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Association

SWISS ASSOCIATION OF NUTRITION INDUSTRIES (SANI)

c/o Food Lex, Dr. iur. Karola Krell Zbinden
Effingerstrasse 6A
CH-3011 Bern
Tel: + 41 31 352 11 88
sani@foodlex.ch
www.sani.swiss / www.nutritionindustries.ch

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Position Paper Swiss Association of Nutrition Industries (SANI)

regarding the

Dutch Decree containing 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) (Netherlands)

*Communication from the Commission - TRIS/(2020) 02814
Directive (EU) 2015/1535
Regulation (EC) No 1925/2006
Notification: 2020/0482/NL*

To whom it may concern

With this position paper, SANI would like to endorse the position paper handed in by the Dutch trade association VNFKD concerning the Dutch Decree in question.

Young child formulae ("YCF") are widely available on the Dutch and Swiss market and have been available for many years. They are marketed as products specifically formulated for the nutritional needs of young children aged 1-3 years.

YCF are not defined in EU legislation and their composition is not regulated by EU law. In the report from the European Commission to the European Parliament and the Council on young child formulae (COM (2016) 169 final)¹ YCF are described as specifically processed/formulated protein-based drinks intended to satisfy the nutritional requirements of young children aged 1-3 years.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0169&from=LT>.

In comparison with cow's milk, **currently marketed YCF contain** more alpha-linolenic acid ("ALA"), docosahexaenoic acid ("DHA") (if added), iron and vitamin D but similar amounts of iodine. The **mean content** of these nutrients in YCF is **within the range of permitted concentrations in follow-on formulae** and, except for iron, also in infant formulae.

The framework of the Regulation on Food for Special Groups (Regulation (EU) No 609/2013; "FSG Regulation") no longer provides any rules for YCF. **With the repeal of Directive 2009/39/EC in 2016, YCF products have been designated as general food.**

In its report concerning YCF, **the European Commission indicated that YCF fall under the scope of Regulation (EC) No 1925/2006**, and have to comply with the rules of this Regulation (e.g. on the addition of vitamins and minerals and on labelling, presentation and advertising). YCF need also to comply with the other relevant rules of EU law that apply to all foods, in particular Regulation (EC) No 178/2002, Regulation (EU) No 1169/2011 and Regulation (EC) No 1924/2006. The Commission also acknowledged that the general food laws must be further elaborated on the points of reference intakes, labelling, etc. for young children.²

Until 20 July 2016, **in the Netherlands YCF were considered food intended for particular nutritional uses** within the meaning of Directive 2009/39/EC.

Since 2016, the Dutch Minister for Medical Care has repeatedly reported to Parliament that **YCF should be able to stay on the market in the Netherlands**, also after the introduction of the FSG Regulation, and that adequate legislation was being drafted for this purpose.

It seems that **the most important concerns and objections of the VNFKD have still not been removed** with the new version of the draft Decree which has now been notified to the Commission. **Several of these concerns and objections relate to EU law.**

According to the **current scientific knowledge and medical standards generally accepted at international level**, and according to the definition of YCF as used by the European Commission, "toddler formula" and "toddler milk" are specifically processed/formulated protein-based drinks intended to satisfy the nutritional requirements of young children aged 1-3 years. Such supplemented products can help improve the nutritional status of young children who do not eat well or to correct deficiencies in dietary intakes of young children known to have such deficiencies. **International scientific studies confirm** that YCF, precisely because of their balanced, specific composition, can in some cases play a role in the daily nutrition of young children, see the recent guidance from the European Society for Paediatric Gastroenterology, Hepatology and Nutrition ("ESPGHAN") Committee on Nutrition ("CoN")³.

In January 2018 the ESPGHAN CoN published its "**Young Child Formula: A Position Paper by the ESPGHAN Committee on Nutrition**".⁴ The ESPGHAN CoN performed a systematic review of the literature to review the composition of YCF and consider their role in the diet of young children. The ESPGHAN CoN also referenced EFSA's Scientific Opinion on the essential composi-

² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0169&from=LT>

³ 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.](#)

⁴ 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.](#)

tion of infant and follow-on formulae⁵, and noted that EFSA did not consider it necessary to propose specific compositional criteria for formulae consumed after one year of age, as formulae consumed during the first year of life can continue to be used by young children. In other words, the established content of different nutrients and other substances in follow-on formulae is also fit for the purpose of being consumed by young children in the ages of 1 – 3 years. Based on the evidence, ESPGHAN CoN found that the nutrient composition of YCF should be similar to that of follow-on formulae with regards to energy and nutrients that may be deficient in the diets of European young children such as iron, vitamin D, and n-3 PUFAs, whereas the protein content should aim toward the lower end of the permitted range for follow-on formulae if animal protein is used. ESPGHAN CoN furthermore suggested that based on available evidence there is no necessity for the routine use of **YCF** in children from 1 to 3 years of life, but they **can be used as part of a strategy to increase the intake of iron, vitamin D, and n-3 PUFA and decrease the intake of protein compared with unfortified cow's milk**. Follow-on formulae can be used for the same purpose. Other strategies for optimizing nutritional intake include promotion of a healthy varied diet, use of fortified foods, and use of food supplements. ESPGHAN CoN furthermore noted that there is a **need for regulation of YCF to avoid inappropriate composition**.

In its 2013 scientific opinion **EFSA noted that it supports the extension of the relevant rules** for infant and follow-on formulae given in Article 4 of Directive 2006/141/EC **to milk-based drinks for young children**, should these be regulated.⁶

No such additional requirements for food safety and quality have been included in the draft Dutch Decree, although it concerns products for young children who are part of the same vulnerable groups as those covered by the FSG Regulation, Regulation (EU) No 2016/127 and Directive 2006/125/EC.

For further details we refer to the respective position of the VFNKD, which we support to keep the current adequate regulation of YCF products in the Netherlands.

Considering these observations, SANI requests the Commission to deliver a negative opinion pursuant to Article 12(3) of Regulation (EC) No 1925/2006 and Article 5 of Directive (EU) 2015/1535.

⁵ [EFSA Journal 2014;12\(7\):3760](#).

⁶ <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2013.3408>, p. 9.