REGULATORY FOCUS

# An update of China's food safety regulatory framework

**Junshi Chen, MD, and Chunzhu Wu, MSc**

This article reviews the changes in China's national food safety control system and update on national food safety standard system and describes the country's unique regulations and requirements for the regulatory control of infant formula, health foods (functional foods), and food for special medical purposes (FSMP).

***Keywords –*** infant formula; food for special medical purposes; food regulatory control; food safety; food standards

## Introduction

Since the melamine crisis in 2008, the overall food safety situation in China has been improved significantly. The first Food Safety Law was promulgated in 2009 and revised in 2015, with specific emphasis on risk analysis. The national food safety standard system has been developed rapidly and is now in line with the Codex system. Food safety inspection by competent authorities has been strengthened. The food industry has made food safety a high priority, which is

reflected in the increased investment of funds and manpower. As a result, no major food safety incidents have been reported in recent years. However, due to the small-scale agriculture production system (more than 100 million individual farming households) and food processing industry (more than 500 thousand manufacturers), violations of regulations and standards (e.g., food additive exceeded maximum use level, pesticide residues) and sporadic occurrences of food-borne diseases have been reported. These food safety issues cannot realistically be entirely eliminated – food safety will remain a long-term effort in China until the Chinese production system of agriculture and food processing industry have been greatly improved.

This article is an update of a previous article published in 2016.[1] In addition to the changes in national food safety control system and update on national food safety standard system, unique regulations and requirements for the regulatory control of infant formula, health foods (functional foods), and food for special medical purposes (FSMP) are described. Personal views on challenges to food industries on the regulatory compliance of these standards are included.

## Update of the national food safety control system

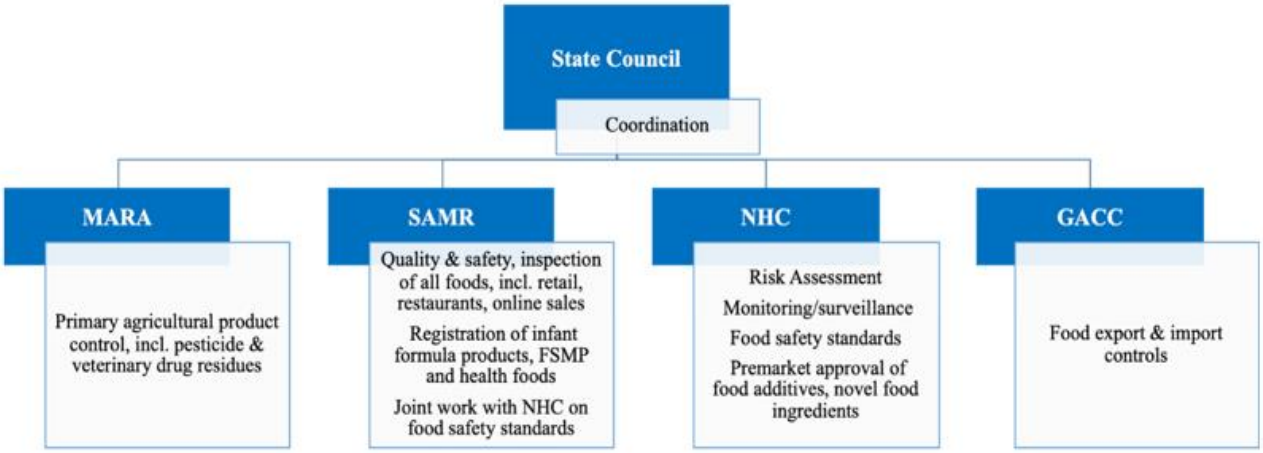
Another re-organization of the national food safety control system took place in 2018.[2] The names and responsibilities of several ministries were changed. The Ministry of Agriculture became the Ministry of Agriculture and Rural Affairs (MARA). It is still responsible for the safety of primary agricultural products, and the development of maximum limits of pesticide residues in foods and veterinary drug residues in animal foods. The name of Health and Family Planning Commission was changed to National Health Commission (NHC). It is responsible for monitoring and surveillance, risk assessment, food safety standards, premarket approval for additives, food contact materials, and new food ingredients.

The most significant change was the merging of the China Food and Drug Administration (CFDA) with the State Administration of Industry and Commerce (SAIC) to form the new State Administration of Market Regulation (SAMR). SAMR is responsible for the quality and safety of all types of commodities, including foods and pharmaceuticals. In addition to the safety control and inspection of all foods in the Chinese market, SAMR is responsible for retailing, restaurants and on-line sales, the regulatory control of infant formula products, the health foods (functional foods) and the FSMP products. In addition, SAMR works with NHC on food safety standards promulgation. The responsibility of food import and export control of the General Administration of Quality Supervision, Inspection and Quarantine was moved to the General Administration of Customs (GACC). **Figure 1** (p. 3) depicts the current structure of the Chinese national food safety control system.

## Update of the national food safety standard system

Under to the 2015 Food Safety Law,[3] the NHC and MARA are jointly responsible for the development and promulgation of new and revised food safety standards. In general, the current Chinese food safety standard system is in line with the Codex system. The procedures for planning new standards and revising

**Figure 1. Current structure of the Chinese national food safety control system[2]**

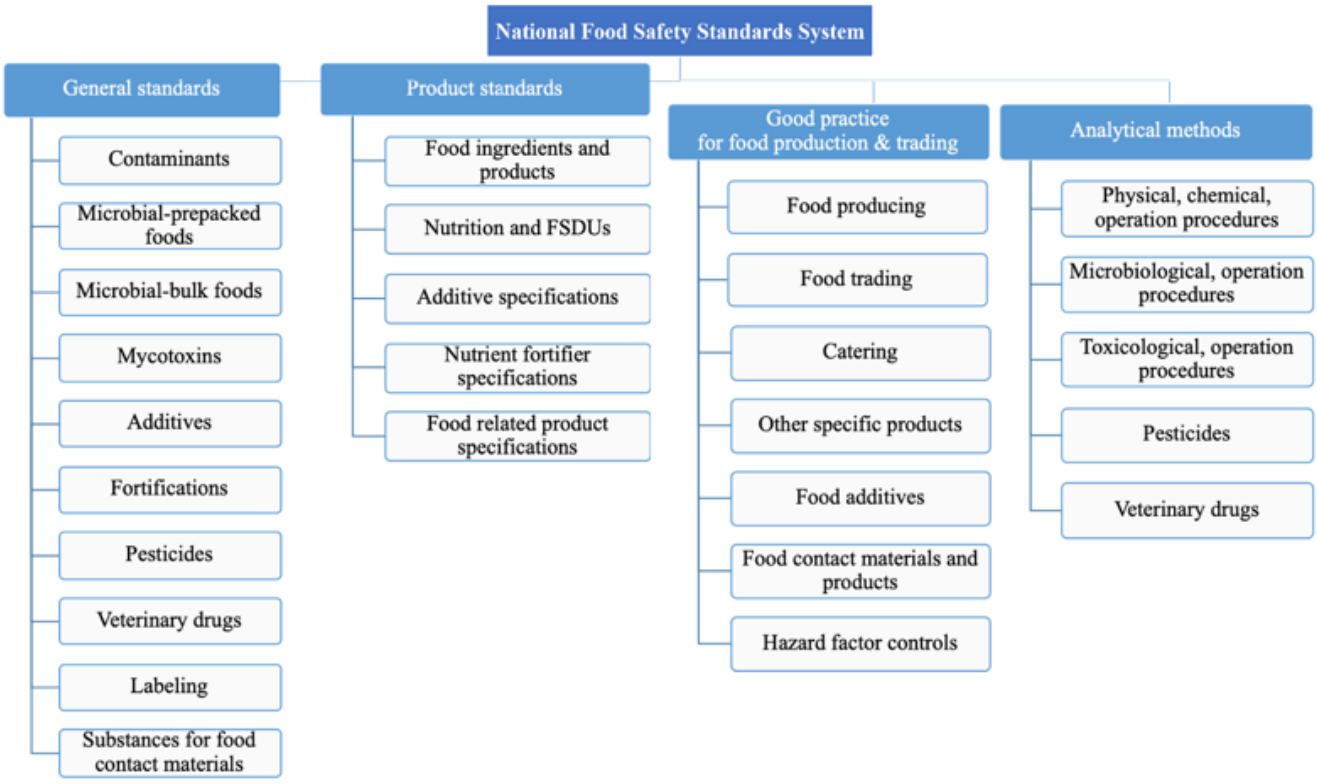



**GACC,** General Administration of Customs; **MARA,** Ministry of Agriculture and Rural Affairs; **NHC,** National Health Commission; **SAMR,** State Administration of Market Regulation.

existing standards, the standard drafting and reviewing, seeking public comments and submitting to the World Trade Organization for comments are well established. From the China National Food Safety Risk Assessment website, the whole process of standard development is transparent and accessible. **Figure 2** (p. 4) depicts the current national food safety standards system. As of 1 November 2021, 1,294 mandatory national food safety standards were promulgated. Among them, more than 250 new standards had been promulgated since 2016.[4] A few highlights and problems are as follows:

- In general, the number of standards and their coverage could meet the needs for government regulatory inspection, and for the industry to comply.
- More new standard development and existing standard revision were based on risk assessment results using Chinese data. For example, the cadmium limit for rice remains at 0.2 mg/kg, even though some local authorities have requested it be raised to 0.4 mg/kg because of the naturally high soil cadmium content in certain areas, and they have used the Codex limit of 0.4 mg/kg to support their request. However, based on repeated comprehensive risk assessment on cadmium in rice and all foods, based on more than 270,000 samples, analysis, and national food consumption data in the Chinese population, the risk assessment results show that, at the national level, the compliance to 0.2 mg/kg limit in rice was not a problem. If the limit were raised to 0.4 mg/kg, the total cadmium intake from the diet would exceed the provisional tolerable monthly intake (25 µg/kg body weight per month) proposed by the UN's Food and Agriculture Organization and World Health Organization's Joint Expert Committee for Food Additives. This was because the rice consumption in Chinese people is much higher than that in other

**Figure 2. National Food Safety Standards System of China**




**FSDU,** food for special dietary uses

Source: Chen & Wu

countries, and the Codex limit was based on the average rice consumption in the Japanese population which is much lower than it is in China.

- A new follow-up assessment has been conducted in the last 3-4 years. The objectives were to assess the scientific basis, feasibility, and effectiveness of promulgated standards, and to seek feedback for all promulgated standards through a questionnaire sent to stakeholders. The next step is to upgrade this initiative to a formal regulatory impact assessment, including cost and benefit assessment.
- Under the Food Safety Law, all the national food safety standards are mandatory, including official analytical methods, which accounted for 38% of the total 1,294 standards. This was not conducive to the adaptation of advanced methods to improve existing methods.
- In the nutrition labeling and the health claims for prepackaged foods, the current standards did not allow for disease risk reduction claims, which were included in the Codex standards and food standards in many countries and regions, including US, Canada, Europe, Australia/New Zealand, Japan, etc. This issue was brought up on a number of occasions by the industry and scientists. Hopefully, it would be put on the agenda of the standard setting agencies for discussion.

## Regulation of infant and young children formula products

After the melamine crisis in 2008, regulatory control of infant and young children formula products became a high priority. Enormous efforts had been made by the government, food safety supervision authorities and the industry, to improve the quality and the safety of infant and young children formula products. Production facility and technology have been improved, and scientific research and development encouraged. Infant and young children formula products were regarded as high-risk items in regulatory control. Under the 2015 China Food Safety Law, premarket approval by SAMR is mandatory for all powdered milk-based formulas for infant and young children according to the specific regulations and standards, in addition to the licensing of the production facilities.

### *Standards for formula products*

In China, formula products for infant and young children are categorized as: Stage 1, infant (0-6 months); Stage 2, older infant (6-12 months); and Stage 3, young children (12-36 months). The recent revision of the infant formulas related food safety standards, published in February 2021,[5] will be effective on 22 February 2023 and will replace the 2010 version of the standards. The main changes were:

- **Two separate standards for formula for older infants and young children (GB10767-2010) –** One standard for older infant formula (GB10766-2021) and another standard for young children formula (GB10767-2021), in line with the ongoing revision of Codex standard for follow-up formula.
- **New minimum or maximum limits for some nutrients were established –** Protein level (minimum and maximum limit) has been reduced to 1.8-3.5 g/100 kcal in Stage 2 formula and to 1.8-4.0 g/100 kcal in Stage 3 formula. Lactose level was increased to minimums of 90% and 50% in stages 2 and 3 formula, respectively.
- **Some optional nutrients were moved to the essential nutrients category,** that is, choline for Stage 1 formula and selenium and manganese for stages 2 and 3 formula, respectively.
- **Maximum limits for contaminants,** for example, mycotoxins and pathogens, were referenced to the related horizontal food safety standards, instead of listed in the standards for infant and young child formula.
- **A new requirement for whey/casein ratio** (minimum of 40%) was added for Stage 2 formula. Amino acid profile was slightly revised for Stage 1 formula and included in Stage 2 formula as well. An overview of infant and young children formula products based on the new standards was shown in **Table 1** (p. 6).

### *Registration of formulas*

Under the 2015 Food Safety Law, all international and domestic companies are required to register their powdered milk-based infant and young children

**Table 1. Overview of formula categories for infants and young children (2021 standards)[5]**

| Product standards | Standard for infants (GB 10765-2021) | Standard for older infants (GB 10766-2021) | Standard for young children (GB 10767-2021) |
|---|---|---|---|
| Age range, months | 0-6 | 6-12 | 12-36 |
| Use of food additives | According to the standard for the use of food additives (GB 2760-2015) | | |
| Use of nutritional substances | According to the standard for the use of nutritional fortifiers (GB 14880 -2012) | | |
| Use of amino acids | GB 10765-2021, Appendix A, B | GB10766-2021, Appendix A, B | NA |
| Labeling | Specific requirements in GB 10765 | Specific requirements in GB 10766 | Specific requirements in GB 10767 |
| | General standard for labeling of prepackaged foods (GB 7718-2010)<br>Standard for labeling of prepackaged foods for special dietary uses (GB 13432-2013) | | |
| Production | Good manufacturing practice for powdered milk-based formula for infant and young children (GB 23790-2010) | | |

formulas (not products) for products to be sold on the Chinese market. Corresponding regulations on registration requirements were promulgated by SAMR in 2016 and are applicable to both domestic and imported infant formula products. The main regulations were SAMR's administrative regulation for registration of powdered milk-based formula for infant and young children and its implementation regulations, including the dossier content, the labeling, the stability tests, the onsite audit procedure, and the key requirements.[6]

Each manufacturer was restricted to submitting no more than 3 brand series, with a total of 9 formulas (one brand series for stages 1, 2 and 3). It was stipulated that there should be significant differences in nutrition composition between the formulas of the same stage submitted by the same manufacturer. Accordingly, the applicant should conduct three batches of production trials on the commercial production line. The companies must provide a comprehensive registration dossier, including the product formula, the production techniques, the labeling, and evidence demonstrating the product safety, formula research and development report, production process validation, and the stability test report. Mandatory onsite audits would be carried out as necessary during the application review by SAMR.

For domestic products, in addition to formula registration, the manufacturer should apply for a production license, which was authorized by local Administration for Market Regulation. For imported infant formula products, the overseas manufacturer should register its manufacturing factory to the GACC and got product registration approval from the SAMR.

By 30 June 2021, a total of 1,342 formulas (from 169 companies) had been registered in China, including 1,016 formulas from 117 domestic companies and

326 formulas from 52 foreign companies. These registered formulas needed to be reformulated according to the 2021 revised Chinese standards and re-registered before 22 February 2023.

***The challenges in complying regulations for the registration of formulas***

The mandatory registration of the infant and the young children formulas is unique in China. The rationale behind this requirement is that there are more than 5,000 formulas for the infant and the young children formula products in the Chinese market, produced mainly by more than 120 domestic companies. Many of the formulas had no significant differences in the nutrition composition and were formulated for commercial purposes only. For regulatory agencies in China, the large number of formulas caused safety and quality risks. The objective of the formula registration initiative was to reduce the number of formulas. However, since the regulations were new and the regulatory agency had no previous experience, there were uncertainties and difficulties when the industry tried to comply with the requirements. The challenges include:

- The duration of approval is usually 1-3 years long and costly. For example, it was requested to do three batches of production trials for each formula on the commercial production line, which is time consuming.
- Due to some significant changes in nutrients limits in the 2021 revised standards, all registered infant formula products must be reformulated and reregistered with the SAMR within the transition period.
- Onsite audit of the infant formula facilities is a major challenge to international companies that have overseas production facilities. With travel restrictions due to the COVID-19 pandemic, no overseas audits have been carried out since early 2020.

## Regulation of health (functional) foods

In China, the legal term for the functional food is health food, which was regulated by the former Ministry of Health from 1987 to 2003 and by the former CFDA from 2014 to 2018. Along with the re-organization of the national food safety control system in 2018, regulatory control of health food was moved to the SAMR. Under the Food Safety Law, health food was for certain specific population groups. They had specific biological functions, but was not for the purpose of treating diseases, and should not cause any acute, subacute, or chronic harm to the human body. The health food was divided into: products with specific functional claims and nutrient supplements, such as vitamins and minerals supplements, without functional claims.

The health food companies must apply for health food products registration for each of their health food products with functional claims before placing the products on market in China, according to the SAMR Administrative Measure on Health Food Registration. The official list of the function claims that could be used by the companies in the label would be revised by the SAMR, according to a public consultation in February 2022. The comparison between the new function list and current function list is depicted in **Table 2** (p. 8).[7] Vitamin and mineral supplements using ingredients according to the ingredient list specified

**Table 2. Changes in functional claims for health foods[7]**

| No. | Current functional claims | New functional claims |
|---|---|---|
| 1 | Immune regulation, enhances immunity | Helps enhance immunity |
| 2 | Delays aging, anti-oxidation | Helps anti-oxidation |
| 3 | Memory improvement, assists memory improvement | Assists memory improvement |
| 4 | Eyesight improvement, alleviates eye fatigue | Alleviates eye fatigue |
| 5 | Clears and nourishes the throat, clears the throat | Clears and nourishes the throat |
| 6 | Sleep improvement | Helps improve sleep |
| 7 | Antifatigue, alleviates physical fatigue | Alleviates physical fatigue |
| 8 | Anti-anoxia, enhances anoxia endurance | Anti-anoxia |
| 9 | Reduces body weight | Helps control body fat |
| 10 | Improves osteoporosis, increases bone density | Helps increase bone density |
| 11 | Improves malnutrition anemia and iron-deficiency anemia | Improves iron-deficiency anemia |
| 12 | Beauty (eliminates acne), eliminates acne | Helps eliminate acne |
| 13 | Beauty (eliminates skin chloasma), eliminates skin chloasma | Helps eliminate skin chloasma |
| 14 | Beauty (improves skin water content/oil content), improves skin water content | Helps improve skin water content |
| 15 | Improves gastrointestinal function (regulates gastrointestinal tract flora), regulates gastrointestinal tract flora | Helps regulate gastrointestinal tract flora |
| 16 | Improves gastrointestinal function (facilitate digestion), facilitates digestion | Helps facilitate digestion |
| 17 | Improves gastrointestinal function (embellish aperient bowel), facilitates feces excretion | Helps embellish aperient bowel |
| 18 | Improves gastrointestinal function (assists protection from gastric mucosal injury), assists protection from gastric mucosal injury | Assists protection of gastric mucosa |
| 19 | Regulates blood lipids (reduces total cholesterol, reduce triglycerides), assists blood lipids reduction | Helps maintain healthy blood lipid levels (cholesterol/triglycerides) |
| 20 | Regulates blood sugar, assists blood sugar reduction | Helps maintain healthy blood sugar levels |
| 21 | Regulates blood pressure, assists blood pressure reduction | Helps maintain healthy blood pressure levels |
| 22 | Protection from chemical liver injury, assists protection from chemical liver injury | Assists protection from chemical liver injury |
| 23 | Antiradiation, assists protection from irradiation hazard | Assists protection from ionizing radiation hazard |
| 24 | Alleviates lead excretion | Helps alleviate lead excretion |

Up to the end of 2021, the total number of health food products (with and without functional claims) had reached more than 15,000. Among the products with functional claims, about 30% of the claims was for enhance immunity and about 10% of the claims was for antifatigue or alleviating physical fatigue. It was quite obvious that the ingredients used in these products with the same claims were not significantly different with each other and, in most cases, very little research and development had been conducted.

***Challenges in health food product registration***

No significant changes have taken place in the regulatory control of health foods in China for the past decade. Each health food product using one or two officially approved functional claims must be registered at the SAMR. Nutrient supplements, such as vitamins and minerals supplements, were not allowed to have functional claims.

Since 2016, the SAMR has announced a new initiative to change all products registration with function claims to some products registration and some products notification, to speed up the approval process. In 2021, the SAMR issued a list of five substances (coenzyme Q10, Ganoderma spore powder, spirulina, fish oil, and melatonin) that could be used in the health food products, in addition to the list of nutrients for vitamin and mineral supplements published in 2020. Products using these substances as ingredients do not need to be registered if they meet the requirements of notification. However, this limited list did not solve the problem and there is no indication that more substances will be added to the list.

Because of the dissatisfaction of this individual product registration procedure by both the regulators and the industry, the approval time became even longer. In recent years, it took more than 7 years to go through the whole reviewing and approval process for most applications. Most of the products approved in 2022 were submitted to the SAMR before 2015. According to the SAMR regulations, new functions in addition to those in the official list could be developed by the industry. However, the requirements are very strict and uncertain and so far, no company tried to do so. As a result, most of the approved health food products were low (science and technology) level repetition, which had impeded the development of the health food industry in China.

## Regulation of FSMP

The promulgation of the FSMP standards in 2013, as part of the national food safety standards (Figure 2), ended the long debate and confusion in China on whether FSMP should be regulated as food or as medicine. FSMP was now defined as especially formulated foods that were produced to meet the special requirements for nutrient or meals of people who suffered from eating limitation, disorder of digestion and absorption, metabolic disorders or special disease state and these products should be eaten individually or with other foods under the guidance of doctors or dietitians. In the revised Food Safety Law, FSMP was categorized as food for special dietary uses (FSDU), same as infant and young children formula foods and health foods. It is also stipulated in

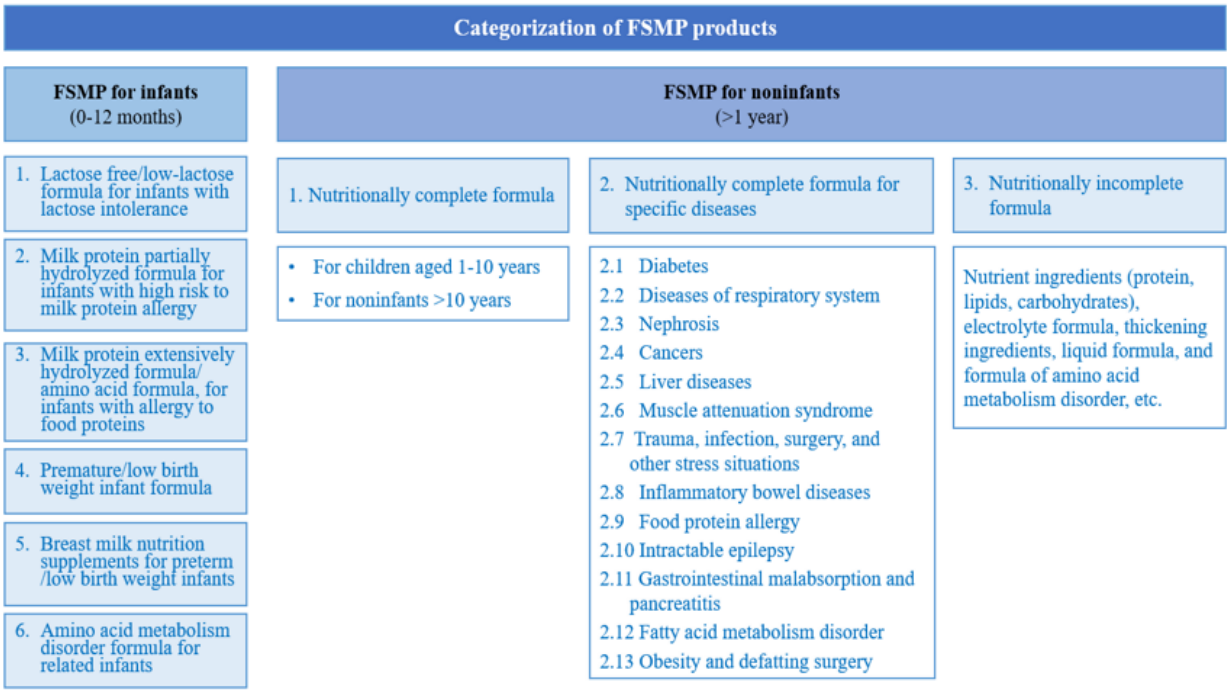
the law that all FSDU products should be approved and registered under the specific regulations of the SAMR.

***FSMP and related food safety standards***

Currently, the FSMP standards included the FSMP standard for infants (GB 25596-2010), General FSMP Standard for children older than 1 year (GB 29922-2013), and good manufacturing practice for FSMP (GB 29923-2013). In general, they are in line with the Codex FSMP standards and regulations and standards in developed countries. The Chinese FSMP standards have more detail provisions, such as the subcategories of the FSMP products and range of nutrients contents. The FSMP products are further divided into 3 classes and 5 subcategories under the GB 25596 and 15 subcategories under the GB 29922 (**Figure 3**).

To facilitate enforcement and inspection by the SAMR as well as product registration by the industry, an on-going major revision of GB 29922 has been carried out, including the development of separated standards for individual subcategories of FSMP for 2.1 to 2.8 and 2.10. In that case, there would be individual standards for each disease (e.g., cancer, diabetes, etc.) in the category of nutritionally complete formula for specific diseases. An overview of FSMP and related applicable food safety standards was shown in **Table 3** (p. 11).

**Figure 3. Categorization of FSMP products in China[8]**




**FSMP,** food for special medical purposes

Complied by Chen & Wu

**Table 3. Overview of FSMP and related food safety standards[8]**

| Product standards | FSMP for infants (GB 25596 -2010) | FSMP (GB 29922-2013) |
|---|---|---|
| Age range | 0-12 months | >1 year |
| Use of food additives | Use of food additives (GB 2760-2010) | |
| Use of nutritional substances | Use of nutritional fortifiers (GB 14880 -2012) | |
| Use of amino acids | GB 25596 -2010, Appendix B | GB 29922-2013, Appendix B |
| Labeling | Specific requirements in GB 25596 | Specific requirements in GB 29922 |
| | General standard for labeling of prepackaged food (GB 7718-2010) Standard for the labeling of prepackaged foods for special dietary uses (GB 13432-2013) | |
| Production | Good manufacturing practice for FSMP (GB 29923-2013) | |

**FSMP,** food for special medical purposes

Complied by Chen & Wu

***FSMP products registration***

Corresponding regulations on the FSMP registration requirements had been promulgated by the SAMR since 2016, which were applicable to both domestic and imported FSMP products. The main regulations were the SAMR administrative regulation for registration of FSMP.[8] Its accompanied implementation regulations provided required information on the dossier content, the labeling, the stability testing, the clinical trial quality management practice, the onsite audit procedure, and the key requirements. Accordingly, the applicants are required to conduct three batches of production trials on the commercial production line, and to provide a comprehensive registration dossier including the product formula, the production techniques, the labeling, and the evidence of product safety, nutritional adequacy and clinical effects, and the stability test report. Mandatory onsite audits would be carried out if considered as necessary during application review by SAMR. For complete nutrition formula for specific diseases products, clinical trial report is required as part of registration dossier. The clinical trial should be conducted in China according to the SAMR's regulation on FSMP clinical trial quality management practice. For domestic FSMP products, in addition to product registration, the manufacturer needs to apply for a production license, which has been authorized by local administration for market regulation. The importation of FSMP products was supervised by the GACC. Before import any FSMP products into China market, the foreign manufacturer needed to register its factory facility with the GACC and product registration approval from the SAMR.

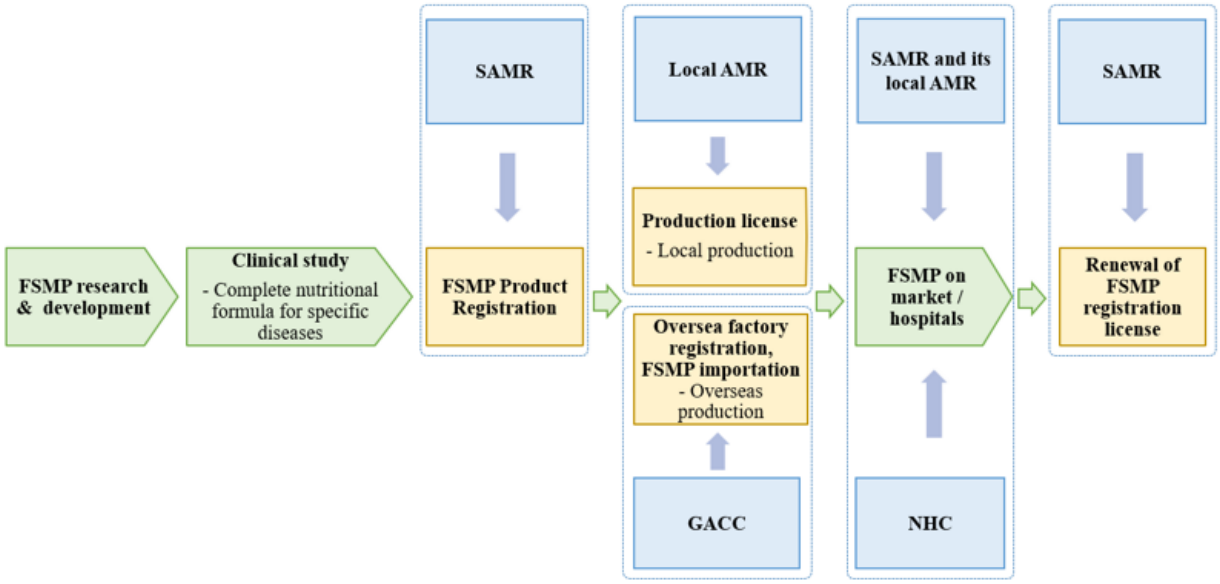
A flow chart of FSMP regulatory control throughout the FSMP lifecycle is shown in **Figure 4**. The time for the completion of a FSMP product registration is at least 2-3 years and could be much longer. As of February 2022, a total of 81 FSMP products were approved and registered under the SAMR. A summary of approved FSMP products by category is showed in **Figure 5** (p. 13). It should be noticed that no single complete nutrition FSMP product for specific diseases had been approved yet.

***Challenges in the regulatory control of FSMP***

The decision of FSMP products regulated as food under the Food Safety Law was a significant progress, which was in line with Codex and most other countries in the world. The set of three FSMP standards were general and had considered the wide divergence of the FSMP products. However, the registration requirements for individual FSMP products were in China.

Because the regulations are new, there are uncertainties in the requirements which presents challenges for the industry applicants. This was one of the major factors of the very long application and review process (2-3 years or much longer). Clinical trials are mandatory for disease-specific complete nutrition formula application. It is expensive and time consuming, and some of the requirements are not feasible. Some nutritionists have questioned the rationale of a fixed designed clinical trial method and not allowing use of data from the real-world study from the FSMP industry.

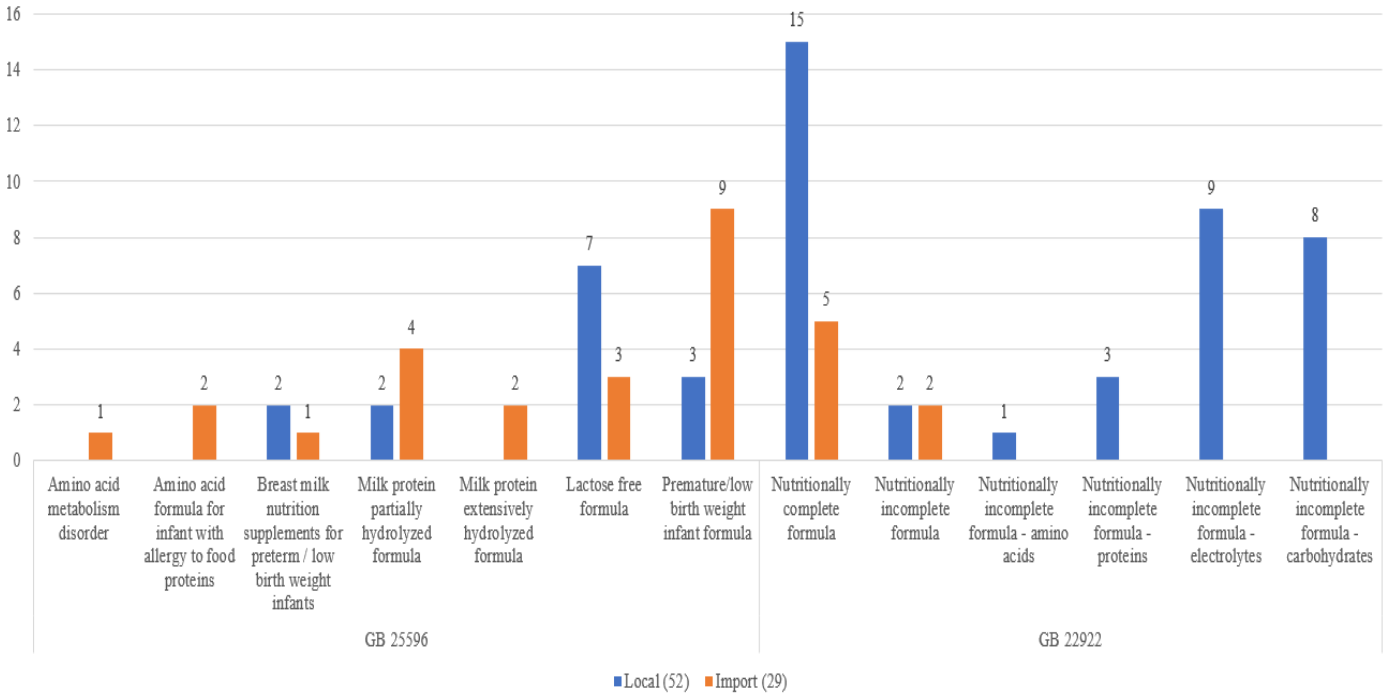
**Figure 4. A flow chart of FSMP regulatory control in China**




**AMR,** Administration for Market Regulation; **FSMP,** food for special medical purposes; **GACC,** General Administration of Customs; **MARA,** Ministry of Agriculture and Rural Affairs; **NHC,** National Health Commission; **SAMR,** State Administration of Market Regulation.

Source: Chen & Wu

**Figure 5. Registered FSMP products in China by category to February 2022[9]**




**FSMP,** food for special medical purposes

Compiled by Chen & Wu

Onsite audit of FSMP facilities is another major challenge for international companies that have overseas production facilities. With travel restrictions due to the COVID-19 pandemic, no overseas audit was conducted since early 2020. The review process for these applications was not able to move forward without onsite audit. FSMP products cannot be used in most hospital pharmacies because they are considered as food and not drugs.

## Conclusions

The development of the modern Chinese food safety regulatory framework was started after China joined the World Trade Organization in 2001. It was improved after the melamine crisis in 2008. Until now, the fragmentation of national food control system was much improved, but the lack of cooperation among the relevant ministries remained as a significant problem, such as antimicrobials resistance control. In general, the current national food safety standard system is in line with the Codex system. The use of risk assessment as the basis for standards development had been improved steadily. The monitoring and surveillance, including regular China Total Diet Study, had provided important data and information to support the risk assessment and early warning systems.

The major unique regulatory issues in China that caused frustrations in the industry compliance were:

- The requirements of infant formula registration, in addition to production license;
- The strict rules and long duration of FSMP product registration;
- Individual product registration in the health foods (functional foods); and
- End product sampling and testing as the major inspection tool, in comparison with the widely recognized and implemented process inspection in other countries.

Recently, the SAMR has been exploring ways to improve the registration of infant and young children formula, the health (function) foods and FSMP. Given the divergent opinions among the administrators, the regulators, the industry and the academic society, the actual reformation would take a quite long time to complete the task.

**Acronyms and abbreviations**

**CFDA,** China Food and Drug Administration; **FSDU,** food for special dietary uses; **GACC,** General Administration of Customs; **MARA,** Ministry of Agriculture and Rural Affairs; **NHC**, National Health Commission; **SAMR,** State Administration of Market Regulation.

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