

SNE comments on the Dutch Decree on Toddler Formula and Toddler Milk (TRIS 2020/482/NL)

On the 27th of July 2020, the Netherlands notified a Decree to the European Commission and Member States through the TRIS notification procedure. This Decree would lay down rules on foods based on (cow or goat milk) protein, to which at least one or more vitamins, minerals or other substances have been added, and which are intended to be used as a drink for young children between the ages of one and three years (Commodities Act Decree on toddler formula and toddler milk).

Since the application of Regulation (EU) No 609/2013 on food for specific groups, Young Child Formula (YCF) is considered as food for normal consumption in the EU. Contrary to infant and follow-on formula (intended for the age group 0-12 months), there are no specific rules governing the composition, labelling and safety requirements of YCF at EU level, which means that these products have to comply only with relevant horizontal EU food legislation. However, Member States are still free to set out specific rules on YCF at national level, provided that these rules do not impede the good functioning of the European single market.

Because of the vulnerability and the specific needs of the targeted population group (12-36 months), SNE is of the view that specific rules on YCF are necessary. The setting of rules at national level can be a means to compensate for the absence of specific EU rules on YCF. However, the text notified by the Netherlands raises serious concerns with regard to several aspects:

- Missing mandatory composition requirements for vitamins and minerals
- No specific food safety requirements
- Possible negative impact on intra-EU trade

1. Inadequate composition requirements

The Dutch Decree would regulate the composition of YCF with regard to macronutrients but fails to set out appropriate mandatory requirements with regard to vitamins and minerals. Indeed, according to the proposed Decree, the addition of at least one or more vitamins, minerals or other substances would be enough to fulfil the definition. This means that the addition of vitamins and minerals is not mandatory: the addition of only one 'other substance' would enable a product that meets the macronutrient requirement to be marketed as a toddler formula, although this product does not contain any vitamin or mineral.

This goes against scientific recommendations, according to which the vitamin and mineral content of YCF should be largely based on the one of follow-on formula (6-12 months)¹. Delegated Regulation (EU) 2016/127 on infant and follow-on formula sets out mandatory requirements for 14 minerals and 13 vitamins for follow-on formula. In addition, in 2013, EFSA concluded that young-child formulae are one of the means to increase intakes of certain nutrients at risk of inadequacy for young children in the EU such as n-3 polyunsaturated fatty acids (ALA, DHA), iron, vitamin D and iodine².

It is also important to note that the text would not be aligned with the micronutrient composition requirements for follow-up formula for young children (12-36 months) which are expected to be set at international level in the revised Codex Standard on follow-up formula³.

¹ See for example Hojsak I et al. (2018) Young Child Formula: A Position Paper by the ESPGHAN Committee on Nutrition. J Pediatr Gastroenterol Nutr 66(1):177-185

² EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013; Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013;11(10):3408, 103 pp. doi:10.2903/j.efsa.2013.3408.

³ See [Report](#) of the 41st session of the Codex Committee On Nutrition And Foods For Special Dietary Uses (CCNFSDU)

2. Missing food safety requirements

Due to the physiological immaturity of their systems, young children are generally more vulnerable to food contaminants and pesticide residues. For this reason, Regulation (EU) 609/2013 on food for specific groups lays down specific safety requirements for infant and follow-on formula and baby foods, in particular a general limit of 0.01mg/kg for pesticide residues and a prohibition of certain particular pesticides for the production of these products. Although targeting the same age group, the Dutch Decree does not include any specific requirement on food safety for YCF and misses the opportunity to set out an appropriate protection level for this vulnerable population group.

3. Risk to mislead consumers and to hinder intra-EU trade

Like the Netherlands, several Member States are considering setting out specific rules on YCF at national level. It is likely that these national rules will lay down stricter provisions in terms of safety and micronutrient composition than the proposed Dutch Decree. Not only manufacturers will have to deal with the complex situation created by the heterogeneity of national rules on YCF in the EU, but there is also a risk to confuse consumers, who expect to buy a product containing the necessary vitamins and minerals, about the quality and nutritional composition of these very specific products.

Moreover, according to the mutual recognition principle, YCF produced in the Netherlands is allowed to be marketed in other Member States. However, in several Member States, like France, the national dietary guidelines recommend the consumption of YCF until the age of 3 years to avoid any nutritional deficiency in this age group. Having products on the market that do not contain the necessary vitamins and minerals could lead to suboptimal nutrient delivery with young children consuming these products. It could also lead health care professionals to warn their patients against these products coming from a specific Member State. This could indirectly harm intra-EU trade.

For these reasons, SNE calls on the Netherlands to revise the proposed text and address the above-mentioned issues before adopting it.