COMMENTS FROM THE EUROPEAN UNION REGARDING NOTIFICATION

G/TBT/N/CHN/1165

FORMULA REGISTRATION REGULATION FOR INFANT AND FOLLOW-UP FORMULA

The European Union (EU) would like to thank the Chinese authorities for providing the opportunity to comment on the draft "*Formula Registration Regulation for Infant and Follow-Up Formula*" notified on 7 January 2016.

The EU shares the aims of the notified draft to ensure the safety of infant and young child formulas and agrees that, in this regard, the principles of scientific basis, impartiality, fairness and transparency mentioned in the draft itself are essential.

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

1. R&D and testing capacity

Article 9 of the notified draft establishes that the applicant for registration shall be a manufacturer with R&D capacity and testing capacity, i.e. an entity consolidating all necessary capacities. However, the actual situation on the market reveals diverse and more complex situations: for example, a brand owner that has designed or acquired a number of recipes can entrust the manufacturing to a second company and ensures quality control via a third company; a fourth company can be responsible for importing the product into China. In particular, many major EU exporters of infant formula, owning recipes, rely on production partners (often called OEM – Original Equipment Manufacturers) for the manufacturing of their products. In these cases, there is a clear contract between the producer and the brand owner/recipe owner which sets out the responsibility and the legal liability for the food safety of the food production. Such arrangements ensure the food safety, guarantee traceability and clarify roles and responsibilities. Such a way of operating is fully in line with the proposed Article 34 in the Implementing Rules of the Food Safety Law of People's Republic of China as published for comments in December 2015. In this regard, the production partner is responsible for complying with Chinese food safety requirements, but does not have the right to hand over the recipe, and only the recipe owner can be responsible for its registration. The EU would like to ask China to consider accommodating such configurations where responsibilities and capacities are split, and in particular to allow the possibility that the recipe owner is the applicant for registration.

2. Maximum number of recipes

Article 12 of the notified draft would limit each company to a maximum of 9 recipes within 3 product lines. This is a major concern for the EU as it would have a serious and unnecessarily negative trade impact on the current exports from the EU to China. The impact of such a limitation would be aggravated by the fact that the limitation would fall upon production companies: these would be deprived of the possibility of

serving major brands of infant formula which, as outlined above, currently rely on them as production partners for their products. It is estimated that, without modification of this article, the number of brands on the Chinese market would be reduced by 80%. The EU does not see a justification to this limitation, neither on the basis of food safety nor on the basis of any other legitimate objective. Moreover, the relevant Codex Standards (CODEX STAN 72-1981 and CODEX STAN 156-1987), while laying down a series of compositional requirements for infant formula and follow-up formula, do not restrict the number of products that operators can place on the market. The EU wishes therefore to kindly ask China to remove such a limitation.

For reference, in the EU, Commission Directive 2006/141/EC on infant formulae and follow-on formulae allows economic operators to place these products on the market without any limitation in the number of recipes or production lines, and also without prior approval of the recipe of the product. For infant formula, a simple notification procedure is in place, whereby operators notify the competent authorities of the placing on the market of the product. The competent authorities can verify on this basis whether the product complies with EU law. Commission delegated Regulation (EU) 2016/127 will extend this notification procedure to most follow-on formulae (as of 2020).

3. Confidentiality of information

Article 10 of the notified draft requires that a number of elements of critical commercial value (e.g. R&D report, production process, test reports) are included in the application for registration. Were such information to become available to market operators other than its legitimate owner, this could unduly affect the owner's opportunity to compete on the market. The EU would like to ask China to kindly explain how the confidentiality of such information is to be ensured and, in particular, to confirm that the exact recipe itself does not need to be included in the application. In this regard the EU would like to refer to the requirements under Annex C.1(d) of the WTO SPS Agreement and Article 5.2.4 of the TBT Agreement related to respecting the confidentiality of information in such a manner that legitimate commercial interests are protected.

4. On-site inspections

Article 15 of the notified draft establishes that CFDA would be responsible for on-site inspections, including of foreign companies. The EU would like to highlight that the current Chinese import conditions already lays down a stringent process for foreign countries and establishments for approval to export dairy and milk products to China. These conditions are even more stringent for exporters of infant formula to China. According to the China Food Safety Law, Article 96, overseas manufacturers exporting foods to China should register with AQSIQ (CNCA), which carries out on-site inspections. If both the CFDA and the AQSIQ must register the products and follow similar procedures, including on-site inspections, this would severely increase the administrative burden for the exporting companies, for the administrations in the exporting country, and also for the Chinese authorities. The international standard of Codex Alimentarius Commission (CAC/GL 26-1997) states that controls on imported food and domestically produced foods should be designed to achieve the same level of protection. The importing country should avoid the unnecessary repetition of

controls where these have been already validly carried out by the exporting country. The EU would like to ask China to consider consolidating the scope of the obligations and responsibilities under China Food Safety Law and under the proposed draft measure, so that the process is clear for exporters, that conflicts and/or duplications are avoided, that international standards are followed and that any requirements are limited to what is reasonable and necessary, in particular in relation to on-site inspections.

In this respect the EU would like to recall Article 2.4 of the TBT Agreement that states "*where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations, except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of the fundamental climatic or geographical factors or fundamental technological problems*".

5. Timeframe for the approval process of registered applications

Article 19 of the notified draft introduces a number of deadlines for the approval process of registered applications. However, the timing for on-site inspection for overseas manufacturers is left completely open, which has negative consequences on the predictability of the process and thus could negatively affect trade. The EU would like therefore to kindly ask China to introduce a clear timeframe 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.

6. Labelling obligations

Articles 27 to 35 of the notified draft would introduce a number of labelling obligations. In this respect China's national standards (GB7718 and GB13432) already include detailed requirements on the labelling of infant formula. According to Article 67 of China Food Safety Law, 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 instead consider introducing the additional labelling requirements as appropriate within the above mentioned national standards.

7. New process for registration and approval of infant formula recipes

The notified draft would introduce a new process for registration and approval of infant formula recipes which would become a condition for the placing of the relevant products on the Chinese market. The EU considers that a reasonable time for transition from the current situation to the new framework should be granted in order to avoid disturbance of trade. Taking into account 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 entry into 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 a WTO TBT notification, the EU would like to request China to also notify this draft legislation under the WTO SPS notification system, in accordance with the provisions of the WTO SPS Agreement.

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