

## Enforcement Rules of the Act Governing Food Safety and Sanitation

- 1.Promulgated on November 20, 1981.
- 2.Amended and Promulgated on December 20, 1985.
- 3.Amended and Promulgated on September 7, 1994.
- 4.Amended and Promulgated on May 15, 2000.
- 5.Amended and Promulgated on May 3, 2001.
- 6.Amended and Promulgated on June 12, 2002.
- 7.Amended and Promulgated on April 1, 2009.
- 8.Amended and Promulgated on August 13, 2014.
- 9.Amended and Promulgated on July 13, 2017.

Article 1. These Enforcement Rules are prescribed in accordance with the provisions of Article 59 of the Act Governing Food Safety and Sanitation (hereinafter referred to as “this Act”).

Article 2. The term “infant and follow-up formula” prescribed in subparagraph 2 of Article 3 of this Act shall include infant formula, follow-up infant formula and infant formula for special medical purposes.

Article 3. The term “approval number granted by central competent authority” referred to in subparagraph 3 of Article 3 of this Act shall mean one of the following circumstances:

1. The registration number and product registration code obtained from the completion of registration under paragraph 3 of Article 8 of this Act.
2. The code prescribed in the Standards for Scope, Application and Limitation of Food Additives of the Appendix 1 of the Standards for Specification, Scope, Application and Limitation of Food Additives under Article 18 of this Act.
3. The registration approval number as stated in Paragraph 1 of Article 21 of this Act.

Article 4. The term “sanitation and safety management systems” referred to in Paragraph 5 of Article 8 of this Act shall mean the regulations on good hygiene practice for foods or the regulations on food safety control system as stated in Paragraph 1 or 2 of Article 8 of this Act.

Article 5. The term “toxic” referred to in subparagraph 3, paragraph 1 of Article 15 of this Act shall mean foods or food additives which contain natural toxins or chemicals and the ingredients or contents of which are harmful to human health or may possibly harm

the human health.

Article 6. The items that are contaminated by pathogenic organisms referred to in subparagraph 4, paragraph 1 of Article 15 of this Act shall mean foods or food additives contaminated by pathogenic organisms, or toxins derived from said pathogenic organisms, which are harmful to human health or may possibly harm human health.

Article 7. The labelling for the product names prescribed in subparagraph 1, paragraph 1 of Article 22 and paragraph 1 of Article 25 of this Act shall be handled in accordance with the following provisions:

1. The product names shall conform to the nature thereof.
2. The names of those that are stipulated by the central competent authority shall be set in accordance with the stipulated names provided; whereas names that are not stipulated by the central competent authority may either be set in accordance with National Standards of the Republic of China (CNS) or by their own.

Article 8. The net weight and capacity prescribed in subparagraph 3, paragraph 1 of Article 22 of this Act shall be labelled using the legal units of measurement or their symbols and shall be handled in accordance with the following provisions:

1. Those ingredients that are a mixture of liquid and solid materials shall indicate their respective contents; whereas those ingredients which are a homogeneous mixture that are hard to separate may merely indicate the net weight thereof.
2. Depending on the nature of the foods, the contents may be indicated as minimum quantity, maximum quantity, or both the minimum and maximum quantities.

Article 9. The name of food additives prescribed in subparagraph 4, paragraph 1 of Article 22 of this Act shall be labelled in accordance with the food additive items prescribed in the Standards for Scope, Application and Limitation of Food additives of the Appendix 1 of the Standards for Specifications, Scope, Application and Limitation of Food Additives or the names commonly known by society, and shall be handled in accordance with the following provisions:

1. Sweeteners, preservatives and antioxidants shall indicate the names of their

respective functions.

2. Food additive combinations shall indicate the name of each material.

The labelling of the food additives is not required when the food additives contained in foods were made through legalized materials and the contents of which are apparently below the normal amount as added to the foods and do not provide functions thereof.

Article 10. The term “manufacturer” referred to in subparagraph 5, paragraph 1 of Article 22 and subparagraph 5, paragraph 1 of Article 24 of this Act shall mean one of the following circumstances:

1. Those businesses that manufacture, process or prepare the end products.
2. Those businesses that are entrusted to manufacture, process or prepare products.
3. For those products made through the repacking process such as sub packaging, cutting, assembling or combining, and that are enough to affect the sanitation and safety of the product, the repacking factory or businesses referred to in the two previous subparagraphs.

The labelling of the manufacturers referred to in the preceding paragraphs shall be handled in accordance with the following provisions:

1. Name and address of the manufacturer of imported foods or food additives shall be labelled in Chinese. For those names that are hard to recognize in Chinese, they may be labelled in commonly known characters or symbols.
2. Where the foods or food additives are manufactured by the factory belonging to the same company and registered under the same country, the labelling of the manufacturer can be either the head company or the manufacturing factory. The name, address and telephone number shall be labelled as of the head company or factory; when the registered place of the factory is different from that of the company's, the manufacturing factory that engaged in the actual manufacturing process shall be on the label.
3. The repacking factory referred to in the preceding subparagraph 3 shall be labelled as “repacking manufacturer.”

Article 11. The responsible domestic company referred to in subparagraph 5, paragraph 1 of Article 22, subparagraph 5, paragraph 1 of Article 24, subparagraph 4 of Article 26 and

subparagraph 4 of Article 27 of this Act shall mean food businesses that are responsible for the liability of the products.

Name, telephone number and address of the manufacturer or that of the responsible domestic company of the imported foods or food additives referred to in subparagraph 5, paragraph 1 of Article 22 and subparagraph 5, paragraph 1 of Article 24 shall mean the labelling of the names, telephone number and address of the responsible domestic company and the names, telephone number and address of the foreign manufacturer can also be labelled in addition. For those foods or food additives manufactured domestically, the labelling thereof shall be either the name, telephone number or address of the manufacturer or that of the responsible domestic company or both.

Article 12. The country of origin referred to in subparagraph 6, paragraph 1 of Article 22 of this Act shall mean the country or region where the end products are manufactured, processed or prepared.

The labelling of the country of origin referred to in the preceding paragraph shall be handled in accordance with the following provisions:

1. The Country of Origin of imported goods shall be determined in accordance with the Regulations Governing the Determination of Country of Origin of an Imported Good.
2. Where the food product is not an assorted product of substantial transformation based on the Regulations Governing the Determination of Country of Origin of an Imported Good, the labelling of which shall be the respective country of origin based on the volume of contents it possesses.
3. Where the address of the manufacturer in Chinese can obviously represent the country of origin, the labelling may be exempted.

Article 13. The labelling of the expiry date prescribed in subparagraph 7, paragraph 1 of Article 22 of this Act shall be printed on the container or package and the year, month and day shall be marked in a way that is customarily decipherable. However, for products of which the shelf life is 3 months or longer, the expiry date may be marked with the year and month only and the last date of that month shall be the expiry date.

Article 14. Where the product names prescribed in subparagraph 1, paragraph 1 of Article 24

of this Act is for a single food additive, it shall be labelled in accordance with the food additive items prescribed in the Standards for Scope, Application and Limitation of Food additives of the Appendix 1 of the Standards for Specifications, Scope, Application and Limitation of Food Additives or the names commonly known prescribed by the central competent authority in a public announcement; whereas when the product name is for food additive combinations, the names may be set by their own.

Product names set by their own in accordance with the preceding paragraph shall be sufficient to reflect the nature or function of the product.

Food additive that has been registered with the central competent authority and received a permit document prior to the amendment of this Enforcement Rules on 13th July 2017, the product name of which is unable to comply with the two preceding paragraphs shall apply for a change of the product name in accordance with paragraph 1 of Article 21 of this Act before 1st July 2018. The changed product name shall be labeled on the container or package from 1st January 2019.

Article 15. The food additive names prescribed in subparagraph 3, paragraph 1 of Article 24 shall be labelled in accordance with the food additive items prescribed in the Standards for Scope, Application and Limitation of Food additives of the Appendix 1 of the Standards for Specifications, Scope, Application and Limitation of Food Additives or the names commonly known prescribed by the central competent authority in a public announcement.

Article 16. The net weight and capacity prescribed in subparagraph 3, paragraph 1 of Article 24 of this Act shall be labelled using the legal units of measurement or their symbols.

Article 17. The labelling of the expiry date prescribed in subparagraph 6, paragraph 1 of Article 24 of this Act shall be printed on the container or package and the year, month and day shall be marked in a way that is customarily decipherable. However, for products of which the shelf life is 3 months or longer, the expiry date may be marked with the year and month only and the last date of that month shall be the expiry date.

Article 18. The country of origin referred to in subparagraph 8, paragraph 1 of Article 24 of this Act shall mean the country or region where the end products are manufacture, processed or prepared.

The labelling of the country of origin referred to in the preceding paragraph shall

be handled in accordance with the following provisions:

1. The Country of Origin of imported goods shall be determined in accordance with the Regulations Governing the Determination of Country of Origin of an Imported Good; whereas the products cannot be determined as a substantial transformation because of classification, categorizations, sub-packaging, packaging, marking or relabeling in our country, the labelling shall still be set as the country or region where the end products are manufactured, processed or prepared.
2. Where the address of the manufacturer in Chinese can obviously represent the country of origin, the labelling may be exempted.

Article 19. The labelling of pre-packaged foods, food raw materials, food additives and their raw materials shall be handled in accordance with the following provisions:

1. The length and width of the characters marked on the labels shall not be less than two millimeters. However, where the area of the largest surface of a package is less than 80 square centimeters, the length and width of characters for all items other than the name of the product, the company name, and expiry date, may be less than two millimeters.
2. Where the products are domestically manufactured and their labels are in a foreign language, the labelling text in Chinese shall be primary and the labelling text in the foreign language is only supplementary.
3. Where the products are imported from overseas, the importer is allowed to import such products when a Chinese label is added in accordance with the provisions of Article 22 and 24 of this Act. However, where products need to be repackaged, sub-packaged or go through other processing procedure, such products shall label the product name, manufacturer name, and date, or have other labels or information for proof of the authenticity of the items at the time of importation, and the labelling in Chinese shall be completed prior to the sale of the products.

Article 20. The bulk foods referred to in paragraph 1 of Article 25 of this Act shall mean that the product is without a package while vending or with a package but meets one of the following circumstances:

1. Does not have unpackaged identifiability.
2. Could not extend the shelf life.
3. Is not sealed.
4. The purpose of selling is no more than vending in a small area.

Article 21. The food utensils, food containers and packages prescribed in Article 26 of this Act shall be labelled in accordance with the following provisions:

1. The position of labels: labels shall be printed, stamped, pressed or marked on the package or object of the smallest unit of the vending products. The labeled content shall be clearly visible at the time of distribution and marketing. For those products prescribed by the central competent authority, the name of materials and thermal resistance temperature of its major part shall be printed, stamped or pressed on the object.
2. The method of labelling: if the labelling is made by way of printing or stamping, the ink shall sustain fading and shall not peel off.
3. Labelling of Date: the labelling of the date shall consist of the year, month and day and date shall be marked in a way that is customarily decipherable. Where the labelling of the date consists of only the year and month, the last day of that month shall be regarded as the last expiry date or date of the shelf life.
4. Font of Labelling: the length and width of the characters marked on the labels shall not be less than two millimetres.

Article 22. The labelling of food cleansers shall be handled in accordance with the following provisions:

1. The position of labels: labels shall be printed, stamped, pressed or marked on the package of the smallest unit of the vending products. The labeled content shall be clearly visible at the time of distribution and marketing.
2. The method of labelling: if the labelling is made by way of printing or stamping, the ink shall sustain fading and shall not peel off.
3. Labelling of Date: the labelling of the date shall consist of the year, month and day and date shall be marked in a way that is customarily decipherable. Where the labelling of the date consists of only the year and month, the last day of that month shall be regarded as the last expiry date or date of the shelf life.

4. Font of Labelling: the length and width of the characters marked on the labels shall not be less than two millimetres.
5. Where the products are imported from overseas, the importer is allowed to import such products when a Chinese label is added in accordance with the provisions of Article 27 of this Act. However, where products need to be repackaged, sub-packaged or go through other processing procedure, such products shall label the product name, manufacturer name, and date, or have other labels or information for proof of the authenticity of the items at the time of importation, and the labelling in Chinese shall be completed prior to the sale of the products.

Article 23. The product name prescribed in subparagraph 1 of Article 26 and subparagraph 1 of Article 27 of this Act shall conform to the nature thereof.

Article 24. The net weight and capacity prescribed in subparagraph 3 of Article 26 and subparagraph 3 of Article 27 of this Act shall be labelled using the legal units of measurement or their symbols.

Article 25. The country of origin referred to in subparagraph 5 of Article 26 and subparagraph 5 of Article 27 of this Act shall mean the country or region where the end products are manufacture, processed or prepared.

The labelling of the country of origin referred to in the preceding paragraph shall be handled in accordance with the following provisions:

1. The Country of Origin of imported goods shall be determined in accordance with the Regulations Governing the Determination of Country of Origin of an Imported Good; whereas the products cannot be determined as a substantial transformation because of classification, categorizations, sub-packaging, packaging, marking or relabeling in our country, the labelling shall still be set as the country or region where the end products are manufactured, processed or prepared.
2. Where the address of the manufacturer in Chinese can obviously represent the country of origin, the labelling may be exempted.

Article 26. The “main ingredients” or “ingredients” referred to in subparagraph 2 of Article 27 of this Act shall mean the ingredients that are contained in the food cleansers and the function of which is to disinfect or clean.

Article 27. Where the foods, food additives, food utensils, food containers, packages or food cleansers are exclusive for export, the labelling based on Article 22, 24, 26, and 27 of this Act may be exempted.

Article 28. The method of test, testing unit and the evidence used in interpreting the results prescribed in Article 40 of this Act, with the content as follows:

1. The method of test: including the basis of the method adopted, experiment procedure, instruments and equipment for the test and standard materials.
2. Testing Unit: including the name, address, contact information and responsible person of the laboratory.
3. Evidence used in interpreting the results: including the sampling method of the specimens, product names, source, package, batch number or manufacturing date or expiry date, data of finalized experiment, interpreting standard and its source or academic reference.

Article 29. Where foods, food additives, food utensils, food containers, food packages or food cleansers are confiscated, destroyed or are notified to be disinfected, reconditioned or remedied with safety measures within a set period in accordance with the provisions of subparagraphs 1 to 3, paragraph 1 of Article 52 of this Act, the scope of such confiscation, destruction, disinfection, reconditioning or remedies shall be extended to the finished products of the same expiry date, and shall be extended to all finished products on which no expiry date is marked or the expiry date is unintelligible. Products that are of unknown origin and cannot be notified to be disinfected, reconditioned or remedied with safety measures within a set time period shall be confiscated and destroyed.

Article 30. To meet the requirements of documentary proof, those engaging in the export of foods, food additives, food utensils or food containers may apply to the competent authority for an inspection and examination. Those that comply with the regulations shall be approved with the issuance of an export proof document such as sanitary certificate, test report or certificate of free sales and manufacture.

Article 31. Other than Article 22 is implemented one year after promulgation, these Enforcement Rules shall be implemented as of its being promulgated.