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MinHealth Publishes Declaration of Conformity Process for Food

Report Categories:

Food and Agricultural Import Regulations and
Standards - Narrative

Food and Agricultural Import Regulations and
Standards - Certification

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Report Highlights:

This report provides an un-official translation of the Ministry of Health's (MOH) Circular 19/2012/TT-BYT, issued on November 9, 2012, providing Guidance on the Declaration of Conformity to Technical and Food Safety Regulations. This is one of MOH's legal circulars implementing the Vietnam Government's Decree 38/2012/ND-CP implementing the Vietnam Food Safety Law (see VM3032).

Summary:

The Ministry of Health's (MOH) Circular 19/2012/TT-BYT, issued on November 9, 2012, provides Guidance on the Declaration of Conformity to Technical and Food Safety Regulations process in Vietnam. Circular 19 is one of MOH's legal circulars implementing the Vietnam Government's Decree 38/2012/ND-CP which implements the Food Safety Law (see VM3032). A Declaration of Conformity is one of the documents required for imports of food products and instruments in contact with food to be cleared by Vietnamese Customs authorities.

Circular 19 applies to processed and /or packed food products, food additives, food processing enhancers, packing materials, and instruments in direct contact with food. The Circular entered into force on December 25, 2012 and supersedes the MOH's Decision 42/2005/QD-BYT regarding the regulation on the declaration of quality of food products. It should be noted that different processed and / or packed food products fall under the food safety jurisdiction of three different Ministries: MOH, the Ministry of Agriculture and Rural Development (MARD), and the Ministry of Industry and Trade (MOIT). A Conformity Declaration is needed for all products considered processed and / or packed regardless of which Ministry's regulatory responsibility the product falls under. VM 3032 provides a rough breakdown of the food safety jurisdictions of MOH, MARD, and MOIT. The full Circular in Vietnamese can be downloaded from the Vietnam Food Administration website: www.vfa.gov.vn.

As stated in the Circular's Article 3, the assessment of conformity is based on technical regulations for food products having corresponding technical regulations and is required in order to receive a Declaration of Conformity. These technical regulations are generated by the Ministry of Science and Technology or Ministry of Health. The assessment of conformity of food products not having technical regulations is based on food safety criteria regulated by relevant food safety regulations.

The procedure for obtaining a conformity declaration consists of the following steps:

- **Step 1: Conformity assessment:** individuals and organizations can conduct the conformity assessment by themselves or via an independent agency appointed by MOH. This involves conducting an analysis of the product which is submitted to MOH to obtain the Declaration of Conformity.
- **Step 2: Conformity registration:** individuals and organizations submit the application dossier for conformity registration with the certificate of analysis to an authorized agency as stipulated in Article 7 of this Circular.

The dossier for conformity registration include: a) related documents stipulated in Article 5 ^(Note 1) and Article 7 ^(Note 2) of Decree 38/2012/ND-CP, and b) the product's testing result occurring within 12 months (original copy and notarized copy for comparison or consularized, notarized copies).

Article 6 regulates the conformity declaration process of imported food products (excluding functional foods) for use in production facilities, supermarkets, and hotels ranked 4 stars or higher. The declaration dossier includes: a) a **List of products (using one of the Forms in the Appendix of Circular 19, depending on the products)**. Form 1 is used for imported food materials, food directly in contact with packing materials and tools used for production in Vietnam; Form 2 is used for imported food additives and food processing enhancers for further food production in Vietnam; and Form 3 is used for imported food products for sale in supermarkets or to be used in hotels four-star or greater; b) **the Importer's**

Trading license (copy stamped by an organization or an individual); and c) **the product testing results** dated within 12 months by the manufacturer, detailed information of the manufacturer's product, testing results by an appointed testing lab, or by a recognized independent testing lab.

U.S. exporters have contacted FAS-Vietnam in the past regarding Circular 19 and the Certificate of Analysis process required to receive the Declaration of Conformity citing the concerns about testing products in a foreign laboratory. As of the writing of this report the Ministry of Health accepts Certificate of Analyses from 3rd party and foreign laboratories.

Authorized agencies in Vietnam for receiving dossier and issuing the certificate for conformity declaration to technical regulations and food safety regulations are:

Vietnam Food Administration (VFA) is authorized by MOH to receive dossiers registering for conformity declaration, and issuing Conformity Declaration Certificates for functional food, food additives, food processing enhancers, imported products including processed/packed food, food packing materials, and instruments in direct contact with food. For products regulated in Article 6 (excluding functional food) of this Circular, VFA provides an official document to certify.

Provincial/City Food Administration is responsible for issuing Conformity Certificate for domestically produced products including processed/packed food, and food packing materials/containers in direct contacting with food (excluding functional food).

For more detail, FAS-Vietnam suggests interested exporters contact the Vietnam Food Administration at the below address:

Vietnam Food Administration
Ministry of Health
135 Nui Truc Street
Hanoi, Vietnam
Tel: 844-38464489; 38463702
Fax: 844-38463739
Email: vfa@vfa.gov.vn
Website: www.vfa.gov.vn

Un-official translation of Circular 19/2012/TT-BYT

THE MINISTRY OF HEALTH SOCIALIST REPUBLIC OF VIETNAM

Independence– Freedom – Happiness

No. 19/2012/TT-BYT

Hanoi, November 09, 2012

CIRCULAR

Guidance on Declaration of Conformity to Technical and Food Safety Regulations

Pursuant to the Law on Technical regulations and standards, of June 29, 2006 and the Government's Decree No.127/2007/ND-CP, of August 01, 2007, detailing the implementation of a number of articles of the Law on Technical regulations and standards;

Pursuant to the Law on quality of product, goods, of November 21, 2007 and the Government's Decree No.132/2008/ND-CP, of December 31, 2008 detailing the implementation of a number of articles of the Law on quality of product, goods;

Pursuant to the Law of Food safety, of June 17, 2010 and the Government's Decree No.38/2012/ND-CP, of April 25, 2012 detailing the implementation of a number of articles of the Law of Food safety;

Pursuant to the Government's Decree No.63/2012/ND-CP, of August 31, 2012, defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the proposal of Director of the Food Safety Bureau;

the Ministry of Health promulgates Circular guiding the regulation conformity announcement and announcement on conformity with regulation on food safety.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

This Circular stipulates the conformity assessment and registration process for the regulation of food safety (hereinafter referred to as the product announcement) with respect to pre-packed processed food, food additives, food processing enhancers, packing materials, instruments in direct contact with food (hereinafter referred to as products); the duties of agencies receiving registration of regulation conformity dossiers and declaration of conformity with regulation on food safety (hereinafter referred to as agencies receiving registration) and of the organizations or individuals conducting product conformity registration (hereinafter referred to as organizations, individuals); and inspection after announcing product conformity.

Article 2. Interpretation of terms

In this Circular, the terms below shall be construed as follows:

1. Announcement on conformity with regulation on food safety: Means when organizations or individuals self-announce that their products are conformable with regulations on food safety for products which do not yet have corresponding technical regulations.
2. Principal quality norms: Means the level or quantity of substances determining nutritious value and typical nature of products in order to identify, classify, and distinguish with foods of the same kind.

3. Detailed information of the product: Means the technical requirements of a product (which includes the common name of product, label, principal quality standards, chemical-physical standards, and micro-organisms) built by organizations or individuals declared to conform with the corresponding National Technical Regulation (QCKT), in conformity with Vietnam regulations on food safety (in case the product does not yet have a QCKT), or in conformity with International Food Standards set by the Codex Alimentarius in the case Vietnam does not yet have a regulation or standard.

4. Appointed testing laboratory: Means a testing laboratory appointed by competent agencies in Vietnam.

5. Recognized independent testing laboratory: Means a testing laboratory of an organization or individual which is recognized by an recognizing organization and independent from the organization or individual producing products.

6. Accepted testing laboratory: Means a testing laboratory of the product producing organization or individual has been recognized by a recognizing organization; and the testing laboratory is approved by an overseas competent agencies.

Article 3. Content of assessment on conformity of announced product compared to the corresponding technical regulation and assessment on conformity of announced product compared to regulation on food safety

1. Assessment of conformity of announced product compared to the corresponding technical regulation (hereinafter referred to as regulation conformity assessment) with respect to products which have technical regulations: Content of regulation conformity assessment applied for each specific product is specified in the corresponding technical regulation.

2. Assessment on conformity of announced product compared to a regulation on food safety (hereinafter referred to as assessment on conformity with regulation on food safety) with respect to products which not yet have a technical regulation: Content of the assessment on conformity with regulation on food safety is applied for each type of product based on criteria on food safety as prescribed by the Law on Food Safety. In case Vietnam does not yet have a regulation, CODEX regulations shall be applied.

Chapter II

ORDER, DOSSIER OF PRODUCT ANNOUNCEMENT

Article 4. Order, dossier of regulation conformity announcement

1. Order of regulation conformity announcement:

a) Step 1: The regulation conformity assessment

Organizations or individuals implement the regulation conformity assessment by one of two methods, as follows: To self-assess regulation conformity based on the content of regulation conformity assessment specified in Clause 1, Article 3 of this Circular and test product in an appointed testing laboratory, recognized independent testing laboratory, or accepted testing laboratory; through an organization certifying the regulation conformity appointed by the Ministry of Health.

b) Step 2: Registration of the regulation conformity announcement

Organizations or individuals announcing a product shall submit a dossier of announcement as prescribed in Clause 2 of this Article to agencies receiving dossiers specified in Article 7 of this Circular.

2. Dossier of regulation conformity announcement:

a) Papers, documents specified in Article 5 and Article 7 of the Government's Decree No.38/2012/ND-CP, of April 25, 2012 detailing the implementation of a number of articles of the Law of Food safety (hereinafter referred to as the Decree No.38/2012/ND-CP);

b) For results of testing product, stipulated as follows: The results of testing product within 12 months (originals or notarized copies enclosed originals for comparison or consular legalized copies), include criteria at the request of the corresponding technical regulations, of the appointed testing laboratory or recognized independent testing laboratory or accepted testing laboratory.

Article 5. Order, dossier of announcement on conformity with regulation on food safety

1. Order of announcement on conformity with regulation on food safety:

a) Step 1: Assessment on conformity with regulation on food safety

Organizations, individuals test products in appointed testing laboratory or recognized independent testing laboratory or accepted testing laboratory; assess conformity with regulation on food safety on based on results of testing and content specified in clause 2 Article 3 of this Circular.

b) Step 2: Registration of announcement on conformity with regulation on food safety

Organizations, individuals announcing product shall make and submit dossier of announcement as prescribed in clause 2 this Article to agencies receiving registration specified in Article 7 of this Circular.

2. Dossier of announcement on conformity with regulation on food safety:

a) Papers and documents specified in Article 6 and Article 7 of Decree 38/2012/ND-CP.

b) For results of testing product, test results for a product within 12 months (originals, notarized copies enclosed originals for comparison, or consular-legalized copies), include key quality norms and safety norms of the appointed testing laboratory, recognized independent testing laboratory, or accepted testing laboratory.

c) The results of testing the effectiveness of a functional food product having a new effective characteristic, being processed from new substances or under new technology, which will be circulated in Vietnam market for the first time and not yet proven safe and effective;

Article 6. Announcement for import products (except for functional food) only aiming to be used internally in production facilities, supermarkets, and four-star hotels or greater

1. Dossier of product announcement includes:

a) The product declaration:

- For food raw materials, packing materials, and instruments in direct contact with import food for internal production of enterprises: Use the declaration specified in Form 2 promulgated with this Circular.

- For imported food additives and food processing enhancers for use in the internal production of enterprises: Use the declaration specified in Form 3 promulgated with this Circular.

- For imported food to be sold in supermarkets, hotels four-stars or greater: Use the declaration specified in Form 4 promulgated with this Circular;

b) Certificate of Business Registration (copy with stamp of the organization or individual);

c) The results of testing product within 12 months of production, the details on product information of producers, results of testing product of the appointed testing laboratory, or recognized independent testing laboratory or accepted testing laboratory.

2. Organizations or individuals announcing products shall submit the dossier of announcement as prescribed in Clause 1 of this Article to agencies receiving registration, specified in Article 7 of this Circular.

Article 7. Authority to receive dossier of registration, to grant receipt of regulation conformity announcement, and conformation on announcement on conformity with regulation on food safety

1. The Ministry of Health assigns the Food Safety Bureau to receive the dossier of registration; grant receipt of regulation conformity announcement (hereinafter referred to as receipt), confirmation on announcement on conformity with regulation on food safety (hereinafter referred to as confirmation) for: Functional foods, food additives, food processing enhancers, imported products being processed, packaged foods, packing materials, instruments in direct contact with foods; the confirmation in writing for imported products (except for functional foods) only for use internally in production facilities, supermarkets, hotels four stars or greater.

2. The Department of Health assigns the Sub-departments of food safety and hygiene to receive dossiers of registration, grant receipts, and confirmations for: Domestically produced processed foods, packaged foods (except for functional foods), packing materials, and instruments in direct contact with food.

3. Domestically produced products for export are registered for conformity product announcement at the Food Safety Bureau or the Sub-departments of food safety and hygiene where the organizations or individuals have their head office, as requested by importing countries.

4. Products with same quality and the same producing organization or individual, but being produced in 2 (two) provinces / cities or more may register the product announcement at the Food Safety Bureau or at the Sub-department of food safety and hygiene where the organizations or individuals have their head office.

5. Agencies receiving registration specified in Clauses 1, 2 of this Article shall receive, grant receipt, and confirmation as prescribed in Clauses 3, 4, and 5 of Article 4 of the Decree 38/2012/ND-CP.

Within 2 (two) months after receiving written notification on the reason of refusal for a grant of a receipt and confirmation of agencies receiving registration, if organization or individual announcing the product fail to supplement and complete the dossier as requested, the agencies receiving the registration shall cancel the announcement dossier.

6. Agencies receiving registration shall grant and manage the number of receipts and confirmations.

a) For receipts and confirmations being granted by the Food Safety Bureau, being regulated to record corresponding notation as follows: (ordinal number)/(issuance year)/ATTP-TNCB and (ordinal number)/(issuance year)/ATTP-XNCB.

b) For receipts and confirmations being granted by the Sub-departments of food safety and hygiene of provinces, cities, being regulated to record corresponding notation as follows: (ordinal number)/(issuance year)/YT-abbreviated name of province, city-TNCB and (ordinal number)/(issuance year)/YT-abbreviated name of province-XNCB.

Convention on abbreviation of name of provinces, cities in receipts and confirmations is specified in Form 5 promulgated with this Circular.

Article 8. Announcement for food additives and food processing enhancers

1. For food additives and food processing enhancers included in the list being permitted for use, promulgated by the Ministry of Health, organizations or individuals should implement the product announcement as prescribed in Article 4, 5, 6, and Article 7 of this Circular.
2. For food additives and food processing enhancers not included in the list being permitted for use in Vietnam; products containing food additives or food processing enhancers not in the list being permitted for use of Vietnam but in the list prescribed by Codex or being permitted for use in producing countries, the Food Safety Bureau shall consider to allow the product announcement.

Article 9. Renewal of receipts and confirmations

1. Renewal of receipts and confirmations is implemented at the competent state agencies which have granted receipts or confirmations the first time for such products and complies with Article 8 of Decree 38/2012/ND-CP.
2. In the case organizations or individuals requesting for renewal fail to implement properly the regime of periodical testing, agencies receiving registration shall hold an inspection at the production or business facilities. Based on the result of handling a violation and remedial action, agencies receiving registration shall decide to renewal or must re-announce.

Chapter III

DUTIES OF AGENCIES RECEIVING REGISTRATION AND ORGANIZATIONS OR INDIVIDUALS ANNOUNCING PRODUCTS

Article 10. Duties of agencies receiving registration

Agencies receiving registration have rights and duties as follows:

1. To receive dossier of regulation conformity announcement or of announcement on conformity with regulation on food safety of organizations or individuals.
2. To grant and renew receipts and confirmations in a proper time limit as prescribed in Clauses 3, 4, and 5 of Article 4 of Decree 38/2012/ND-CP.
3. Within 7 (seven) working days, after granting receipt or confirmation, agencies receiving registration shall notify the public about the products granted receipts or confirmations on their websites.
4. To affix with an integrity seal between the pages on the detailed product information and affix with seal on label of products in order to confirm the contents labeled compulsorily as prescribed by law. This stamp affixing has no value to confirm about industrial ownership. The agency receiving registration shall return to the organization or individual announcing the product one dossier of the product and store one dossier, as prescribed.
5. To hold management and use of charges and fees from grant of receipts, and confirmations as guided by the Ministry of Finance.

Article 11. Duties of organizations or individuals announcing products

Organizations, individuals announcing products have rights and duties as follows:

1. To announce products and re-announce products at agencies receiving registration specified in Article 7 of this Circular; pay charges and fees fully as prescribed by law.

2. Self-supervising the quality and food safety of their own products. To implement the periodic examination and testing (of their products) as regulated and being responsible for announcing conformity of their products with Vietnamese standards to the public.
3. To announce the name of products clearly, presenting properly the nature (structural components, functions, processing technology) of the product. If name of product does not indicate the nature of the product, it must be written together with name of product group and detailed the compulsory labeling contents.
4. To submit official label after one (1) month of being granted receipt or confirmation, in case having just submitted the drafting design of labeling content upon announcement.
5. When detecting products breaching provisions of the law on quality and food safety of product, labeling, advertisement, dishonest announcement, organizations or individuals shall:
 - a) Timely notify competent state management agencies and agencies receiving registration about conformity of product;
 - b) To conduct measures to remedy non-conformity;
 - c) When necessary or having request of competent state management agencies, they must temporarily stop production or distribution of products from the factory, and conduct recall of non-conforming products circulating in the market;
 - d) To notify to competent state management agencies and agencies receiving registration about remedying non-conformity before continuing to bring products into production and trading.
6. To keep the dossier of product announcement under a time limit as basis of examination, inspection or in order to prove conformity of their products with contents announced and committed in dossier.
7. In the case of changing contents in the detailed product information relating to the form of label, packing specification, quality norms, non-compulsory labeling contents, address of head office of organizations, individuals, or production place, name of organizations or individuals (in case of changing Certificate of Business registration), organizations or individuals may submit an official dispatch to request for supplement enclosed with confirmation on contents changed, supplemented of organizations, individuals taking responsibility for product in order to continue use of number of receipts or confirmations which have been granted or re-granted.

Chapter IV

EXAMINATION AFTER ANNOUNCEMENT

Article 12. Examination after announcement

Agencies receiving registration and Sub-departments of food safety and hygiene where production-business facilities are placed have authority to examine the implementation of the law on food safety and the regime of periodical testing for the announced products.

Article 13. Taking samples for periodical testing

1. The periodic testing regime is implemented as follows:
 - a) 1 (one) time/year for products of facilities having a certificate on an advanced quality control system: GMP, HACCP, ISO 22000 or equivalent.
 - b) 2 (two) times/year for products of facilities not yet granted the above-mentioned certificates.

2. The taking samples for periodic testing is performed by organizations or individuals or the organizations or individuals proactively invite competent agencies for periodic testing.
3. Criteria for periodical testing are the principal quality norms announced in the detailed product information or on the label of products circulating; some chemical and physical norms, micro-organism norms announced in the detailed product information or as prescribed by law.
4. Result of testing of teams inspecting, examining irregularly, periodically, results of state examination on imported food safety may be used by organizations or individuals as the result of periodical testing if meeting requirements specified in Clause 3 or this Article.

Chapter V

PROVISIONS OF IMPLEMENTATION

Article 14. Transitional provisions

The product quality standard certificates granted under Decision 42/2005/QĐ-BYT, of December 8, 2005 of the Ministry of Health on the regulation on the statement of food product specifications are still valid until the effective duration stated on such certificates has expired.

Article 15. Effect

1. This Circular takes effect on December 25, 2012.
2. The Decision 42/2005/QĐ-BYT of the Ministry of Health, dated December 15, 2005 promulgating the regulation on the statement of food product specifications is invalid since this Circular takes effect.

Article 16. Organizing implementation

1. The Ministry of Health assigns the Food Safety Bureau to implement, examine implementation of this Circular in nationwide.

Each six months, the Food Safety Bureau shall report to the Minister of Health on the task of granting receipts and confirmations.

2. The Departments of Health assigns the Sub-department of food safety and hygiene to implement and examine implementation of this Circular in their management localities.

Each month, the Sub-department of food safety and hygiene shall report to Departments of Health and the Food Safety Bureau on task of granting receipts and confirmations.

**FOR THE MINISTER OF HEALTH
VICE MINISTER**

Nguyen Thanh Long

Appendix-

(Promulgated with MOH Circular 19/2012/TT-BYT dated November 9, 2012)

Form-1	Sheet to declare list of imported food materials, food directly contacting packing materials and tools used for the company's production only.
Form-2	Sheet to declare to list of imported food additives and food processing supporting products used for company's production only
Form-3	Sheet to declare the list imported products for trading in supermarkets, and four-star or upward hotels only
Form-4	Convention on short name of provinces/cities printed on receiving paper and certificate

Form- 1

Sheet to declare list of imported food materials, food directly contacting packing materials and tools used for the company's production only.

No .	Name of materials	Composition s	Name of manufacturer and exporting country	Level of key quality and food safety criteria	Shelf life	Packing specification	Used for product
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

....., *day**month**year*

Representative for organization, individual

(signature, stamp)

Form-2

Sheet to declare to list of imported food additives and food processing supporting products used for company's production only

No	Name of materials	Compositions	Name of manufacturer and exporting country	Level of key quality and food safety criteria	Shelf life	Packing specification	Used for product
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

....., *day**month**year*

Representative for organization, individual

(signature, stamp)

Form- 3

Sheet to declare the list imported products for trading in supermarkets, and four-star or higher hotels only

No .	Name of materials	Compositions	Name of manufacturer and exporting country	Level of key quality and food safety criteria	Shelf life	Packing specification	Used for product
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

....., *day**month**year*

Representative for organization, individual

(signature, stamp)

Form- 4**Convention on short name of provinces/cities printed on receiving paper and certificate**

No.	Name of province/city	XXX	No.	Name of province/city	XXX
1	An Giang	AG	33	Kon Tum	KT
2	Bắc Cạn	BC	34	Lai Châu	LC
3	Bình Dương	BD	35	Lâm Đồng	LĐ
4	Bình Định	BĐ	36	Lạng Sơn	LS
5	Bắc Giang	BG	37	Lào Cai	LCa
6	Bạc Liêu	BL	38	Long An	LA
7	Bắc Ninh	BN	39	Nam Định	NĐ
8	Bình Phước	BP	40	Nghệ An	NA
9	Bến Tre	BT	41	Ninh Bình	NB
10	Bình Thuận	BTh	42	Ninh Thuận	NT
11	Bà Rịa-Vũng tàu	BV	43	Phú Thọ	PT
12	Cao Bằng	CB	44	Phú Yên	PY
13	Cà Mau	CM	45	Quảng Bình	QB
14	Cần Thơ	CT	46	Quảng Nam	QNa
15	Đà Nẵng	ĐNa	47	Quảng Ngãi	QNg
16	Đắc Lắc	ĐL	48	Quảng Ninh	QN
17	Đắc Nông	ĐNô	49	Quảng Trị	QT
18	Điện Biên	ĐB	50	TP.Hồ Chí Minh	HCM
19	Đồng Nai	ĐN	51	Sơn La	SL
20	Đồng Tháp	ĐT	52	Sóc Trăng	ST
21	Gia Lai	GL	53	Tây Ninh	TN
22	Hà Giang	HG	54	Thái Bình	TB
23	Hà Nam	HNa	55	Thái Nguyên	TNg
24	Hà Nội	HN	56	Thanh Hoá	TH
25	Hà Tĩnh	HT	57	Thừa Thiên Huế	TTH
26	Hải Dương	HD	58	Tiền Giang	TG
27	Hải Phòng	HP	59	Tuyên Quang	TQ
28	Hậu Giang	HGi	60	Trà Vinh	TV

29	Hoà Bình	HB	61	Vĩnh Long	VL
30	Hưng Yên	HY	62	Vĩnh Phúc	VP
31	Kiên Giang	KG	63	Yên Bái	YB
32	Khánh Hoà	KH			

End of the translation

Note 1:

Article 5 of Decree 38/2012/ND-CP regulates dossier for declaration of conformity for products for that technical regulations are available. It says:

1. Declaration of conformity based on results certified by a designated certifying organization (third party), a dossier shall include:

- a) Declaration of conformity to technical regulation as regulated in Appendix 02 of this Decree;*
- b) Detailed Product Specification as regulated in Appendix 03a or 03c of this Decree (cross-sealed by a third party);*
- c) Certificate of conformity to technical regulation granted by third party (public notarized copy or copy submitted together with the original for reference);*
- d) A certificate of HACCP or ISO 22000 or equivalent if the organizations or individuals producing the products have a quality control system certified for conformity to HACCP or ISO 22000 or equivalent (public notarized copy or copy submitted together with the original for reference).*

2. Declaration of conformity based on results of self assessment by organizations, individuals producing and trading food (first party), a dossier shall include:

- a) Declaration of conformity to technical regulation as regulated in Appendix 02 of this Decree;*
- b) Detailed Product Specification as regulated in Appendix 3a or Appendix 3c of this Decree (cross-sealed by a third party);*
- c) Testing results of the products within 12 months, including criteria regulated by relevant technical regulations, granted by the following agencies: a testing lab designated by a state competent agency or by recognized independent lab (original copy or public notarized copy) or a foreign testing lab of the country of origin that is recognized by Viet Nam competent authority (original copy or public notarized or a consular legalized copy).*
- d) Quality Control Plan developed and applied as regulated in Appendix 04 of this Decree (certified by the first party);*
- đ) Periodically monitoring Plan (certified by the first party);*
- e) Report of Conformity Assessment (certified by the first party);*
- g) A certificate of HACCP or ISO 22000 or equivalent where the organizations or individuals producing the products have a quality control system certified for conformity to HACCP or ISO 22000 or equivalent (public notarized copy or copy submitted together with the original for reference).*

Note 2:

Article 7 of Decree 38/2012/ND-CP on submission of a dossier for declaration of conformity to technical regulation or food safety regulations says:

1. A dossier should be prepared as follow:

a) General legal documents, should be made in 1 booklet, the book shall include:

- Business registration certificate with food trading sector or Certification of legal entity status for individuals and organizations (notarized copies with seal of organization or individual);

- Certificate of satisfaction of food safety conditions for establishments if they are subject to a certificate of satisfaction of food safety conditions under the law (copies certified by organization or individual);

- A certificate of HACCP or ISO 22000 or equivalent if the organizations or individuals producing the products subject to a quality control system certified for conformity to HACCP or ISO 22000 or equivalent (a notarized copy; or copy together with the original for reference);

b) Dossier of declaration of conformity to technical regulations or to food safety regulation shall be made into 2 booklets, including documents listed in Article 5 and 6 of the Decree, except documents listed in item a, Clause 1 of this Article.

2. Organization, individual shall submit the dossier to competent agencies of Ministry of Health and Provincial Department of Health in person or by mail.

3. For food producing/trading organizations or individuals, that conduct conformity declaration for the second product or more, they are required to submit one set of general legal documents only.