Hoa Province Tel: 84.258.3884812; Fax: 84.258.3884811 Email: <u>branch3.nafi@mard.gov.vn</u>

National Agro-Forestry and Fishery Quality Assurance Department - Branch IV in HCMC 30 Ham Nghi, Ben Nghe Ward District 1, Ho Chi Minh City Tel: 84.28.39146944; Fax: 84.28.39142161 Email: <u>branch4.nafi@mard.gov.vn</u>

National Agro-Forestry and Fishery Quality Assurance Department - Branch V in Ca Mau 171 Phan Ngoc Hien, Ward 6, Ca Mau Province Tel: 84.290.3838396 Email: <u>branch5.nafi@mard.gov.vn</u>

National Agro-Forestry and Fishery Quality Assurance Department - Branch VI in Can Tho 386C, Cach Mang Thang 8 street, Binh Thuy District, Can Tho Tel: 84.292.3883 257 Email: <u>branch6.nafi@mard.gov.vn</u>

Department of Animal Health /Regional Animal Health Office I Phuong Mai, Dong Da, Ha Noi Tel: 84.24.38686971; Fax: 84.24.38685390

Department of Animal Health /Regional Animal Health Office II 23 Da Nang, Ngo Quyen District, Hai Phong Tel: 84.225.3836304; Fax: 84.225.3551698

Department of Animal Health /Regional Animal Health Office III 51 Nguyen Sinh Sac, Vinh City, Nghe An Tel: 84.238.3854390; Fax: 84.238.3584159

Department of Animal Health /Regional Animal Health Office IV 12 Tran Quy Cap, Hai Chau district, Da Nang Tel: 84.236.3887714

Department of Animal Health /Regional Animal Health Office V Buon Ma Thuat, Dak Lak Tel: 84. 262.3877795

Department of Animal Health /Regional Animal Health Office VI 521/1 Hoang Van Thu, Tan Binh District, Ho Chi Minh City Tel: 84.28.39830722; Fax: 84.28.38569050

Department of Animal Health /Regional Animal Health Office VII 88 Cach Mang Thang 8, Can Tho

Tel: 84.292.3767048

List of Food Safety Inspection Bodies assigned by MOH and MOIT (as of December 2017)

No.	Institute	Assigned by MOH	Assigned by MOIT	•
1	National Institute of Nutrition	х	х	
	48 Tang Bat Ho, Hanoi			
	Tel: (84-24) 3971 7090			
	Email: <u>ninvietnam@viendinhduong.vn</u>			
2	National Institute for Food Control (NIFC)	х	х	
	65 Pham Than Duat, Hanoi			
	Tel: (84-24) 3933 5741			
	Email: vienkiemnghiem@moh.gov.vn			
3	Pasteur Institute in Nha Trang	х		
	8-10 Tran Phu, Nha Trang City			
	Tel: (84-258) 3822 406			
	Email: <u>info@ipn.org.vn</u>			
4	Pasteur Institute in Ho Chi Minh City	х		
	167 Pasteur, Ward 8, District 3, Ho Chi Minh City			
	Tel: (84-28) 3823 0352			
	Email: pasteur@pasteur-hcm.org.vn			
	Website: <u>www.pasteurhcm.gov.vn</u>			
5	Institute of Public Health in Ho Chi Minh City	x	х	
	159 Hung Phu, Ward 8, District 8, Ho Chi Minh City			
	Tel: (84-28) 3855 9503			
	Email: <u>vienytcc@iph.org.vn</u>			
6	Quality Assurance and Testing Centre 1 (QUATEST1)	х	x	
	8 Hoang Quoc Viet, Hanoi			
	Tel: (84-24) 3836 1399			
	Email: <u>contact@quatest1.com.vn</u>			
7	Quality Assurance and Testing Centre 2 (QUATEST2)	х	х	

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No.	Institute	Assigned by MOH	Assigned by MOIT	-
	02 Ngo Quyen, Da Nang			
	Tel: (84-23) 6383 3009			
	Email: <u>quatest2@quatest2.com.vn</u>			
8	Quality Assurance and Testing Centre 3 (QUATEST3)	х	х	
	49 Pasteur street, District 1, Ho Chi Minh City			
	Tel: (84-28) 3829 4274			
	Email: info@quatest3.com.vn			
9	Hai Phong Preventive Medicine Centre	X	х	
	21 Le Dai Hanh street, Minh Khai, Hong Bang, Hai			
	Phong city, Vietnam			
	Tel: (84-22) 5382 1247			
10	Da Nang Preventive Medicine Centre	х	x	
	315 Phan Chu Trinh street, Hai Chau, Da Nang City			
	Tel: (84-23) 6382 1469			
	Email: <u>khoaxetnghiemnk@gmail.com</u>			
11	Ho Chi Minh City Branch of Vinacontrol	х	х	
	80 Ba Huyen Thanh Quan street, District 3, Ho Chi Minh City			
	Tel: (84-28) 3931 6323			
	Email : vinahochiminh@vinacontrol.com.vn			
12	Quang Tri Preventive Medicine Centre		x	
	Hoang Dieu street, Dong Ha city, Quang Tri Province			
	Tel: (84-233) 852 582			
13	VinaControl Certification Joint Stock Company		x	
	54 Tran Nhan Tong street, Hanoi			
	Tel: (84-24) 3943 3840			
14	Tay Ninh Preventive Medicine Centre	Х		
	628 Lane 30/4, Block 1, Ward 3, Tay Ninh town, Tay Ninh			
	Tel: (84-276) 3822 474			

No.	Institute	Assigned by MOH	Assigned by MOIT	•
15	Tay Nguyen Institute of Hygiene and Epidemiology	Х		
	34 Pham Hung, Tan An, Buon Ma Thuot, Dak Lak			
	Tel: (84-262) 366 3979			
	Email: <u>info@tihe.org.vn</u>			
	Website: http://tihe.org.vn			

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