The Government Decree No 38/2012/N• -CP: Regulating in detail the implementation of a number of articles of the Law on Food Safety

THE GOVERNMENT

THE SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness

No: 38/2012/N• -CP

Ha Noi, 25^{th} April 2012

DECREE

Regulating in detail the implementation of a number of articles of the Law on Food Safety

Pursuant to the Law on Government Organisation dated 25 December 2001;

Pursuant to the Law on Food Safety dated 17 June 2010;

Pursuant to the Law on Standards and Regulated Technical Standards dated 29 June 2006;

Pursuant to the Law on Quality of Products and Goods dated 21 November 2007;

At the proposal by the Minister of Public Health,

The Government promulgates the Decree regulating in detail the implementation of a number of articles of the Law on Food Safety.

Chapter I

GENERAL PROVISIONS

Article 1. Governing Scope

This decree regulates in detail the implementation of a number of articles of the Law on Food Safety, including the provisions for:

- 1. Announcement of conformity or announcement of compliance to regulations on food safety.
- 2. Safety requirements for genetically modified foods.
- 3. Granting and revoking Certificates of satisfaction of food safety requirements for food establishments.
- 4. State inspection on food safety of imported and exported foods.

- 5. Labelling of foods.
- 6. Assignment of responsibilities for state management of food safety:
 - a) Responsibilities for state management of food safety by the Ministry of Public Health;
 - b) Responsibilities for state management of food safety by the Ministry of Agriculture and Rural Development;
 - c) Responsibilities for state management of food safety by the Ministry of Industry and Trade;
 - d) Responsibilities for state management of food safety by the People's Committees at all government levels.
 - e) Coordination among line ministries in implementing functions of state management of food safety.
- 7. Sector-specific specialised inspection on food safety.

Article 2. Applicable Entities

This decree applies to Vietnamese agencies, organisations, and individuals; foreign individuals, and organisations operating in Vietnam that engage in the production and trading of foods; organisations, and individuals that engage in activities related to food safety in Vietnam (hereinafter referred to as organisations, and individuals).

Chapter II

ANNOUNCEMENTS OF CONFORMITY TO REGULATED TECHNICAL STANDARDS AND ANNOUNCEMENTS OF COMPLIANCE WITH FOOD SAFETY REGULATIONS

Article 3. Announcements of conformity to regulated technical standards and announcements of compliance with food safety regulations

- Pre-packaged processed foods; food additives; substances used as food processing aids; utensils, packaging materials, and food containers (hereinafter referred to as products) whose regulated technical standards have been provided for shall be announced to conform to those standards; and announcements of conformity shall be filed with authorised government agencies prior to the products being put into circulation.
- 2. Those products whose regulated technical standards have not yet been provided for shall be announced to comply with food safety regulations, and announcements of compliance with food safety regulations shall be filed with authorised government agencies prior to the

products being put into circulation until relevant regulated technical standards are adopted and come into effect.

Article 4. Receiving announcements of conformity to regulated technical standards and announcements of compliance with food safety regulations

- The Ministry of Public Health shall be responsible for the logistics of receiving and managing announcements of conformity to regulated technical standards and announcements of compliance with food safety regulations filed by organisations, and individuals that manufacture and trade products including: functional foods; food additives; substances used as food processing aids; pre-packaged and processed imported food products; utensils, packaging materials, and food containers.
- 2. Provincial/Municipal Departments of Public Health shall be responsible for the logistics of receiving and managing announcements of conformity to regulated technical standards and announcements of compliance with food safety regulations for domestically made products filed by the products' manufacturers and traders located in the localities, except for the products stipulated in Clause 1 of this Article.
- 3. Within 7 business days of receiving adequately appropriate documents, the authorised government agency shall grant the Receipt of Announcement of Conformity to regulated technical standards to the application for the Announcement of Conformity to regulated technical standards, specified as Form No 01a in the appendices to this Decree; in case of refusal to grant a Receipt, the authorised government agency shall explain in writing the reason(s) for such refusal.
- 4. Within 15 business days of receiving adequately appropriate documents, the authorised government agency shall grant the Certificate of Announcement of Compliance with food safety regulations to the application for the Announcement of Compliance with food safety regulations, specified as Form No 01b in the appendices to this Decree; in case of refusal to grant a Certificate, the authorised government agency shall explain in writing the reason(s) for such refusal.
- 5. Within 30 business days of receiving adequately appropriate documents, the authorised government agency shall grant the Certificate of Announcement of Compliance with food safety regulations to the application for the Announcement of Compliance with food safety regulations for functional foods, and foods enriched with micro-nutrients, specified as Form No 01b in the appendices to this Decree; in case of refusal to grant a Certificate, the authorised government agency shall explain in writing the reason(s) for such refusal.
- 6. The agencies that receive announcements of conformity to regulated technical standards or announcements of compliance with food safety regulations shall be responsible for publicising, on their websites and in other mass media upon request, the products for which Receipts of Announcement of Conformity to regulated technical standards or Certificates of Announcement of Compliance with food safety regulations have been adopted.

Periodically every month, Provincial/Municipal Health Departments shall report to the Ministry of Public Health the results of receiving and managing announcements of conformity to regulated technical standards and announcements of compliance with food safety regulations.

Article 5. Documents required for announcements of conformity for products whose regulated technical standards have been provided for

- 1. For an announcement of conformity based on conformity certification by a designated certifier (the third party), the application shall include:
 - a) Announcement of conformity to regulated technical standards specified as Form No 02 in the appendices to this Decree;
 - b) Product specifications specified as Form No 03a or Form 03c in the appendices to this Decree (with a stamp superimposed on overlapping pages by the third party);
 - c) Certificate of conformity issued by the third party (a notarised copy, or a copy accompanied by the original for verification);
 - d) Certificate of conformity to HACCP standards or ISO 22000 or equivalent where the organisations or individuals manufacturing the product(s) have a quality control system that has been certified to conform to HACCP standards or ISO 22000 or equivalent (a notarised copy, or a copy accompanied by the original for verification).
- 2. For an announcement of conformity based on conformity self-assessment by organisations, and individuals that manufacture and trade foods (the first party), the application shall include:
 - a) Announcement of conformity to regulated technical standards specified as Form No 02 in the appendices to this Decree;
 - b) Product specifications specified as Form No 03a or Form No 03c in the appendices to this Decree;
 - c) 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 authorised government agency or a recognised independent testing lab (the original or a notarised copy); or a testing lab from the country of origin recognised by an authorised agency in Vietnam (the original, a notarised copy, or a consular legalised copy).
 - d) Quality control plan that is developed and executed based on the format specified as Form No 04 in the appendices to this Decree (the first party's authentication);
 - •) Periodic monitoring plan (the first party's authentication);
 - e) Report of Conformity Assessment (the first party's authentication);

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

Article 6. Documents required for announcements of compliance with food safety regulations for products whose regulated technical standards have not yet been provided for

- 1. For imported products (except for functional foods, and foods enriched with micro-nutrients), the application shall include:
 - a) Announcement of compliance with food safety regulations specified as Form No 02 in the appendices to this Decree;
 - b) Product specifications specified as Form No 03a or Form No 03c in the appendices to this Decree;
 - c) Product testing results in the most recent 12 months, including the major quality criteria, and safety criteria; issued by the following agencies: a testing lab designated by an authorised government agency or a recognised independent testing lab (the original or a notarised copy); or a testing lab from the country of origin recognised by an authorised agency in Vietnam (the original, a notarised copy, or a consular legalised copy).
 - d) Periodic monitoring plan (authenticated by the organisation or individual);
 - •) Sample of the product label as circulated in the country of origin and the supplementary label in Vietnamese (authenticated by the organisation or individual).
 - e) Sample of the finished product for products that are imported into Vietnam for the first time for verification when the application is filed;
 - g) Business registration certificate with a licence in food business or a certificate of legal entity for food importers (copies authenticated by the organisation or individual);
 - h) 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 organisation or individual);
 - i) Certificate of conformity to HACCP standards or ISO 22000 or equivalent where the organisations or individuals manufacturing the product(s) have a quality control system that has been certified to conform to HACCP standards or ISO 22000 or equivalent (a notarised copy, or a copy accompanied with the original for verification).
- 2. For domestically made products (except for functional foods and foods enriched with micronutrients), the application shall include:
 - a) Announcement of compliance with food safety regulations specified as Form No 02 in the appendices to this Decree;

- b) Product specifications specified as Form No 03a or Form No 03c in the appendices to this Decree:
- c) Product testing results in the most recent 12 months, including the major quality criteria, and safety criteria, issued by a testing lab designated by an authorised government agency or a recognised independent testing lab (the original or a notarised copy);
- d) Quality control plan that is developed and executed based on the format specified as Form No 04 in the appendices to this Decree (authenticated by the organisation or individual);
- •) Periodic monitoring plan (authenticated by the organisation or individual);
- e) Sample of the product label (authenticated by the organisation or individual).
- g) Business registration certificate with a licence in food business or a certificate of legal entity for organisations or individuals (copies authenticated by the organisation or individual);
- h) Certificate of satisfaction of food safety requirements for the establishments that are legally required to be certified to satisfy food safety requirements (copies authenticated by the organisation or individual);
- i) Certificate of conformity to HACCP standards or ISO 22000 or equivalent where the organisations or individuals manufacturing the product(s) have a quality control system that has been certified to conform to HACCP standards or ISO 22000 or equivalent (a notarised copy, or a copy accompanied with the original for verification).
- 3. For imported functional foods, and imported foods enriched with micro-nutrients, the application shall include:
 - a) Announcement of compliance with food safety regulations specified as Form No 02 in the appendices to this Decree;
 - b) Product specifications specified as Form No 03b in the appendices to this Decree (with a stamp superimposed on overlapping pages by the organisation or individual);
 - c) Certificate of permission to circulate, or public health certificate, or equivalent certificate granted by an authorised 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, or a notarised copy, or a consular legalised copy);
 - d) Product testing results in the most recent 12 months, including the major quality criteria, and safety criteria; issued by the following agencies: a testing lab designated by an authorised government agency or a recognised independent testing lab (the original or a notarised copy); or a testing lab from the country of origin recognised by an authorised agency in Vietnam (the original, a notarised copy, or a consular legalised copy).
 - •) Periodic monitoring plan (authenticated by the organisation or individual);

- e) Sample of the product label as circulated in the country of origin and the supplementary label in Vietnamese (authenticated by the organisation or individual).
- g) Sample of the finished product for verification when the application is filed;
- h) Business registration certificate with a licence in food business or a certificate of legal entity for food importers (copies authenticated by the organisation or individual);
- i) 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 organisation or individual);
- k) Certificate of conformity to HACCP standards or ISO 22000 or equivalent where the organisations or individuals manufacturing the product(s) have a quality control system that has been certified to conform to HACCP standards or ISO 22000 or equivalent (a notarised copy, or a copy accompanied with the original for verification);
- Scientific information and documents proving the effect(s) of each ingredient that helps generate the announced functions (copies authenticated by the organisation or individual).
- 4. For domestically made functional foods, and domestically made foods enriched with micronutrients, the application shall include:
 - a) Announcement of compliance with food safety regulations specified as Form No 02 in the appendices to this Decree;
 - b) Product specifications specified as Form No 03b in the appendices to this Decree (with a stamp superimposed on overlapping pages by the organisation or individual);
 - c) Product testing results in the most recent 12 months, including the major quality criteria, and safety criteria, issued by a testing lab designated by an authorised government agency or a recognised independent testing lab (the original or a notarised copy);
 - d) Sample of the product label (authenticated by the organisation or individual);
 - •) Sample of the finished product for verification when the application is filed;
 - e) Business registration certificate with a licence in food business or a certificate of legal entity for organisations or individuals (copies authenticated by the organisation or individual);
 - g) Certificate of satisfaction of food safety requirements for the establishments that are legally required to be certified to satisfy food safety requirements (copies authenticated by the organisation or individual);
 - h) Certificate of conformity to HACCP standards or ISO 22000 or equivalent where the organisations or individuals manufacturing the product(s) have a quality control system

- that has been certified to conform to HACCP standards or ISO 22000 or equivalent (a notarised copy, or a copy accompanied with the original for verification);
- Scientific information and documents proving the effect(s) of each ingredient that helps generate the announced functions (copies authenticated by the organisation or individual);
- k) Report on testing the efficiency of the food product's uses for products circulated in the market for the first time (a notarised copy, or a copy accompanied with the original for verification);
- Quality control plan that is developed and executed based on the format specified as Form No 04 in the appendices to this Decree (authenticated by the organisation or individual);
- m) Periodic monitoring plan (authenticated by the organisation or individual);

Article 7. Filing an application for announcement of conformity to regulated technical standards or announcement of compliance with food safety regulations

- 1. An application for announcement of conformity to regulated technical standards or announcement of compliance with food safety regulations shall be prepared as follows:
 - a) General legal documents, which shall be made into 01 book, include:
 - Business registration certificate with a licence in food business or a certificate of legal entity for organisations or individuals (copies authenticated by the organisation or individual);
 - Certificate of satisfaction of food safety requirements for the establishments that are legally required to be certified to satisfy food safety requirements (copies authenticated by the organisation or individual);
 - Certificate of conformity to HACCP standards or ISO 22000 or equivalent where the organisations or individuals have a quality control system that has been certified to conform to HACCP standards or ISO 22000 or equivalent (a notarised copy, or a copy accompanied with the original for verification).
 - b) Documents for announcement of conformity to regulated technical standards or announcement of compliance with food safety regulations for the product shall be made into 02 books, including those documents listed in Article 5, and Article 6 of this Decree, except for those listed in Item a of Clause 1 of this Article.
- 2. The organisation or individual that manufactures or trades the product(s) shall file the application for announcement of conformity to regulated technical standards or announcement of compliance with food safety regulations directly with authorised government agencies under the Ministry of Public Health and Provincial/Municipal Departments of Public Health or by mail.

Those food manufacturers and traders that file an application for announcement of
conformity to regulated technical standards or announcement of compliance with food safety
regulations for the second product or more shall submit only one set of general legal
documents.

Article 8. Re-granting Receipts of Announcement of Conformity to regulated technical standards and Certificates of Announcement of Compliance with food safety regulations

- In the absence of changes in the process of producing and processing foods that affect quality criteria, and violate the announced limits of food safety, the organisation or individual that manufactures or trades foods shall undertake periodic re-registration for Announcement of Conformity to regulated technical standards and Announcement of Compliance with food safety regulations:
 - a) 05 years for food products by those establishments that have one of the certificates of advanced quality control systems: HACCP, ISO 22000 or equivalent;
 - b) 03 years for food products by those establishments that do not have the aforementioned certificates.
- 2. Re-registration for Announcement of conformity to regulated technical standards and Announcement of compliance with food safety regulations shall be done at the same authorised government agency that granted the Receipt of Announcement of Conformity to regulated technical standards and Certificate of Announcement of Compliance with food safety regulations for the product for the first time.
- 3. The application for re-granting Receipt of Announcement of Conformity to regulated technical standards or Certificate of Announcement of Compliance with food safety regulations shall include:
 - a) Application form for re-granting Receipt of Announcement of Conformity to regulated technical standards or Certificate of Announcement of Compliance with food safety regulations, specified as Form No 05 in the appendices to this Decree (authenticated by the organisation or individual);
 - b) The most recent Receipt of Announcement of Conformity to regulated technical standards or Certificate of Announcement of Compliance with food safety regulations (copy);
 - c) Periodic product testing results by a recognised testing lab designated by an authorised government agency (a notarised copy, or a copy accompanied with the original for verification):
 - Once per year for those establishments that have one of the certificates of advanced quality control systems: GMP, HACCP, ISO 22000 or equivalent;

- -Twice per year for those establishments that do not have the aforementioned certificates.
- d) Certificate of conformity to HACCP standards or ISO 22000 or equivalent where the organisation or individual has a quality control system that has been certified to conform to HACCP standards or ISO 22000 or equivalent (a notarised copy, or a copy accompanied with the original for verification);
- 4. Within 7 business days of receiving the application, the authorised government agency shall re-grant Receipt of Announcement of Conformity to regulated technical standards or Certificate of Announcement of Compliance with food safety regulations; in case of refusal to re-grant the Receipt/Certificate, the authorised government agency shall explain in writing the reason(s) for such refusal.
- 5. If there is any change in the process of producing and processing foods that affects quality criteria, and violates the announced limits of food safety, the organisation or individual that manufactures or trades foods shall re-register for Announcement of Conformity to regulated technical standards and Announcement of Compliance with food safety regulations with authorised government agencies in accordance with Articles 4, 5 and 6 of this Decree.

Article 9. Stamps of conformity to regulated technical standards for products

Products specified in Clause 1 of Article 3 of this Decree will be given stamps of conformity to regulated technical standards in accordance with laws on standards and regulated technical standards after authorised government agencies have received their announcements of conformity.

The use of stamps of conformity shall be in compliance with Item c of Clause 1 of Article 49 of the Law on Standards and Regulated Technical Standards, and Article 15 of Decree No 127/2007/N• -CP dated 01 August 2007 regulating in detail the implementation of a number of articles of the Law on Standards and Regulated Technical Standards.

Chapter III

SAFETY REQUIREMENTS FOR GENETICALLY MODIFIED FOODS

Article 10. Safety requirements for foods whose ingredients include genetically modified organisms (GMO), and GMO products

1. Regulations on eligibility for a GMO to be certified as safe for food production; the process and procedures of granting and revoking certificates of satisfaction of food safety requirements; the list of GMOs certified as such shall be in compliance with Section 1, Chapter VI of Decree No 69/2010/N• -CP dated 21 June 2010 on bio-safety for GMOs, genetic samples, and GMO products.

2. The Minister of Agriculture and Rural Development shall be responsible for granting and revoking certificates of satisfaction of food safety requirements for GMOs; developing and publicising the list of GMOs that have been certified as safe for food production; establishing the Committee of Safety of GMOs and GMO products used as foods, and specifying the functions, duties and operational mechanisms of the Committee.

Article 11. Labelling of goods containing GMOs, and GMO products used as foods

- 1. Those organisations and individuals that market foods containing GMOs that account for more than 5 percent of each ingredient, in addition to compliance with laws and regulations on goods labelling, shall provide GMO-related information on labels of the goods.
- 2. The Ministry of Agriculture and Rural Development, in coordination with the Ministry of Science and Technology, shall take charge of providing detailed guidelines on the labelling of foods containing GMOs, and GMO products.

Chapter IV

GRANTING AND REVOKING CERTIFICATES OF SATISFACTION OF FOOD SAFETY REQUIREMENTS FOR FOOD ESTABLISHMENTS

Article 12. Granting certificates of satisfaction of food safety requirements for food establishments

- Certificates of satisfaction of food safety requirements for food establishments shall be granted for each individual establishment that manufactures or trades foods; each independent plant at one location (hereinafter referred to as establishments), except the following:
 - a) Small-scale food producers at the initial phase;
 - b) Small-scale food retailers;
 - c) Street food vendors;
 - d) Establishments selling pre-packaged foods that are not legally required to meet special storage conditions.
- 2. The Minister of Public Health, the Minister of Agriculture and Rural Development, and the Minister of Industry and Trade shall specify the authority of granting and revoking certificates of satisfaction of food safety requirements for food establishments within the scope of their responsibilities as assigned in Articles 62, 63, and 64 of the Law on Food Safety and this Decree, and shall specify regulations governing the establishments listed at Items a, b, c and d of Clause 1 of this Article.

Article 13. Revoking certificates of satisfaction of food safety requirements for food establishments

Food establishments shall have their certificates of satisfaction of food safety requirements revoked in the following cases:

- 1. An establishment has no operations in their registered food line of business;
- 2. There is a ruling by an authorised government agency to change the line of business at a previous establishment.
- 3. An establishment shall be denied the right to use their certificate as a result of legal sanction(s) for administrative violations against food safety.

Chapter V

STATE INSPECTION ON FOOD SAFETY OF IMPORTED AND EXPORTED FOODS

Article 14. Inspection of imported foods

- 1. All kinds of imported foods, food raw materials, food additives, substances used as processing aids, utensils, packaging materials, and food containers, upon being imported into Vietnam, shall be inspected by authorised government agencies designated by the line ministries, except for the cases specified in Clause 2 of this Article.
- 2. The following cases of imported foods shall be exempted from state inspection on food safety:
 - a) Foods that accompany passengers for personal use and are within the duty-free limit;
 - b) Foods transported in diplomatic bags and consular bags;
 - c) Foods in transit or transfer;
 - d) Foods placed in bonded warehouses;
 - •) Foods used as samples for tests or research;
 - e) Foods used for display as samples at trade fairs and expositions.
- 3. The Ministry of Public Health shall be responsible for inspection and issuing inspection reports for import shipments containing various kinds of foods that are within the scope of authority of two or more ministries.

The Ministry of Agriculture and Rural Development shall be responsible for inspection and issuing inspection reports for import shipments containing various kinds of foods that are within the scope of authority of two or more ministries, and include raw and fresh foods.

Article 15. State inspection on food safety at exporting countries

1. In case of assessment for the purpose of mutual recognition, relevant authorised government agencies from Vietnam shall develop inspection plans, notify, and coordinate with relevant authorities from the exporting country to inspect food safety control system(s) of the

exporting country, and of the manufacturers and traders exporting foods to Vietnam in accordance with international treaties to which the Socialist Republic of Vietnam is a party:

- a) The relevant authorities from the exporting country shall send registration files to the relevant line ministries in Vietnam;
- b) Within 30 business days of receiving from the relevant authorities from the exporting country adequate registration files listing food exporters to Vietnam, authorised government agencies of the relevant line ministries shall review the files, and notify the relevant authorities from the exporting country of the review reports and the inspection plan in case inspection is deemed needed for foods to be imported into Vietnam from the exporting country.
- 2. The relevant authorities from the exporting country shall send 01 set of registration files to the relevant authorities in Vietnam: the Ministry of Public Health, or the Ministry of Agriculture and Rural Development, or the Ministry of Industry and Trade, including:
 - a) A register of food manufacturers and traders exporting to Vietnam, specified as Form No 06 in the appendices to this Decree;
 - b) Information on the system of food safety management and the capacities of food safety control of the relevant authorities from the exporting country, specified as Form No 07 in the appendices to this Decree;
 - c) Brief information on the conditions to ensure food safety of the said food manufacturers and traders exporting to Vietnam, specified as Form No 08 in the appendices to this Decree.

Article 16. State inspection on food safety of exported foods

- 1. The Minister of Public Health, the Minister of Agriculture and Rural Development, and the Minister of Industry and Trade shall specify the authority of state inspection on food safety of exported foods within the scope of their responsibilities as assigned in Articles 62, 63, and 64 of the Law on Food Safety.
- 2. The Ministry of Agriculture and Rural Development shall be responsible for inspection of export shipments containing various kinds of foods that are within the scope of authority of two or more ministries.

CHAPTER VI

LABELING OF FOODS

Article 17. Showing shelf-life on food labels

1. The mandatory shelf-life labelling shall show "Expiry Date," or "Use by Date" on labels of functional foods, food supplements, health-protecting foods, medical nutrient foods, foods

enriched with micro-nutrients, and perishable foods likely to be spoiled by microorganisms. The shelf-life labelling for other foods may show "Best Before Date" as deemed appropriate for the types of foods.

- 2. Foods labelled with "Expiry Date," or "Use by Date" shall not be marketed after the date.
- 3. Foods labelled with "Best Before Date" shall still be marketed after the date if the manufacturers can prove the safety of the foods to the relevant authorised government agencies, and the labels shall show clearly their shelf-life as either "Expiry Date," or "Use by Date". Only the food manufacturers can extend the shelf-life of their food products, and the maximum extended shelf-life shall not exceed the original shelf-life.

Article 18. Mandatory contents shown on labels

- 1. Pre-packaged foods shall be labelled in accordance with laws and regulations on labelling of foods.
- 2. Depending on each type of pre-packaged foods, in addition to provisions in Clause 1 of this Article, the mandatory contents shown on labels shall comply with the following provisions:
 - a) The information on the label shall be true as to the nature of the product, honest, accurate, clearly legible, and shall not mislead consumers;
 - b) Labels of functional foods, and foods enriched with micro-nutrients shall show the following main contents: nutrition ingredients; bioactive compounds; health effects; intended users, dosage, administration, and precautions if any;
 - c) Labels of medical nutrient foods, and foods supplemented with vitamins, minerals, and micro-nutrients that are not recommended for the general public such as nutritional formulas for pregnant women, nutritional formulas for infants younger than 36 months, and foods for syringe feeding shall declare the levels needed to meet nutritional demand, dosage for each intended user and instructions by physicians.
 - d) Labels of functional foods, foods enriched with micro-nutrients, food additives, and some genetically modified foods (which are required to be labelled in accordance with laws and regulations on labelling on genetically modified foods) shall clearly show the ingredients and their contents in the foods;
 - •) When the product is named after any of the ingredients of the product, the contents of that ingredient shall be clearly shown next to the product name;
 - e) The product name shall be shown in the largest and clearest font size and it shall be at least 3 times larger than the other font sizes used on the label.
 - g) A translated label shall have the contents as the original label does.
- 3) The Ministry of Public Health, in coordination with the Ministry of Agriculture and Rural Development and the Ministry of Industry and Trade, shall take charge of providing detailed guidelines on the labelling of foods.

Chapter VII

ASSIGNING OF RESPONSIBILITIES FOR STATE MANAGEMENT OF FOOD SAFETY

Article 19. Principles of assigning responsibilities for state management of food safety

- 1. On the basis of the provisions of the Law on Food Safety and in compliance with the existing legislations.
- 2. On the basis of uniform state management of food safety.
- 3. Ensuring regulation throughout the entire process of manufacturing and trading foods.
- 4. Close coordination among line ministries.
- 5. Ensuring the "one-stop" principle in which each product, each manufacturer, or each trader shall be regulated by only one government authority.
- 6. Ensuring that it shall be scientific, thorough, and feasible.
- 7. Decentralisation of state management of food safety among the central government and the local governments at all levels.
- 8. During the process of state management, should any issue arise with indistinguishable responsibilities among ministries, the Ministry of Public Health, in coordination with the Ministry of Agriculture and Rural Development and the Ministry of Industry and Trade, shall take charge of developing an Inter-ministerial Circular to provide detailed guidelines.

Article 20. Responsibilities for state management of food safety by the Ministry of Public Health

- 1. The Ministry of Public Health shall be accountable to the Government for performing uniform state management of food safety.
- 2. Within the scope of its duties and authority, the Ministry of Public Health shall be responsible for:
 - a) Implementing the provisions of general responsibilities for state management of food safety stipulated at Clause 1 of Article 62 of the Law on Food Safety;
 - Providing the Government with periodic and extraordinary reports on state management of food safety, on the basis of supervision over and consolidation of reports of other line ministries;
 - c) Appraising and developing the plan and roadmap for developing and reviewing national regulated technical standards for all kinds of foods, food additives, substances used as processing aids, utensils, packaging materials, and food containers in accordance to state management requirements and in line with the social-economic development in each period;

- d) Taking charge of developing national regulated technical standards for the products within the scope of its state management responsibilities as assigned in Article 62 of the Law on Food Safety; promulgating national regulated technical standards or regulations on safety criteria and safety limits for all food products, food additives, substances used as processing aids, utensils, packaging materials, and food containers;
- •) Designating authorised agencies to certify conformity to regulated technical standards for food products, food additives, substances used as processing aids, utensils, packaging materials, and food containers whose regulated technical standards have been provided for on the basis of consultation with line ministries when necessary;
- e) Regulating food safety throughout the entire process of production, preliminary processing, food processing, storage, transportation, export, import, and trading of food additives, substances used as processing aids, bottled water, natural mineral water, functional foods, foods enriched with micro-nutrients, utensils, packaging materials and food containers;
- g) Providing detailed regulations on functional foods, food additives and food enriched with micro-nutrients;
- h) Organising the granting of Receipts of Announcements of Conformity to regulated technical standards, Certificates of Announcements of Compliance with food safety regulations, and Certificates of contents of food advertisements for foods within the scope of its assigned state management responsibilities.
- Organising and decentralising the granting of certificates of satisfaction of food safety requirements for organisations and individuals that manufacture and trade products within the scope of its state management responsibilities as assigned in Item e of Clause 2 of this Article;
- k) Granting public health certificates for foods; food additives; substances used as processing aids, utensils; packaging materials, and food containers at the request of organisations or individuals;
- Stipulating requirements for testing labs, designating authorised agencies to conduct food testing for the purpose of state management within the scope of its responsibilities; designating authorised agencies to undertake food testing for the purpose of arbitration, and to make final rulings when there are discrepancies between testing results done by testing agencies affiliated to and not affiliated to the Ministry of Public Health;
- m) Stipulating food safety requirements for collective kitchens, hotels, resorts, restaurants, and catering establishments.
- n) Designating authorised agencies to conduct state inspection on food safety of imported food products within the scope of its state management responsibilities as assigned in Item e of Clause 2 of this Article, and Clause 3 of Article 14 of this Decree.

Article 21. Responsibilities for state management of food safety by the Ministry of Agriculture and Rural Development

- 1. Coordinating in the development of national regulated technical standards for food products
- 2. Regulating food safety for the preliminary production of agricultural, forestry, and aquatic products, and of salt, including cultivation, animal husbandry, harvesting, fishing, exploitation of agricultural, forestry, and aquatic products; and salt production.
- 3. Regulating food safety throughout the entire process of production, collection, slaughtering, preliminary processing, processing, storage, transportation, export, import, and trading of grains; meat and meat products; aquatic living creatures and aquatic products; vegetables, tubers, fruits, and products made from vegetables, tubers, fruits; egg and egg products; fresh raw milk; honey and honey products; genetically modified foods; salt; spices; sugar; tea; coffee; cacao; black pepper; cashew nuts and other agricultural food products; utensils, packaging materials, and food containers within the scope of its assigned state management responsibilities.
- 4. Organising the granting of Certificates of contents of food advertisements for foods within the scope of its assigned state management responsibilities. The certification of contents of advertisements for foods claimed to have health effects shall seek advice from the Ministry of Public Health.
- 5. Organising and decentralising the granting of certificates of satisfaction of food safety requirements for organisations and individuals that manufacture and trade products within the scope of its responsibilities as assigned in Clauses 2, 3, and 7 of this Article.
- 6. Developing and promulgating regulations on food safety requirements for establishments engaging in the production, preliminary processing, processing, and trading of food products within the scope of its responsibilities as assigned in Clause 3 of this Article, on the basis of regulations by the Ministry of Public Health on general food safety requirements for food manufacturers and traders.
- 7. Regulating food safety for wholesale and auction markets of agricultural products.
- 8. Stipulating requirements for testing labs; designating authorised testing agencies and testing agencies for verification; communicating testing results for foods within the scope of its assigned state management responsibilities.
- 9. Designating authorised agencies to conduct state inspection on food safety of imported food products within the scope of its responsibilities as assigned in Clause 3 of this Article, and Clause 3 of Article 14 of this Decree.

Article 22. Responsibilities for state management of food safety by the Ministry of Industry and Trade

1. Coordinating in the development of national regulated technical standards for food products

- 2. Regulating food safety throughout the entire process of production, processing, storage, transportation, export, import, and trading of wines and alcohols, beers, soft drinks, processed milk, vegetable oil, processed flour and starch, bakery products, confectionary, candies and sweets, packages and containers within the scope of its state management responsibilities.
- 3. Organising the granting of Certificates of contents of food advertisements for foods within the scope of its assigned state management responsibilities. The certification of contents of advertisements for foods claimed to have health effects shall seek advice from the Ministry of Public Health.
- 4. Organising and decentralising the granting of certificates of satisfaction of food safety requirements for organisations and individuals that manufacture and trade products within the scope of its responsibilities as assigned in Clauses 2, and 5 of this Article.
- 5. Regulating food safety for markets, supermarkets, and stores in systems of food storage and distribution.
- 6. Conducting inspection for the purpose of fraud control against fake foods, and commercial frauds for all kinds of foods, food additives, substances used as processing aids, utensils, packaging materials, and food containers.
- 7. Stipulating requirements for testing labs; designating authorised testing agencies and testing agencies for verification; communicating testing results for foods within the scope of its assigned state management responsibilities.
- 8. Designating authorised agencies to conduct state inspection on food safety of imported food products within the scope of its responsibilities as assigned in Clause 2 of this Article.

Article 23. Responsibilities for state management of food safety by the People's Committees at all levels

- 1. The People's Committees of provinces and cities directly under the central government shall perform state management of food safety in their respective localities, and shall be accountable to the central government for food hygiene and safety in their respective localities.
 - a) Organising and directing the Inter-departmental Steering Committee on food hygiene and safety in the province or city under the central government's management;
 - b) Directing the implementation of food safety regulations by the central government, and the line ministries.
- 2. Issuing local regulated technical standards of food safety for locality-specific food products.
- 3. The Departments of Public Health shall be accountable to the People's Committees of provinces and cities directly under the central government for performing state management

of food safety in their respective localities; and shall act as the primary contact point for the Inter-departmental Steering Committees on food safety in their respective localities.

- a) Acting as the primary contact point for consolidating and relaying reports on the status of food safety from local authorities to the People's Committees of provinces and cities directly under the central government, and the Ministry of Public Health;
- b) Organising annual periodic inspections on the status of food safety in their respective localities; acting as the primary contact point for monitoring food contamination in their respective localities;
- c) Inspecting and examining products and establishments manufacturing and trading food additives, substances used as processing aids, bottled water, natural mineral water, functional foods, food enriched with micro-nutrients in their respective localities as decentralised by the Ministry of Public Health; catering establishments, and street food vendors.
- d) In coordination with other sector-specific specialised Departments, taking charge of unscheduled inspection and examination of the entire process of manufacturing and trading foods within the scope of state management responsibilities by other line ministries at the direction of the People's Committees, and the Head of the Inter-departmental Steering Committees on food safety of the provinces and cities directly under the central government, the Ministry of Public Health; upon exposing violations that are likely to cause severe adverse effects on consumers' health with regard to foods, food additives, substances used as processing aids, utensils, packaging materials, and food containers in circulation in their respective localities; in case of discrepancies in inspection rulings by sector-specific specialised departments; at the request of the sector-specific specialised department.
- •) Receiving announcements of conformity to regulated technical standards, or certifying announcements of compliance with food safety regulations; certifying contents of food advertisements for foods as assigned in Clause 2 of Article 4 of this Decree; granting certificates of satisfaction of food safety requirements for organisations and individuals that manufacture and trade types of products as decentralised by the Ministry of Public Health;
- e) Being responsible for state management of food safety in their respective localities; controlling the satisfaction of food safety requirements at small-scale food manufacturers and traders, street food vendors, catering establishments, food safety in markets in their respective localities and other entities within the scope of their decentralised responsibilities.
- 4. The Departments of Agricultural and Rural Development shall be responsible for:

- a) Inspecting and examining products and food manufacturers and traders as decentralised by the Ministry of Agriculture and Rural Development;
- b) Organising the granting of certificates of satisfaction of food safety requirements for manufacturers and traders of types of products as decentralised by the Ministry of Agriculture and Rural Development;
- c) Organising the granting of certificates of contents of food advertisements as decentralised by the Ministry of Agriculture and Rural Development;
- d) Submitting periodic and extraordinary reports to Standing Members of the Interdepartmental Steering Committee (Departments of Public Health) for inputs towards consolidated reports to the People's Committees of provinces and cities directly under the central government, the Ministry of Public Health, and specific line ministries.
- 5. The Departments of Industry and Trade shall be responsible for:
 - a) Inspecting and examining products of food manufacturers and traders as decentralised by the Ministry of Industry and Trade
 - b) Organising the granting of certificates of satisfaction of food safety requirements for manufacturers and traders of types of products as decentralised by the Ministry of Industry and Trade;
 - c) Organising the granting of certificates of contents of food advertisements as decentralised by the Ministry of Industry and Trade;
 - d) Conducting inspection for the purpose of fraud control against fake foods, and commercial frauds in the markets for all kinds of foods, food additives, substances used as processing aids, utensils, packaging materials, and food containers;
 - •) Submitting periodic and extraordinary reports to Standing Members of the Interdepartmental Steering Committee (Departments of Public Health) for inputs towards consolidated reports to the People's Committees of provinces and cities directly under the central government, the Ministry of Public Health, and specific line ministries.
- 6. The District People's Committees shall be accountable to the People's Committees of provinces and cities directly under the central government for food safety in their respective localities.
 - a) Organising and directing the District's Inter-departmental Steering Committee on food hygiene and safety in their districts;
 - b) Directing and implementing food safety regulations by the central government, the line ministries, and the People's Committees of provinces and cities directly under the central government
 - c) Supervising the food trading business by street food vendors, restaurants, hotels in their respective districts as decentralised.

- 7. The Commune People's Committees shall be accountable to the District People's Committees for food safety in their respective localities.
 - a) Organising and directing the Commune's Inter-departmental Steering Committee on food hygiene and safety in their districts;
 - b) Implementing food safety regulations by the central government, the line ministries, and the superior-level People's Committees;
 - c) Being accountable to the District People's Committees for supervising the food trading business by street food vendors, restaurants, hotels in their respective communes as decentralised.

Article 24. Collaboration among the line ministries in state management of food safety

The line ministries, within the scope of their state management responsibilities, shall be responsible for coordinating with the Ministry of Public Health in carrying out state management activities to ensure efficient uniform state management of food safety.

- 1. The Ministry of Public Health, the Ministry of Agriculture and Rural Development, and the Ministry of Trade and Industry shall implement programmes to monitor, to prevent, and to stop food safety incidents in accordance with Article 52 of the Law on Food Safety.
- 2. When food poisoning occurs, the Ministry of Public Health shall be responsible for arranging emergency first aid, and timely treatment for people with food poisoning. The specific line ministry shall be responsible for providing adequate files and information related to the origin of the food(s) suspected to have caused food poisoning within the scope of its state management responsibilities; for coordinating with the Ministry of Public Health to carry out and to monitor an investigation into the cause(s), to trace the origin and handle the food(s) causing the food poisoning incident.

Chapter VIII

SECTOR-SPECIFIC SPECIALISED FOOD SAFETY INSPECTION

Article 25. Agencies assigned to conduct food safety inspection

Food safety inspection shall be sector-specific specialised inspection, conducted by the sectors of health, agriculture and rural development, and industry and trade. The assignment of sector-specific specialised food safety inspection to authorised agencies shall be in accordance with the Government's regulations on authorised agencies assigned with sector-specific specialised inspection tasks.

Article 26. Coordination among the ministries, sectors, and other forces in food safety inspection

- 1. The Ministries of Public Health, Agriculture and Rural Development, and Trade and Industry shall be responsible for food safety inspection during the entire process of production, processing, storage, transportation, export, import, and trading of foods within the scope of their assigned state management responsibilities in accordance with Articles 62, 63, 64, 65, and 67 of the Law on Food Safety.
- 2. The Ministry of Public Health, and the standing body of the central inter-ministerial Steering Committee on food hygiene and safety, in coordination with the line ministries and related forces, shall take charge of the organisation and assignment of inter-sectoral inspection.
- 3. The Ministry of Public Health shall carry out unscheduled inspections of the entire process of production, export, import, and trading of foods within the scope of state management responsibilities by other ministries in the following cases:
 - a) At the direction of the Prime Minister or Chair of the central inter-ministerial Steering Committee on food hygiene and safety;
 - b) Upon exposing violations that are likely to cause severe adverse effects on consumers' health with regard to foods, food additives, substances used as processing aids, utensils, packaging materials, and food containers;
 - c) In case of discrepancies in inspection rulings by the specific line ministries.
 - d) At the request of the specific line ministries

Chapter IX

IMPLEMENTATION PROVISIONS

Article 27. Effectiveness

This Decree takes effect on 11 June 2012.

Article 28. Responsibilities for Implementation

The Ministers, Heads of ministerial-level agencies, Heads of Government-affiliated agencies, Chair-people of the People's Committees of provinces and cities directly under the central government, and other related organisations and individuals shall be responsible for implementing this decree.

ON BEHALF OF THE GOVERNMENT PRIME MINISTER

(signed)

Nguyen Tan Dung

Recipients:

- The Secretariat of Vietnamese Communist Party's Central Committee
- Prime Minister, Deputy Prime Ministers;
- The Ministries, Ministerial-level Agencies, Government-affiliated Agencies;
- Office of the Central Steering Committee on corruption prevention and control;
- People's Committees of provinces and cities directly under the central government;
- The Party's Central Offices and Committees;
- Office of the President;
- Council of Nations, and Committees of the National Assembly;
- Office of the National Assembly
- The Supreme People's Court;
- The Supreme People's Procuracy;
- State Auditor-General's Office;
- National Financial Supervisory Committee;
- Bank for Social Policies;
- Development Bank of Vietnam;
- Central Committee of Fatherland Front of Vietnam;
- Central offices of associations;
- Office of the Government: Chair-Minister, Vice Chairs, E-government Portal, departments, sub-departments, affiliated units, Official Gazette;
- Archives: Secretarial Office, Department of Science, Education, Culture and Society (5 copies).

Document attributes

Number/Notation: 38/2012/N• -CP

Date of promulgation: 25 April 2012

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Signed by: Nguyen Tan Dung

RE: Regulating in detail the implementation of a number of articles of the

Law on Food Safety

Promulgated by: The Government

Category: Decree

Attached files: - <u>38ND.doc</u> (148480 Byte)

- <u>38ND_PL.doc</u> (158208 Byte)

Other Documents

Promulgating the Statute on task collaboration between the Government and the Central Executive Committee of Ho Chi Minh Communist Youth League (14 December 2012)

Regulations on foreign military ships visiting the Socialist Republic of Vietnam (05 December 2012)

Adopting the policy of production loans to highly underprivileged households of ethnic minorities in the period of 2012 to 2015 (04 December 2012)

Regulations on regional minimum wages for employees working for business enterprises, collectives, collaborative teams, farms, households, individuals, and agencies and organisations employing labour (04 December 2012)

On the organisation and activities of the Coast Guard (29 November 2012)

Organising public opinion polls on the Draft of Amendments of the Constitution of 1992 (23 November 2012)

On continuing the pilot implementation of the institution of court ushers (23 November 2012)

LAW ON AMENDING AND SUPPLEMENTING A NUMBER OF ARTICLES IN THE LAW ON CORRUPTION PREVENTION AND CONTROL (23 November 2012)

On adopting the roadmap for applying the ratio of mixing bio-fuels with traditional fuels (22 November 2012)

LAW ON AMENDING AND SUPPLEMENTING A NUMBER OF ARTICLES IN THE LAW ON PERSONAL INCOME TAXATION (22 November 2012)