COMMENTS FROM THE EUROPEAN UNION REGARDING NOTIFICATION

G/TBT/N/CHN/1164

REGISTRATION REGULATION FOR FOOD FOR SPECIAL MEDICAL PURPOSE

The European Union (EU) would like to thank the Chinese authorities for providing the opportunity to comment on the draft "*Registration Regulation for Food for Special Medical Purpose*" notified on 7 January 2016.

The EU shares the aims of the notified draft to ensure the safety of Food for Special Medical Purpose (FSMP) and agrees that, in this regard, the principles of scientific basis, impartiality, fairness and justice mentioned in the notified draft are essential.

Having examined the notified draft, the EU considers that, without modification, a number of its provisions could be more trade-restrictive than necessary to achieve those aims, and consequently would like to share with China the following concerns:

1. Application for registration

Article 8 of the notified draft requires that non-domestic production enterprises intended to export formula food for special medical purposes (FSMP) to China shall be the applicants for the registration of the product. In some cases, R&D departments and production plants may be separated and may belong to different corporate entities. According to the notified draft, only manufacturers are allowed to be the applicants, while this possibility is not given to the recipe owners. The EU would like to ask China to reconsider these requirements, and in particular to allow the possibility for the recipe owner to be the applicant for registration.

Article 8 of the notified draft establishes that the applicant for registration shall be a manufacturer with testing capacity. The EU considers that the fact that each factory has full testing capacity will not necessarily reinforce food safety. Certain analysis requires very specific equipment and competences, which are available in expertise centres. FSMP manufacturers have already established Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Points (HACCP) systems to ensure food safety. In practice, FSMP manufacturers could conduct routine tests and need to entrust qualified third-party testing agencies to conduct tests which require special equipment and competencies. Therefore, the EU would like to ask China to consider amending the notified draft accordingly and, in addition to the laboratories owned by the manufacturer, to also recognise the use of the laboratories of associated companies and centralised laboratories of internationally active manufacturers and qualified third-party testing agencies as part of testing capacities of non-domestic plants.

2. Approval process of registered applications

Articles 12 and 16 of the notified draft introduce a number of deadlines for the approval process of registered applications. However, the timing for on-site inspection for non-domestic manufacturers is left completely open, which has negative consequences on the predictability of the process. The EU would therefore

kindly like to ask China to introduce a clear procedure with timeframes on the different steps for inspection of foreign sites, guaranteeing a procedure undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products.

Article 14 of the notified draft provides for the selection of experts for the evaluation of formula food for special medical purposes. The EU would like to suggest to allow applicants to provide to the review panel examining the application, responses and additional documentation relevant to any question the review panel might have in the course of its examination.

Article 15 of the notified draft relates to approval/disapproval decisions. The EU would like to ask the Chinese authorities to consider allowing enterprises to provide additional information during the approval procedure, if there is a slight defect in the application or incomplete data.

Article 18 of the notified draft lists the information to be included in the Registration Certificate for formula FSMP. Among the information required, the notified draft includes the product formula and the production process. The EU would like to highlight that both the product formula and the production process are trade secrets. Therefore the EU considers that they should not be listed in the registration certificate. In order to guarantee this confidentiality whereby legitimate commercial interests are protected, the EU would like to suggest to revise points 5 to 7 of Article 18 of the notified draft as follows:

"*(5) list of ingredients of product*
(6) brief statement on production process
(7) product label samples and insert sheet".

The third paragraph of Article 19 of the notified draft covers cases where a change to the product name, product category, product formula, production process, etc. has a possible effect on food safety, nutritional adequacy, and a possible clinical application effect for special medical purpose. In order to ensure an appropriate transition between products covered by one registration certificate and its successor, the EU would like to request that it is made explicit in this article that products manufactured under the old certificate can be placed on the market for 12 months after receiving the new registration certificate from the China Food and Drugs Administration (CFDA), and that such products can be sold until the end of their shelf life.

Article 22 of the notified draft provides that, for a change of registration and re-registration, the provisions of registration apply. The EU would like to request an explanation of the meaning of this article.

According to Article 26 of the notified draft the production conditions have to be consistent with the requirements of the GMP for formula FSMP. The EU understands that, at the moment, the food GMP certificate in China does not include FSMP. Therefore, the EU would like to ask China to explain how manufacturers may obtain GMP certification for the production of FSMP and, if that is not possible at the moment, to introduce appropriate transition provisions.

Article 27 of the notified draft provides that "*The food evaluation body under the CFDA shall organize on-site investigation of clinical trial data and sampling inspection of test samples*". The EU understands that in accordance with the notified draft clinical trials have to be completed before registration, and that in accordance with the "*Drugs Clinical Test Quality Management Norms*" the relevant test samples need to be returned or destroyed at the end of the test, therefore test samples obtained during clinical trials cannot be tested during the on-site investigation. Taking these elements into account, the EU would like to request an explanation of the scope and the purpose of the sampling inspection.

Articles 28 to 33 of the notified draft would introduce a number of labelling obligations. In this respect China's national standard "*GB 7718-2011 National Food Safety Standard General Rules for the Labelling of Pre-packaged Foods*" already includes detailed requirements also covering the labelling of FSMP. According to the "*China Food Safety Law*", Article 67, the food label shall comply with national standards, which thus become mandatory. The additional labelling obligations in the notified draft would supplement or conflict with some of the labelling requirements in the national standards. It is unclear how the existing and the new requirements would combine and, in order to avoid uncertainty and unnecessary barriers to trade, the EU would like to ask China to clarify which labelling requirements will be applicable.

3. Transition period

The notified draft would introduce a new process for registration and approval of FSMP recipes which would become a condition for the placing of the relevant products on the Chinese market. A reasonable time for transition from the current situation to the new frameworks should be granted in order to avoid disturbance of trade. Taking into account the delays necessary to prepare the applications, to proceed with inspections, to obtain approval and to adapt the labelling of products, the EU would like to suggest a period of 18 months between the publication of the final measure and its application.

With regard to the above comments, the EU would like to refer to Article 2(2) of the TBT Agreement according to which "*Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create*".

The draft legislation includes food safety measures which may affect international trade, therefore, in addition to this WTO TBT notification, the EU would like to request China to notify this draft legislation also under the WTO SPS notification system, in accordance with the provisions under the WTO SPS Agreement.

The EU would be grateful if the above-mentioned comments could be taken into account and replied to.