

Administrative Measures for Food Recalls

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INTRODUCTION

Food recall management measures enacted to strengthen the supervision of most agricultural products. This will greatly enhance the overall quality of agricultural products.

The Administrative Measures for Food Recalls, as deliberated and adopted at the executive meeting of the China Food and Drug Administration (“CFDA”), are hereby issued and shall come into force on September 1, 2015.

Chapter I General Provisions

Article 1 In order to strengthen the administration of food production and business operation, reduce and avoid the damage of unsafe foods, and protect the physical health and safety of the public, these measures are developed in accordance with the provisions of the Food Safety Law of the People's Republic of China and the regulation on its implementation as well as other relevant laws and regulations.

Article 2 These Measures shall apply to the cessation of food production and business operation, recall and disposal of unsafe foods as well as the supervision and administration thereof within the territory of the People's Republic of China.

“Unsafe foods” means the foods prohibited from production and business operation in accordance with the laws and regulations on food safety and other foods that may damage human health as proved by evidence.

Article 3 Food producers and dealers shall, in accordance with the law, be the primary persons responsible for food safety, establish and improve the relevant management rules, collect and analyze food safety information, and perform the obligations to cease the food production and business operation, recall and disposal of unsafe foods in accordance with the law.

Article 4 The CFDA shall direct the supervision and administration of the cessation of food production and business operation, recall and disposal of unsafe foods nationwide.

Local food and drug administration at or above the county level shall oversee and administer the cessation of food production and business operation, recall and disposal of unsafe foods within their respective administrative regions.

Article 5 Food and drug administrations at or above the county level shall organize the establishment of food safety expert databases consisting of experts in related fields such as medical science, toxicology, chemistry, food, and law, so as to provide professional support for the cessation of food production and business operation, recall and disposal of unsafe

foods.

Article 6 The CFDA shall summarize and analyze the information on the cessation of food production and business operation, recall and disposal of unsafe foods nationwide, and improve the measures for the supervision and administration of food safety according to the risk factors related to food safety.

Local food and drug administrations at or above the county level shall collect, analyze and process the information on the cessation of food production and business operation, recall and disposal of unsafe foods within their respective administrative regions, and oversee their performance of responsibilities of food producers and dealers.

Article 7 Food industry associations are encouraged and supported to strengthen industrial self-discipline, develop industry rules, and direct and promote food producers and dealers' lawful performance of obligations to cease the production and business operation, recall, and disposal of unsafe foods.

The public is encouraged and supported to conduct social supervision of such activities as the cessation of food production and business operation, recall and disposal of unsafe foods.

Chapter II Cessation of Food Production and Business Operation

Article 8 Where any food producer or dealer finds that any of the foods it produced or sold is unsafe, it shall immediately cease the production or sale of such food, and by making a notice or an announcement, notify the relevant food producer or dealer to cease production and business operation and notify consumers to stop consuming it, and take necessary measures to prevent and control food safety risks.

Where the food producer or dealer fails to suspend the production or business operation of any unsafe food in accordance with the law, the food and drug administration at or above the county level may order it to cease the production or business operation of the unsafe food.

Article 9 Where the sponsor of a centralized food market, the lessor of food booths or the organizer of a food exhibition finds that the food sold by any food dealer is unsafe, it shall take effective measures in a timely manner to ensure that the relevant dealer ceases the business operation of such unsafe food.

Article 10 Where the provider of a third-party online food distribution platform finds that the food sold by any online food dealer is unsafe, it shall, in accordance with the law, stop the online trading platform services and take other measures so as to ensure that the online food dealer ceases the business operation of such unsafe food.

Article 11 Where any unsafe food produced or distributed by a food producer or dealer is not sold to consumers and under the control of any other producer or dealer, the food producer or dealer shall immediately recover such unsafe food and take necessary measures to eliminate risks.

Chapter III Recall

Article 12 Where a food producer knows that any food it produced and distributed is unsafe by such means as self-examination, complaints and reporting of the general public, and notification of dealers and regulatory authorities, it shall voluntarily recall such food.

Where any food producer should have voluntarily recalled any unsafe food, the food and drug administration at or above the county level may order it to recall such food.

Article 13 Based on the seriousness and degree of urgency of food safety risks, food recall is divided into three levels:

(1) Level I recall: Where the food has caused or may cause serious health damage or death after consumption, the food producer shall initiate the recall within 24 hours after knowing of the food safety risks, and report the recall plan to the local food and drug administration at or above the county level.

(2) Level II recall: Where the food has caused or may cause ordinary health damage after consumption, the food producer shall initiate the recall within 48 hours after knowing of the food safety risks, and report the recall plan to the local food and drug administration at or above the county level.

(3) Level III recall: Where the food label or mark has false indications, the food producer shall initiate the recall within 72 hours after knowing of the food safety risks, and report the recall plan to the local food and drug administration at or above the county level. If there is any flaw in the label or mark, and no health damage is caused after the food is consumed, the food producer shall make corrections and may voluntarily recall the food.

Article 14 The food producer shall recall unsafe foods based on the recall plan.

The local food and drug administration at or above the county level may, after receiving the recall plan of a food producer, organize experts to assess the recall plan when necessary. If it deems in the assessment conclusion that the recall plan shall be amended, the food producer shall immediately make amendments, and recall the food according to the amended recall plan.

Article 15 The food recall plan shall cover:

(1) The title, domicile, legal representative, specific person in charge, contact information and other basic information of the food producer;

(2) The food name, trademark, specifications, date of production, batch number, quantity, and recall area;

(3) The reasons for recall and damage;

(4) The recall level, process and time limit;

(5) The content of the recall notice or announcement and the issuance method;

(6) The obligations and responsibilities of the relevant food producer or dealer;

(7) The measures for disposing of the recalled foods and the assumption of expenses; and

(8) The expected result of recall.

Article 16 The food recall announcement shall cover:

(1) The title, domicile, legal representative, specific person in charge, contact information and e-mail address of the food producer;

(2) The food name, trademark, specifications, date of production, and batch number, etc.

(3) The recall reasons, level, beginning and ending dates, and area; and

(4) The obligations of the relevant food producer or dealer and the process for consumers' goods return and compensation.

Article 17 Where any unsafe food is sold in a province, autonomous region or municipality directly under the Central Government, the food recall announcement shall be issued on the website of the provincial food and drug administration and major provincial media. The recall announcement issued on the website of the provincial food and drug administration shall be linked with the website of the CFDA.

Where any unsafe food is sold in two or more provinces, autonomous regions or municipalities directly under the Central Government, the food recall announcement shall be issued on the website of the CFDA and major media of the Central Government.

Article 18 Where level I recall is conducted, the food producer shall accomplish the recall within 10 working days as of the date of issuance of the announcement.

Where level II recall is conducted, the food producer shall accomplish the recall within 20 working days as of the date of issuance of the announcement.

Where level III recall is conducted, the food producer shall accomplish the recall within 30 working days as of the date of issuance of the announcement.

Where the circumstances are complicated, with the approval of the local food and drug administration at or above the county level, the food producer may appropriately extend the time for recall and make an announcement.

Article 19 After a food dealer knows that a food producer recalls any unsafe food, it shall immediately cease the purchase and sale of it, seal it, post the recall announcement of the producer in an eye-catching position of its business premises, take other measures, and assist the food producer in the food recall.

Article 20 A food dealer shall, in accordance with the provisions of relevant laws and regulations, voluntarily recall unsafe foods caused due to its own reason within its business scope.

The food dealer shall inform the supplier of its recall of any unsafe food. The supplier shall inform the producer in a timely manner.

The food dealer shall, in particular, indicate in the recall notice or announcement that the food is unsafe due to its own reason.

Article 21 Where any unsafe food cannot be recalled for the reason that the producer cannot be determined, or is bankrupt, among others, the food dealer shall voluntarily recall the unsafe food within its business scope.

Article 22 The relevant provisions on the recall of unsafe foods by food producers shall apply, by reference, to the procedures for the recall of unsafe foods by food dealers.

Chapter IV Disposal

Article 23 Food producers and dealers shall, in accordance with the provisions of the relevant laws and regulations, take remedial, harmless treatment, destruction and other disposal measures for the unsafe foods withdrawn from the market due to the cessation of food production and business operation, recall or any other reason.

Where any food producer or dealer fails to dispose of any unsafe food in accordance with the law, the local food and drug administration at or above the county level may order it to dispose of the unsafe food in accordance with the law.

Article 24 For any unsafe food that seriously damages human health and life safety, such as food to which non-edible materials are added in violation of any law, putrid or deteriorated food, and livestock and poultry that died from diseases, the food producer or dealer shall immediately destroy it on the spot.

Where the conditions for on-site destruction are not met, the unsafe food producer or dealer may destroy and dispose of such food in a centralized manner. Before centralized destruction and disposal, the food producer or dealer shall report to the local food and drug

administration at or above the county level.

Article 25 A food producer may continue selling the food recalled because the food label or mark fails to meet the food safety standards, provided that it takes remedial measures and is able to ensure food safety; and when selling such food, it shall expressly disclose the remedial measures to consumers.

Article 26 Where resource recycling can be realized through the harmless treatment of an unsafe food, the food producer or dealer may dispose of the food in accordance with the relevant provisions of the state.

Article 27 Where a food producer or dealer is unable to determine the methods for the disposal of unsafe foods, it shall organize the relevant experts to conduct assessment, and handle according to the assessment opinions.

Article 28 A food producer or dealer shall faithfully record the name, trademark, specifications, date of production, batch number, quantity and other content of the unsafe food of which the production and business operation is ceased, and which is recalled and disposed of. The record shall be retained for no less than two years.

Chapter V Supervision and Administration

Article 29 Where the local food and drug administration at or above the county level finds any unsafe food, it shall notify the relevant food producer or dealer to cease the production or business operation of it, or recall the food and take the relevant measures to eliminate food safety risks.

Article 30 Where the local food and drug administration at or above the county level finds that the food produced or traded by any food producer or dealer may be unsafe, it may conduct investigation and analysis, and the relevant food producer and dealer shall provide active assistance.

Article 31 The local food and drug administration at or above the county level may conduct on-site supervision and inspection of food producers and dealers' cessation of food production and business operation, recall and disposal of unsafe foods.

Article 32 Where the unsafe food of which the production or business operation is ceased and which is recalled and disposed of by a food producer or dealer has relatively large risks, the food producer or dealer shall submit a written report to the local food and drug administration at or above the county level within five working days as of the cessation of food production or business operation, recall and disposal.

Article 33 The local food and drug administration at or above the county level may require food producers and dealers to report the cessation of food production and business operation, recall and disposal of unsafe foods on a periodical basis or from time to time.

Article 34 The local food and drug administration at or above the county level may assess the reports on the cessation of food production or business operation, recall and disposal of unsafe foods submitted by food producers and dealers.

Where the local food and drug administration at or above the county level deems in its assessment conclusion that the measures taken by a food producer or dealer is insufficient to control food safety risks, it shall order the food producer or dealer to take more effective measures to cease the food production or business operation, recall and disposal of unsafe foods.

Article 35 To prevent and control food safety risks, the local food and drug administration at or above the county level may issue early warning information, require the relevant food producer or dealer to cease the production or business operation of the unsafe food, and remind consumers to stop consuming the unsafe food.

Article 36 The local food and drug administration at or above the county level shall record the information on the cessation of food production and business operation, recall and disposal of unsafe foods in the credit archives of food producers and dealers.

Chapter VI Legal Liability

Article 37 Where any food producer or dealer violates any provision of these Measures on the cessation of food production and business operation, recall and disposal of unsafe food, or any law or regulation on food safety, it shall be punished in accordance with the relevant provisions.

Article 38 Where any food producer or dealer, in violation of paragraph 1 of Article 8, paragraph 1 of Article 12, Article 13, Article 14, paragraph 1 of Article 20, Article 21, paragraph 1 of Article 23, or paragraph 1 of Article 24 of these Measures, fails to immediately cease the production or business operation, or voluntarily recall the unsafe food, fails to initiate the recall of unsafe food within the prescribed time limit, fails to recall the unsafe food according to the recall plan, or fails to dispose of the unsafe food as required, the food and drug administration shall give it a warning, and impose a fine of 10,000 yuan up to 30,000 yuan on it.

Article 39 Where any food dealer fails to assist the food producer in recalling unsafe food in violation of Article 19 of these Measures, the food and drug administration shall give it a warning, and impose a fine of 5,000 yuan up to 30,000 yuan on it.

Article 40 Where any food producer or dealer fails to perform the relevant reporting obligation in violation of Article 13, paragraph 2 of Article 24, or Article 32 of these Measures, the food and drug administration shall order it to make correction and give it a warning; and if it refuses to make correction, impose a fine of 2,000 yuan up to 20,000 yuan on it.

Article 41 Where any food producer or dealer violates paragraph 2 of Article 23 of these Measures, the food and drug administration shall order the food producer or dealer to dispose of the unsafe food in accordance with the law, and if the food producer or dealer rejects or delays the disposal, the food and drug administration shall give it a warning, and impose a fine of 20,000 yuan up to 30,000 yuan on it.

Article 42 Where any food producer or dealer fails to record or retain the cessation of food production or business operation, recall and disposal of unsafe foods in violation of Article 28 of these Measures, the food and drug administration shall order it to make correction and give it a warning; and if it refuses to make a correction, impose a fine of 2,000 yuan up to 20,000 yuan on it.

Article 43 The food producer or dealer's cessation of production or business operation, recall and disposal of unsafe foods shall not exempt other legal liabilities it shall assume in accordance with the law.

Where any food producer or dealer fails to voluntarily cease the production or business operation, recall and disposal of unsafe food to eliminate or reduce the damage, a lighter or

mitigated punishment shall be imposed on it in accordance with the law; and if the circumstances on the violation of law are minor and corrected in a timely manner, and no damage is caused, no administrative penalty shall be given.

Article 44 Where the local food and drug administration at or above the county level fails to perform the functions as prescribed in these Measures in accordance with the law, which has caused any adverse consequences, disciplinary sanctions shall be imposed on the directly responsible person in charge and other directly liable persons in accordance with the relevant provisions of the Food Safety Law of the People's Republic of China.

Chapter VII Supplementary Provisions

Article 45 These Measures shall apply to foods, food additives and health foods.

These Measures shall apply, by reference, to food producers and dealers' cessation of production and business operation, recall and disposal of edible agricultural products that enter the wholesale and retail markets or production and manufacturing enterprises.

Article 46 These Measures shall come into force on September 1, 2015.

Remark: Sincerely hope that after the entry into force of the act, all kinds of foods and agricultural products have a better regulatory environment.

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