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1. Introduction

In continuance of our first article on "General Food Safety Regulations in Vietnam" (which can be accessed here), this article will continue discussing the regulations governing genetically modified (GM) foods, as well as food packaging, labeling and advertising. Those issues are important for the relevant authorities to manage and control food safety during the process of distribution of food products to the market and to consumers.

As introduced in the first article, in addition to the primary legislation governing food safety, which includes the Food Safety Law,¹ Decree 15,² and Decree 115,³ this article will touch upon many other key pieces of legislation that deal specifically with the relevant matters, such as: GM foods, labeling and packaging decrees and circulars, advertising, laws to protect consumers' rights, and the subordinate guiding legislation. In the aggregate, this legislation creates an inclusive legal framework that provides both general and detailed regulations for the packaging and labeling of food products, including without limitation the rights and obligations of food-related business operators, requirements for food packaging and containers to ensure safe, intact food, the required contents of food product labeling, registration obligations for food advertisements, and other relevant rules.

State oversight of GM foods and food labeling, packaging, and advertising involves multiple government agencies at both the centralized and local levels; most materially, this involves Vietnam's Ministry of Health ("MOH"), Ministry of Industry and Trade ("MOIT"), Ministry of Agriculture and Rural Development ("MARD"), Ministry of Science and Technology ("MOST"), their respective provincial departments, and the provincial people's committees.

2. GM Foods

As mentioned in the first article, under Vietnamese law, "food" includes GM food, along with other types of foods and food products. Legally, "GM food" means food that has one or more genetic ingredients that

Law on Food Safety No. 55/2010/QH12 dated 17 June 2010, as amended in 2018 (the "Food Safety Law")

² Decree No. 15/2018/ND-CP dated 02 February 2018 guiding certain articles of the Food Safety Law ("Decree 15")

Decree No. 115/2018/ND-CP on food safety administrative sanctions dated 04 September 2018, as amended by Decree No. 124/2021/ND-CP dated 28 December 2021 ("**Decree 115**")

have been modified by genetic engineering.⁴ In Vietnam, GM Food falls under the management and control and of the MARD.⁵ GM food is subject to general food safety rules, as mentioned in Item 5.1 of our first article (which can be accessed here). As specific, unique types of food, GM foods are subject to stricter controls and safety regulations relating to human health and the environment.⁶ In particular, producers must ensure that all genetically modified organisms ("GMO"), GMO products,⁷ and certain genetically modified plants ("GMP"),⁸ used in the production of GM foods must receive a certificate verifying that the relevant GMO/GMP are eligible for use as food ("GMO/GMP as Food Cer tificate") from the MARD before the relevant food can be placed in the Vietnamese market.⁹ The procedure to obtain a GMO/GMP as Food Certificate normally takes about 1 year from the date of initial submission of the application dossier. A list of GMO/GMP that have been granted a GMO/GMP as Food Certificate is supposed to be posted and updated on the MARD portal.¹⁰ Unfortunately, it seems that no such list actually is published on the MARD portal, although it may be possible to confirm GMOs that have received the certificate at the following link: GMO SEARCH – An toàn sinh hoc (antoansinhhoc.vn).

3. Genome Editing and Genome Edited Foods

Although recently the concept of "genome editing" has been discussed in many scientific forums and at seminars in Vietnam, like the novel food mentioned in our first article, genome editing is a relatively new field in Vietnam; therefore, Vietnamese authorities have not issued any regulations directly addressing genome editing methods applicable to or permissible in food industry, or governing genome edited foods.

4. Food Packaging

Under Vietnamese regulations, one aspect of food safety rules requires that food utensils, packaging materials, and containers (collectively, "**Packaging Products**") must satisfy certain safety assurance conditions before being used for food products.¹¹ MOH, MARD, and MOIT are in charge of Packaging Products; the specific agency responsible for oversight depends on the type of foods in question. For instance, MOH has responsibility for Packaging Products that are directly in contact with food, other than those that fall within the jurisdiction of MARD and MOIT (e.g., bottled water, functional food, and food additives). MARD deals with Packaging Products directly in contact with foods under its jurisdiction (e.g., GM

⁴ Food Safety Law, Article 2.24

⁵ Food Safety Law, Article 63.3; Decree 15, Annex III, Item VIII.

⁶ Food Safety Law, Article 15

Under Article 3.2 of Decree No. 69/2010/ND-CP dated 21 June 2010, as amended by Decree No. 108/2011/ND-CP dated 30 November 2011 and Decree No. 118/2020/ND-CP dated 02 October 2020, on biosafety for GMO, genetic specimens and GMO products (collectively, "Decree 69"), "GMO products" means a product wholly or partly containing constituents originating from genetically modified organisms, including genetic specimens of genetically modified organisms which cannot themselves create new individuals under natural conditions.

⁸ Under Article 3.1 of Circular No. 02/2014/TT-BNNPTNT ("**Circular 02**"), "GMP" means are the genetic specimens, plants and direct products of plants carrying one or more new genes created by recombinant DNA technology.

Decree 69, Article 28.1; Circular 02, Article 5. In case of GMP, a GMP As Food Certificate requires for (i) GMP carrying the single transformation event as a result of transformation of a gene specifying a desired trait by the transgenic technology and (ii) GMP carrying the vector stacked transformation event as a result of transformation of two or many genes specifying one or many desired traits by the transgenic technology.

Decree 69, Article 31; Circular 02, Article 11

¹¹ Food Safety Law, Article 10.2(b); Article 18

foods and agricultural products), and MOIT oversees Packaging Products directly in contact with food under its jurisdiction (e.g., alcohol, non-alcoholic beverages, processed milk, and confections.)¹² Packaging Products must satisfy the following safety conditions:¹³

- Be manufactured from safe materials, to ensure that no harmful substances or strange flavors are released into food, and that food quality is ensured within the shelf life;
- Be compliant with regulations applicable to Packaging Products, and satisfy the relevant technical specifications issued by the MOH. The MOH has issued four sets of technical regulations applicable to various types of Packaging Products, depending on the materials used. Specifically:¹⁴
 - (i) QCVN 12-1: 2011 / BYT: National technical regulation on hygiene and safety for synthetic plastic implements, containers, and packaging in direct contact with food.
 - (ii) QCVN 12-2: 2011 / BYT: National technical regulation on hygiene and safety for rubber implements, containers, and packaging in direct contact with food.
 - (iii) QCVN 12-3: 2011 / BYT: National technical regulation on hygiene and safety for metal implements, containers, and packaging in direct contact with food.
 - (iv) QCVN 12-4: 2015 / BYT: National technical regulation on hygiene and safety for packaging and utensils made of glass, ceramic, porcelain, and enamel in direct contact with food.
- Producers or traders must perform a self-declaration with regard to food utensils, packaging, and containers in direct contact with food before the relevant materials circulate in the market (excluding products manufactured or imported for production or processing for export purposes or internal production, which are not sold domestically). The self-declaration must be made in accordance with the relevant law. One of the key documents used for this purpose is the results of food safety testing of the Packaging Products, issued by a designated testing laboratory or an ISO 17025 qualified laboratory. The self-declaration is made available to the public on mass media, or on a portal, or is displayed at the head office of the producer or trader. Concurrently, the producer or trader must file the self-declaration dossier with the competent local authority.

5. Food Labeling

One of the general food safety conditions imposed by Vietnamese law is proper food labeling, which is a compulsory requirement imposed on organizations and individuals that manufacture and import food, food additives, and food processing aids in or into Vietnam, in accordance with the prevailing goods labeling regulations. Goods labeling regulations generally are set forth in Decree No. 43/2017/ND-CP dated 14

Decree 15, Annexes I, III and III.

Food Safety Law, Article 18; Decree 15, Article 4

Circular No. 34/2011/TT-BYT dated 30 August 2011 promulgating national technical regulations on safety and hygiene for utensils, packaging materials, and containers in direct contact with food; and Circular No. 35/2015/TT-BYT dated 28 October 2015 promulgating national technical regulations on safety and hygiene for glass, ceramic, porcelain, and enamel in direct contact with food.

Food Safety Law, Article 10.2(b) and Article 44; Decree 15, Article 24; Law on protection of consumer's rights No. 59/2010/QH12, Article 12.1

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April 2017 on goods labeling, as amended by Decree No. 111/2021/ND-CP dated 09 December 2021 (collectively, "**Decree 43**"). In addition to the general goods labeling regulations, for food safety purposes, foods are subject to certain specific labeling requirements under the Food Safety Law and its guiding, subordinated, decrees and circulars. MOST is primarily in charge of the food labeling issue in Vietnam. Some of the basic food labeling requirements are discussed below.

(1) Definition and purpose

By law, "goods labels" are writings, prints, drawings, copies of words, drawings, images that are affixed, printed, attached, molded, carved, engraved directly on goods, on the commercial packaging of goods, or on other materials attached thereto.¹⁷ Accordingly, the purpose of "goods labeling" is to display basic and necessary information about goods for consumers to recognize and use as a basis for selection, consumption, and use, for manufacturers or traders to use when providing information about and promoting their goods, and for authorities to use when carrying out inspection and control of goods.¹⁸ Since food is a type of goods, food labeling and general goods labeling have the same basic purpose.

(2) Scope of "food" for labeling purposes

As discussed in our previous article, "food" includes products that humans eat and drink in a fresh, raw, processed, or preserved form, and excludes cosmetics, tobacco, and substances used as pharmaceuticals.¹⁹ Currently the law recognizes many categories of foods, including "fresh and raw foods," "micro nutrition-fortified foods," "functional foods," "GM foods," "irradiated foods," and "packaged foods." All types of foods must adhere to labeling requirements applicable to general goods as well as to foods, except for fresh, raw, and processed foods that are sold directly to consumers in an unpackaged state.²⁰

Despite the diversity of this definition, there has yet to be any formal legal definition of certain new types of foods, for instance, genome-edited foods and novel foods; as a result, the labeling regulations for these foods remains unclear.

(3) Formal labeling requirements²¹

Goods labels, including food labels, must comply with the following basic requirements as to form and content:

- <u>Position</u>: Labels containing all of the contents must be shown on goods or commercial packages of goods, or both, in a position that is easy to see, without disassembling the items of goods or their components.
- <u>Dimension and font size</u>: Organizations or individuals responsible for labeling may decide the label

Decree 43, Article 20.1

Decree 43, Article 3.1

¹⁸ Decree 43/2017, Article 3.2

¹⁹ Food Safety Law, Article 2.20

Decree 43, Article 1.2(dd)

Decree 43, Article 4 to Article 8

dimensions, and text and number size used on the label, as long as (i) all compulsory content is included and (ii) the text and numbers are of a size that can be read by the naked eye.

- Color: The color of any word, number, drawing, picture, sign, or symbol on a label must be clearly readable. In the case of mandatory information, adequate contrast must be ensured between the color of words or numbers and the background color.
- Language: Compulsory contents to be shown on labels circulating in the Vietnamese market must be written in Vietnamese, except for exported goods that are not consumed domestically or special cases where international names of countries and territories are mentioned.
- Secondary labels: With regard to secondary labels for imported goods, the content inscribed on the secondary label must be an original Vietnamese translation of the mandatory content written on the original label, and additional, missing mandatory content must be added, according to the nature of the goods, as described above in Item 5.2.

(4) Mandatory label content

Food labels must include the following compulsory content:²²

- Product name;
- Name and address of organization or individual responsible for products;
- Origin of products; and
- Other compulsory content, depending on the nature of the relevant goods, as required by law. In particular, the following compulsory content must be displayed on the labels of the relevant foods:

No.	Type of food products	Compulsory contents
1.	General foods	- Quantity, date of manufacture, expiration date (i.e., "expiry date," "use by" or "best before"), composition or ingredient quantity, nutritional composition, nutritional value (if any), ²³ warnings, and usage and preservation instructions.
2.	Health supplement foods	- Quantity date of manufacture, expiration date, quantitative ingredients and ingredients (not applicable to the recording of quantitative ingredients for food additives and auxiliary materials) or nutritional value, usage and preservation instructions, utility (object of use, how to use), risk warning announcement (if any) - The phrase: "Thực phẩm bảo vệ sức khỏe" (meaning "Health supplement food"); and

²² Decree 43, Article 10 and Appendix 1

²³

This content, if any, must follow the MOH's guidance. MOH is drafting a guidance circular requiring nutrition facts labels (nutrition facts) on foods. It appears that starting 1 January 2024, all foods being circulated in Vietnam must comply with nutrition labeling requirements, except for homemade foods, which are granted a 1 year grace period (i.e., 1 January 2025)

No.	Type of food products	Compulsory contents
		- The phrase: "Thực phẩm này không phải là thuốc, không có tác dụng thay thế thuốc chữa bệnh" (meaning "This food is not a medicine, and cannot substitute for medicine")
3.	Food supplements, medical foods, foods for special diets	- Quantity, date of manufacture, expiration date, ingredients, quantities of extra nutrients (or nutritional value), caution (if any), usage and preservation instructions, health risk warnings (if any).
		- The phrase: " <i>Thực phẩm bổ sung</i> " ("Food supplement") for food supplements.
		- The phrase: "Thực phẩm dinh dưỡng y học" ("Medical nutritional food") and "sử dụng cho người bệnh với sự giám sát của nhân viên y tế" ("use for patient under supervision of health worker") for medical nutritional foods;
		- The phrase: "Sản phẩm dinh dưỡng (cho đối tượng cụ thể)" ("Nutritional product (for a particular entity)") for foods for special diets.
4.	Irradiated foods	- Quantity, date of manufacture, expiration date, composition or ingredient quantity, and caution.
		- The phrase: "Thực phẩm đã qua chiếu xạ" (meaning "Irradiated food").
5.	GM Foods	- Quantity , date of manufacture, expiration date, composition or ingredient quantity, and caution.
		- The phrase: "Thực phẩm biến đổi gen" (meaning "Genetically modified food") or "biến đổi gen" (meaning "genetically modified") next to the name of the genetically modified organism (GMO) content (this would apply if foods contain GMOs, or GMO products that contain at least one GMO ingredient that constitutes more than 5% of the total ingredients used to produce the food, except for certain exceptions) ²⁴
6.	Food additives, processing aids	- Quantity, date of manufacture, expiration date, composition or ingredient quantity, usage and preservation instructions, caution (if any).
		- The phrase: "Phụ gia thực phẩm" (meaning "Food additives") or "Chất hỗ trợ chế biến thực phẩm" (meaning "Food processing aids"), respectively.
7.	Food materials	- Material name, quantity, date of manufacture, expiration date, and usage and preservation instructions.
8.	Packaged Products	- Composition, technical specifications, usage instructions, caution (if any).

Decree 15, Article 10; Circular No. 05/2019/TT-BKHCN dated 26 June 2019 detailing a number of regulations in Decree 43 ("Circular 05"), Article 10

(5) Responsibilities of food processors and importers²⁵

Food processors and importers are required to label food products to comply with the following general requirements:

- Ensuring the label and secondary label (if any) are truthful, clear, and accurate, and reflect the true nature of the goods.
- Food processors are responsible for labeling the goods produced for domestic circulation; where the labeling is entrusted to a third party, food processors still have full responsibility for the labels.
- Food importers must label imported products with obligatory labeling content required by law.

6. Nutritional claims and health claims²⁶

Basically, nutrition and health claims relating to food products might be considered implicit, based on the composition or ingredient quantity presented as part of the mandatory content on the label for the subject food. This includes the names of the raw materials, including additives, used to produce the product, which exist in the finished product even if the form of the raw materials has been changed.

Depending on the nature and state of the products, the quantitative ingredients must be recorded as the mass of the relevant ingredient that is present in a product unit, or in one of the following ratios: Mass to volume, mass with dimension, dimension with dimension, mass percentage, dimension percentage. If the composition of goods is quantified in metrological quantities, the quantity must be recorded in accordance with the provisions of the Vietnamese law on measurement.

The Vietnamese authorities have established some basic rules regulating nutritional content claims and health claims, which apply only to certain types of foods. In particular:²⁷

- Nutritional content claims and health claims relating to a specific substance (e.g., vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, prebiotics, and other biologically active substances) contained in food shall be calculated based on Recommended Nutrition Intakes (RNI) applicable to Vietnamese persons, issued by the MOH.
- Health claims must be supported by scientific evidence.
- For food supplements, nutritional content claims and health claims must not apply to a substance if the content of that substance in the relevant food is lower than 10% of RNI thresholds.
- For health supplements, nutritional content claims and health claims must not apply to a substance if the content of that substance in the relevant food is lower than 15% of RNI thresholds. No claims can be made with regard to the effects of vitamins, minerals, and active ingredients if the relevant product contains a lower quantity than is present in the scientific evidence.
- For medical foods and foods for special diets, nutritional content claims and health claims shall be made for all nutritional substances on the basis of RNI per serving size or per 100g. The health claims must specify the RNI applied to various users.

Decree 43, Article 9

Decree 43, Article 16, Article 17.5; Circular 05, Article 9

²⁷ Circular No. 43/2014/TT-BYT, Chapters III to V.

7. Food advertising²⁸

Food is treated as one of the special products and goods that directly affect human health and the environment,²⁹ and as such food advertising is subject to stricter advertising requirements than other, "normal" goods and products in Vietnam. MOH, MARD, and MOIT are the designated entities that control the content of food advertising, in each case with regard to the foods that fall within the relevant entity's oversight and jurisdiction.³⁰

In general, in order to advertise foods and food additives, certificates issued by state authorities must be obtained (e.g., for locally produced milk or nutritious products for children, some foods and food additives, certificates of standards and food safety and hygiene certificates are required; for imported nutritious products, certificates of product quality issued by the producing country and certificates of free sale are required; and for some foods and food additives, receipts of standard announcements issued by the relevant authorities are also be required as conditions for advertisement.)³¹

For certain types of foods, as determined by MOH, MARD, and MOIT, advertisements may be released only after verification of the advertisement's content by the relevant authorities, and only verified content may be advertised.³² For instance, foods for the protection of health, medical nutrition foods, foods for special diets, and nutritional products for children up to 36 months old, where advertisements are permitted by law, the content of the advertisement must be registered and a certificate confirming the content of the advertisement must be obtained before the advertisement can be released, and the content of the advertisement as released must conform to the corresponding registered content. The statutory time limit for issuance of the certificate confirming the content of an advertisement is 10 working days from the date a complete and valid application is submitted.³³

Advertisers may decide the content of food advertisements at their discretion, on the condition that they comply with certain advertising rules, as follows:

- The content of the advertisement must be consistent with the product's uses and reactions/effects, which must be as announced in the product announcement.
- It is not permitted to use images, equipment, costumes, names, correspondence from medical units, facilities, doctors, pharmacists, medical staff, thank you notes from patients, doctor's articles, pharmacists, or medical staff to advertise foods or in advertising content.
- For all foods and food additives, advertisements must specify the names of the foods and additives, and the name and address of the organization/individual who is responsible for circulating the products in the market.
- For functional foods, the main effects and side effects, if any, must be stated, along with a
 compulsory caution: "This product is not medicine and cannot substitute for medicine," which must be
 added to the advertisement. Advertisement content that is misleading with regard to these foods
 being or serving as medicine is not allowed.

Food Safety Law, Chapter VII; Decree 15, Chapter VIII; Law on Advertising No. 16/2012/QH13 dated 21 June 2013 ("Advertising Law"), Article 20.4; Decree No. 181/2013/ND-CP, Articles 5 and 12

²⁹ Advertising law, Article 2.12

³⁰ Food Safety Law, Article 43.3

³¹ Advertising Law, Article 20.4(d) and (dd)

Food Safety Law, Article 43.3; Decree 15, Article 27.6

Decree 15, Article 27.5

For health protection foods, it is necessary to include a compulsory caution: "This food is not
medicine and cannot substitute for medicine," which can be presented in different forms depending
on the type of media broadcasting the advertisement.

8. Prohibited acts and sanctions

(1) Prohibited acts relating to the subject matter

By law, the following acts, and others, are prohibited:

- Manufacturing food and engaging in food-related business that involves: violations of the law on goods labeling; food that fails to conform to relevant technical regulations; food that is denatured; food that has unsafe packaging or containers, or where packaging or containers are broken, torn or deformed during transportation causing food contamination; food that has no identification of origin or has expired.³⁴
- Advertising milk as substitutes for breast milk for children under 24 months old, nutritional supplements for children under 6 months old; feeding bottles and artificial nipples;³⁵
- Providing incorrect or misleading advertisements about the quantity, quality, price, utility, design, packaging, trademark, origin, type, service method, warranty period for registered or announced products;³⁶
- Publishing inaccurate or untruthful information, education, and communications and publications on food safety; providing false or counterfeit food test results; posting inaccurate or untruthful information about food safety on mass media;³⁷
- Using food utensils, packaging, and containers/materials that do not conformity to national technical regulations and safety requirements in producing and trading foods.³⁸

(2) Sanctions and compulsory remedial measures

Depending on the nature and severity of the noncompliance, violators may be subject to administrative or criminal liability. ³⁹

Administrative liability

The types of violations and penalties described herein may apply not only with regard to food safety regulations but also labeling and advertising regulations, pursuant to different legal rules on administrative sanctions. The maximum administrative penalty applicable to an organization for these violations is VND 200,000,000, or, depending on the type of violation, up to 7 times the value of the noncompliant food, in which case the amount is unlimited.⁴⁰ Depending on the nature and severity of the violation, additional penalties

³⁴ Food Safety Law, Article 5

³⁵ Advertising Law, Article 7.4 and 8.1

Food Safety Law, Article 5.11; Advertising Law, Article 8.9

³⁷ Decree 115, Article 23.4

³⁸ Decree 115, Article 8, Article 14

³⁹ Food Safety Law, Article 6.1

⁴⁰ Decree 115, Article 3.1

might be imposed, including temporary revocation of food-related certificates for a stated period (e.g., in the case of a certificate of food safety eligibility for food production and trading, the period of suspension is between 1 and 6 months), or suspension of operations for 1 to 12 months and confiscation of the items that caused or were responsible for the violation.⁴¹

Apart from the monetary fines and penalties referenced above, the violators also may be subject to one or multiple remedial measures, depending on the type and nature of the violation.⁴²

Criminal liability

Violations that lead to severe consequences may be subject to criminal liability. Depending on the value of the relevant products and the severity of the violation, the penalty shall consist of a monetary fine of up to VND 300,000,000 or imprisonment from 1 to 20 years; relevant persons may be banned from holding certain positions, practicing certain professions, or doing certain jobs for a period of 1 to 5 years.⁴³ Apart from the foregoing, the act of false advertising of goods, which already was subject to administrative sanctions, or where a person convicted of the same act, where the act has not been remedied, may be subject to a monetary fine of up to VND 100,000,000 or a non-custodial reform penalty of up to 3 years.⁴⁴

In addition to the administrative and criminal liability discussed above, in the event that harm or damage is caused to other persons, violators might be liable to pay compensation for damages in accordance with law.⁴⁵

The foregoing are general notes to assist your understanding of Vietnam's basic regulations on GM Foods, as well as food packaging, labeling, and advertising. Should you need further detailed information on this topic in Vietnam, please contact us directly.

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Decree 115, Article 2.2

Decree 115, Article 2.3

Penal Code 2015, as amended by the Amended Penal Code 2017, Article 317

⁴⁴ Penal Code 2015, as amended by the Amended Penal Code 2017, Article 197

Food Safety Law, Article 6.1