



CIRS



Guideline on New Food Contact Substance Chinese Market Access

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Foreword

With the rapid development of the food industry and food supply globalization, food contact materials (FCMs) have been attracted increasing attention since they could significantly affect food safety. In China, the regulatory system and supervision on FCMs have been improved gradually, lowering the risks and ensuring the safety of the consumers.

For the purpose of regulating the use of FCMs, the Food Safety Law proposes that manufacturing new food contact substances (including resins and additives) need to pass the safety assessment of the National Health Commission of the People's Republic of China (NHC). As long as the new food contact substances pass the assessment and obtain the registration approval, they are permitted to be sold or used.

Therefore, in order to help enterprises better understand the status and requirements of the notification of new food contact substances, Food Regulatory Team from CIRS Group made this guide which comprehensively introduces and interprets the current management mechanism of new food contact substances in China and the approval status of new food contact substances, and summarizes the approved substances as a list for reference.



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Chapter 1: Introduction of New Food Contact Substance

According to the article 37 of the *Food Safety Law of the People's Republic of China*: using new food raw materials to produce food, or producing new food additives and new food related products, the safety assessment materials shall be submitted to the health administration department under the state council (namely, the National Health Commission of the People's Republic of China, hereinafter referred to as NHC). Meanwhile, according to the article 93, the import of foods produced with new food raw materials or the import of new food additives and new food related products shall be handled in accordance with the article 37 of the law.

Food related product, refers to new materials or additives used in food packaging materials, containers, detergents, disinfectants and tools and equipment used in food production and management, it should meet the following requirements:

- 1) Clear in use and technical necessity (namely, why it should be used);
- 2) Cannot cause harm to human health under normal and reasonable use;
- 3) Cannot cause changes of food ingredients, structure or color and aroma, etc.;
- 4) Reduce the amount of use as much as possible when the desired effect is achieved;

New food contact substance belongs to new food related product, and the notification of new food contact substance should be carried out in accordance with *Administrative Measures on New Food Related Product*, to NHC.

New food contact substance includes:

- 1) Food contact substances that have not been listed in the following national food safety standards or related announcements:
 - GB 9685-2016 *National Food Safety Standard for the Use of Food Additives in Food Contact Materials and Articles*;
 - Product standard, such as GB 4806.6-2016 *National Food Safety Standard for Food Contact Plastic Resin*;
 - Food contact substances permitted to be used in the announcements from NHC (former National Health and Family Planning Commission of the People's Republic of China and Ministry of Health)
- 2) Food contact resins and additives with the intention of expanding using scope and amount.

Chapter 2: Status and Analysis of New Food Contact Substance Notification

2.1 Analysis on Acceptance of New Food Contact Substance Notification

From 2014 to the end of June, 2019, the NHC has accepted 201 types of food contact substances notification, including 50 for domestic and 151 for imported, detailed information are demonstrated in figure 2-1.

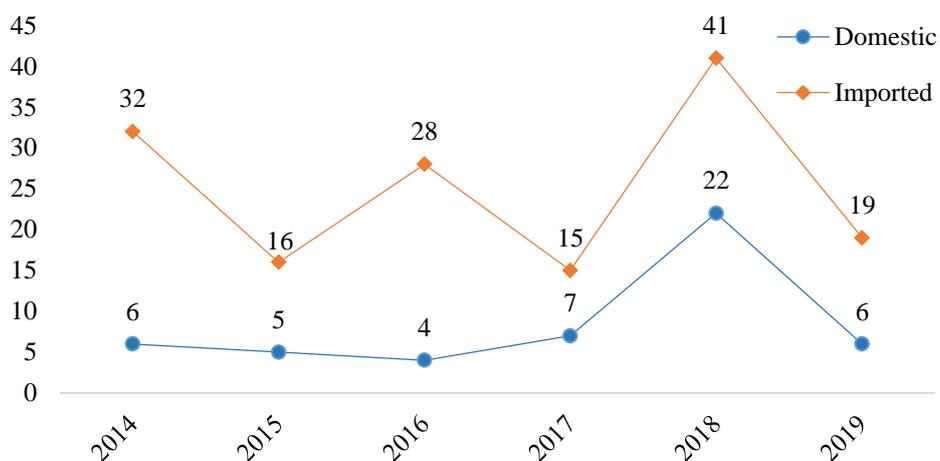


Figure 2-1 Acceptance numbers of FCS in China within 2014-2019

It can be noticed from figure 2-1 that, the number of notifications have been fluctuated recent years. Former National Health and Family Planning Commission of the People's Republic of China (NHFPC) released 53 food safety national standards on 18 November, 2016, therefore, taking time for companies to adapt to new regulatory system and management models could be one of the reasons why the number of notifications was declined in 2017.

Chapter 3: The Present Laws and Regulations of New Food Contact Substance

3.1 Relevant Laws and Regulations of New Food Contact Substance

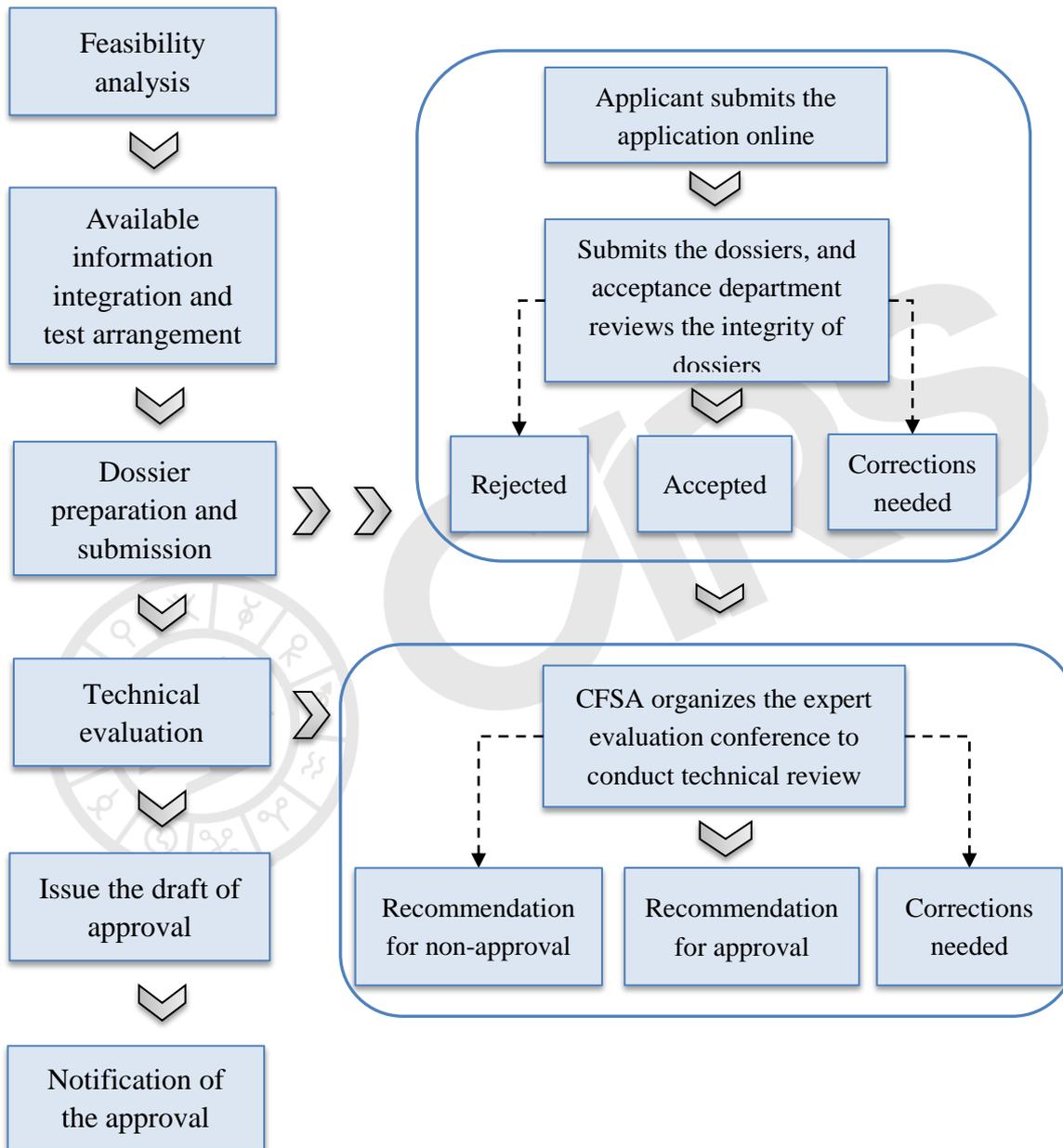
Table 3-1 The Present Laws and Regulations of New Food Contact Substance

Category	Main Laws and Regulations
Laws and Regulations	<Food Safety Law of the People’s Republic of China> (2015)
	<Regulation on the Implementation of the Food Safety Law of the People's Republic of China> (2016 Revision)
Relevant Regulations for Review	<Administrative Measures on New Food Related Product>
	<Regulations on Application and Acceptance of New Food Related Product>
Relevant Regulations for Production Management	<Regulation of the People's Republic of China on the Administration of Production License for Industrial Products>
	<Implementation Rules for the Supervision and Administration on the Quality and Safety of the Food Manufacturing and Processing Enterprise (For Trial) >



Chapter 4: Notification Requirements of New Food Contact Substance

4.1 Notification Procedure



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