NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** China  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** State Administration for Market Regulation (SAMR)  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Infant formula milk powder; (HS: 040210); (ICS: 67.100.01) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Management Measures for Registration of Food for Special Medical Purpose (17 page(s), in Chinese) |
| **6.** | **Description of content:** In order to further make it clear that enterprises should take the major responsibility for the whole process of registration i.e. research, development, production, inspection, etc, to effectively guarantee the quality and safety of foods for special medical purposes (FSMP), to strengthen the review and maintenance of product safety, nutritional adequacy and clinical effects for food for special medical purposes, and to maintain the health and safety of the people, the Management Measures for Registration of Food for Special Medical Purpose issued in 2016 is hereby revised with the main contents of the revision as follows: (1) Optimize FSMP approval administration: firstly, reduce the time limit for clinical verification from 40 working days to 30 working days; secondly, set up review and approval priority procedures and clarify the scope of application and policy measures thereof to guide and encourage enterprises to develop and register special medical foods that are used for urgent clinical needs and rare diseases; thirdly, cancel the re-examination procedure in the evaluation process for products that are not allowed to be registered to improve the efficiency of the registration; fourthly, make it clear that the registration certificate of foods for special medical purposes is  electronic certificate. (2) Set stricter requirements for product registration: firstly, make it clear that the products that are applying for registration shall be subject to on-site and sampling inspection; secondly, considering that the current national food safety standards for special medical care are not completed, make it clear that the product technical requirements (including testing methods) shall added in the registration certificate appendix; thirdly, further strengthen the requirements on labelling and marking to highlight the characteristics of special medical food and warnings thereof, so as to remind consumers that these products should be purchased and used under the guidance of doctors or clinical nutritionists and to guide consumers to choose and purchase correctly. (3) Carry out the most strict supervision: firstly, emphasize that applicants shall undertake the main responsibilities and obligations for the application and be responsible for the authenticity, accuracy, completeness and traceability of application materials. They shall also mark trade secrets and business information as required and cooperate in registration-related work; secondly, clarify nine situations of review termination and non-registration. (4) Implement the most severe punishment and accountability requirements: firstly, make it clear that the applicants shall take major responsibility for the registration process, and if the application process is illegal, the applicant will be transferred to the public security organ and be prosecuted for criminal liabilities in accordance with the law; secondly, according to the relevant provisions of the newly revised *"Administrative Punishment Law*", for those who conceal the truth or provide false materials for the application, use fraud, bribery and other improper means to obtain registration certificates, or altering, reselling, renting, lending and transferring the certificates, more punishment measures, such as making announcements to the public for the penalties, will be implemented in addition to corresponding punishment; thirdly, clarify the responsibilities of institutions and personnel that are in charge of registration application acceptance, technical review, on-site and sampling inspection, and expert judgement. Any violations of laws and regulations in their work shall be verified and dealt with in a timely manner. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  - |
| **9.** | **Proposed date of adoption:**  To be determined.  **Proposed date of entry into force:**  To be determined. |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  China WTO/TBT National Bulletin Consulting Center Tel：+86 10 57954633/ 57954627 Email：[tbt@customs.gov.cn](mailto:tbt@customs.gov.cn)  <https://members.wto.org/crnattachments/2021/TBT/CHN/21_7469_00_x.pdf> |