VNFKD
Vereniging van Nederlandse Fabrikanten
van Kinder- en Dieetvoedingsmiddelen

VNFKD Position Paper re. 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
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Introduction

Young child formulae ("YCF") are widely available on the Dutch market, and have been for many years, and are marketed as **products specifically formulated for the nutritional needs of young children aged 1-3 years** or, in certain cases, for narrower sub-groups (1-2 and 2-3 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.

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 on and the Dutch Commodities Act Decree on Foodstuffs Intended for Particular Nutritional Uses.[3]

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0169&from=LT.
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0169&from=LT.
[3] Warenwetbesluit Producten voor bijzondere voeding.

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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. In connection with this legislative process, the Dutch trade association VNFKD has had consultations about this subject with the Ministry of Health on several occasions in recent years. In 2019, **the VNFKD also provided input** for a draft Commodities Act Decree on Toddler Formula and Toddler Milk several times.

Unfortunately 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**.

The draft Decree

According to the Statement of Grounds provided by the Netherlands, the notified draft Decree "*allows the industry to continue marketing toddler formula and milk as a general food with minor adjustments to the current composition, as is the practice in other EU Member States. In the event of possible nutrient deficiencies, these products could certainly play a role. In special cases and based on scientific advice, the addition of specific vitamins, minerals or other substances to foods may be required. This scientific advice is lacking for toddler formula and toddler milk. Therefore, this Decree does not contain any obligation to add specific vitamins, minerals or other substances to toddler formula and milk*." (emphasis added).

Article 1(c) of the draft Decree defines "toddler formula" ("peuterdrank") as "a food based on protein, to which at least one or more vitamins, minerals or other substances have been added, and which is intended to be used as a drink for young children between the ages of one and three years". Further to Article 1(d) of the draft Decree "toddler milk" shall mean "a drink intended for toddlers that is based exclusively on cow or goat milk protein". Based on these definitions, **the addition of vitamins and minerals is not mandatory**. The addition of only one "other substance" within the meaning of Article 2(2) of Regulation (EC) No 1925/2006 (see Article 1(a) draft Decree), such as nucleotides or galacto-oligosaccharides ("GOS") would be sufficient to fulfil the definition.

Further to Article 2 of the draft Decree it is prohibited to manufacture or market toddler formula and toddler milk in any manner other than in accordance with the rules laid down in this Decree.

Article 3 of the draft Decree establishes by means of a dynamic reference to the certain parts of Annex II of Regulation (EU) No 2016/127 a list of **other substances** (i.e. protein, lipids – including limits for transfat and erucic acid – and carbohydrates) that **may be added voluntarily** to YCF, as well as the respective conditions under which these substances may be used in the manufacture of YCF. Because of the dynamic reference to Article 2 of Annex II of Regulation (EU) No 2016/127 only protein isolates from cows' milk or goats' milk and soya protein isolates shall be used in of YCF.

Article 4(1) of the draft Decree establishes by means of a dynamic reference to the certain parts of Annex II of Regulation (EU) No 2016/127 a list of **vitamins, minerals and other substances** of Annex II to Regulation (EU) No 2016/127 (i.e. taurine, linoleic acid, ALA, DHA, long-chain polyunsaturated fatty acids, phospholipids, FOS/GOS, minerals, vitamins, and nucleotides) that **may be added voluntarily** to YCF in accordance with the rules regarding composition indicated therein.

Based on the draft Decree, YCF are also considered fortified food within the meaning of the Commodities Act Decree on the Addition of Micronutrients to Foods.[4] Further to Article 5 of the draft Decree, some of the requirements and restrictions of the Commodities Act Decree on the Addition of Micronutrients to Foods do not apply to toddler formula and toddler milk (i.e. some elements of Article 2(2), 5 and 6 of the Commodities Act Decree), but some requirements and restrictions of that Commodities Act Decree do apply to YCF.

Further to Article 6 of the draft Decree the name "peuterdrank" / "peutermelk" ("toddler formula" / "toddler milk") is mandatory for YCF, and is thus a **legal name** within the meaning of Article 2(2)(n) of Regulation (EU) No 1169/2011.

Article 7 of the draft Decree furthermore lists **4 additional mandatory particulars** for YCF, which should be used in the marketing of YCF: (a) the age category between one and three years for which it is intended; (b) a statement that the product is not a substitute for a balanced diet; (c) a statement that the product is not a substitute for vitamin D supplementation (in Dutch: "*suppletie*"); and (d) a statement that the product is not a substitute for breast milk.

Further to Article 8 of the draft Decree any text, pictures and colours used in **the labelling and presentation of YCF** shall be carried out in such a way as to not be presented as a follow-on product to infant formula or follow-on formula.

In its Statement of Grounds the Netherlands refer to Article 13d of the Commodities Act[5], which includes a **mutual recognition clause**. The trade in goods with an equivalent level of protection originating from other EU Member States falling under the scope of this Decree shall not be prohibited by virtue of the requirements set out in this draft Decree. According to the Netherlands, this is in accordance with Article 10 of Regulation (EC) No 1925/2006, which states that Member States may not restrict or forbid trade in foods which comply with the requirements of that regulation and of Community acts adopted for its implementation by the application of non-harmonised national provisions governing the addition of vitamins and minerals to foods.

Concerns and objections of the VNFKD

As noted above, **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. **Several of these concerns and objections relate to EU law.**

Compositional requirements are not in accordance with generally accepted scientific evidence; serious risk of misleading consumers

Traditionally, the composition of YCF in the Netherlands is similar to that of follow-on formula. YCF products that are currently on the market as "peuterdrank" or "peutermelk" ("toddler formula" and "toddler milk") are 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 polyunsaturated fatty acids ("n-3 PUFAs"), and usually contain the mineral substances and vitamins listed in Article 8, 8.1, 8.2 and 9 of Annex II to Regulation (EU) No 2016/127.

If the draft Decree would be adopted without fundamental changes, **a product bearing the legal name "peuterdrank" or "peutermelk" ("toddler formula" and "toddler milk") could be put on the market without satisfying the compositional requirements of "toddler formula" / "toddler milk" as understood in the evolving generally acceptable scientific knowledge** on the role of vitamins and minerals in nutrition and consequent effects on health of

[4] The Warenwetbesluit Toevoeging micro-voedingsstoffen aan levensmiddelen.

[5] Article 13d of the Warenwet

young children aged between one and three years. **Such a product would not meet the realistic expectations of consumers either**.

Based on the draft Decree the composition of toddler formula and toddler milk is only assured as far as other macronutrients ("other substances") is concerned, but not as far as vitamins and minerals are concerned. The VNFKD is concerned that this will result in a proliferation of poor-quality "toddler formula" and "toddler milk", especially since the Netherlands does not have a monitoring system for foods to which vitamins and minerals or other substances have been added.[6] The draft Decree will not introduce such a system for "toddler formula" and "toddler milk" either.

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. On various occasions the VNFKD has drawn the attention of the Ministry of Health to **international scientific literature** showing that YCF, precisely because of their balanced, specific composition, can in some cases play a role in the daily nutrition of young children. The VNFKD specifically referred to recent guidance from the European Society for Paediatric Gastroenterology, Hepatology and Nutrition ("ESPGHAN") Committee on Nutrition ("CoN")[7], and other recent scientific publications by Dutch research institutes.[8]

In January 2018 the ESPGHAN CoN published its "**Young Child Formula: A Position Paper by the ESPGHAN Committee on Nutrition**".[9] 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 composition of infant and follow-on formulae[10], 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**.

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[6] As referred to in Article 15 of Regulation (EC) No 1925/2006.
[7] 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.
[8] Akkermans M *et al.* (2016) Iron and Vitamin D deficiency in healthy young children in Western Europe despite current Nutritional Recommendations. J Pediatr Gastroenterol Nutr 62(4):635-42, Goldbohm R *et al.* (2016) Food consumption and nutrient intake by children age 10 to 48 months attending day care in the Netherlands. Nutrients 8(7):428.
[9] 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.
[10] EFSA Journal 2014;12(7):3760.

Further to the explanatory notes to the draft Decree, a previous version of the draft Decree has been submitted to other stakeholders for external consultation. Further to that version **Dutch paediatricians indicated that they would prefer mandatory requirements** of certain vitamins, minerals and other substances.

The draft Decree ignores this international scientific evidence, without giving any explanation why. The draft Decree also largely ignores the VNFKD's evidence-based proposal for compositional requirements as submitted in May 2018. Neither has the Netherlands provided any evidence why the mandatory compositional criteria for follow-on formula as far as it concerns vitamins and minerals should not be applied to toddler formula and toddler drink. In the explanatory notes to the draft Decree the Netherlands merely notes that further to Dutch nutritional recommendations it is recommended that young children learn a healthy and varied diet, and that the Dutch Health Council ("*Gezondheidsraad*") has not yet issued any advice on supplementing certain nutrients (except for vitamin D).

Based on the proposed legal definitions of "toddler formula" and "toddler milk" (Article 1(c) and (d) of the draft Decree) and further to Articles 3 and 4 of the draft Decree, **the addition of vitamins and minerals is not mandatory**. The addition of only one "other substance" within the meaning of Article 2(2) of Regulation (EC) No 1925/2006, such as nucleotides or GOS, would be sufficient to fulfil the definition. This would mean that a "stripped" product based on milk powder could be labelled and marketed as "toddler milk". This would certainly **impair the food category** "toddler formula" and "toddler milk", and would **not be in line with the ESPGHAN guidelines from a nutritional perspective** either.

Moreover, as mentioned above, **such a product would not meet the realistic expectations of consumers** based on the composition of YCF sold in the Dutch market traditionally. With food supplements, a consumer can search for a multi-vitamin/mineral food supplement for the specific age range. The labelling of such food supplements can detail complete multi-vitamin. A consumer who will be looking for "toddler formula" or "toddler mill" ("peuterdrank" or "peutermelk") with complete composition will have difficulties finding the right product, even more so because claims on complete composition will not be allowed further to Article 7 of the draft Decree. It will also make it **more difficult for health care professionals or other professionals responsible for maternal and child care to advise on the correct product**.

Therefore, the marketing of a product bearing the legal name "peuterdrank" or "peutermelk" without added vitamins and minerals – although legally allowed under the Decree – would be **likely to deceive the average consumer** (even if the information is factually correct) in relation to the main characteristics of the product, in particular its composition. As long as such a product meets the compositional requirement of the draft Decree that at least one other substance is added, such a product could not be avoided from the market. This would therefore also result in the **erosion of the food category**.

<u>Important food safety and quality requirements are missing</u>

The FSG Regulation and Regulation (EU) No 2016/127 impose extra stringent requirements on the food safety and quality of products for particular nutritional purposes, on top of the requirements following from the general food laws. There is a good reason why these requirements are imposed, since **these foods are intended for vulnerable groups**.

Within the scope of the FSG Regulation, young children between 0 and 36 months are considered part of these vulnerable groups. Similarly, Commission Directive 2006/125/EC with regard to processed cereal-based foods and baby foods for infants and young children considers young children between 1 and 3 years as vulnerable groups. The draft Decree is also aimed at young children between 1 and 3 years, and therefore **(partly) overlaps** with the groups defined in the FSG Regulation, Regulation (EU) No 2016/127 and Directive 2006/125/EC.

Both Regulation (EU) No 2016/127 and Directive 2006/125/EC encompass **specific rules on the presence of pesticides residues** previously set put in Commission Directive 99/39/EC. Directive 2006/125/EC with regard to processed cereal-based foods and baby foods for infants and young children requires that **this type of food contains no detectable levels of pesticide residues**, meaning not more than 0.01 milligrams of pesticide residues per kilogram. In addition, the Directive **prohibits the use of certain very toxic pesticides in the production of processed cereal-based baby foods and baby foods** and establishes levels lower than the general maximum level of 0.01 milligrams per kilogram for a few other very toxic pesticides. These measures have been adopted based on the **precautionary principle**.

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.[11]

No such additional requirements for food safety and quality have been included in the draft 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. This is a point of great concern to the VNFKD. The Netherlands is well aware of these concerns, but has still failed to give a satisfactory explanation why no additional safety and quality requirements have been included in the draft Decree.

No clear distinction from fortified foods and food supplements

Another point of concern is that the draft Decree **does not establish a clear distinction** between YCF and other fortified foods or food supplements.

The draft Decree does not clearly explain that it concerns national legislation within the meaning of Article 11(2) of Regulation (EC) No 1925/2006. It furthermore does not clearly state that the provisions of the draft Decree do not apply to food supplements covered by Directive 2002/46/EC. This is cause for concern, since The Netherlands allow food supplements on the market in the form of protein-based powders with added vitamins and minerals that need to be prepared in accordance with the manufacturer's instructions. This is permitted under the Food Supplements (Commodities Act (Decree).[12]

There is also an **overlap between the draft Decree and the Commodities Act Decree on the Addition of Micronutrients to Foods**. This Commodities Act Decree was notified as existing national legislation within the meaning of Article 11(1) of Regulation (EC) No 1925/2006. Further to Article 5 of the draft Decree a number of requirements of the Commodities Act Decree on the Addition of Micronutrients to Foods also apply to YCF. Some of these requirements seem to be contradictory or at least confusing, such as Article 4 of the draft Decree and Article 9a of the Commodities Act Decree on the Addition of Micronutrients to Foods insofar as it concerns iodine.

As a result, it is **not sufficiently clear from the text of the draft Decree that "toddler formula"/"toddler milk" is a product category that differs from fortified foods and drinks, and food supplements**. Because of the remaining overlap between the draft Decree and the Commodities Act Decree on the Addition of Micronutrients to Foods it will be more difficult for all concerned to verify that the Dutch measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto.

[11] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2013.3408, p. 9.

[12] Warenwetbesluit voedingssupplementen.

In order to prevent practices which may mislead the consumer, to increase transparency and to avoid enforcement problems as much as possible, the VNFKD believes that it would be helpful to include a provision, **clarifying** that the provisions of the draft Decree shall not apply to food within the meaning of the Commodities Act Decree on the Addition of Micronutrients to Foods and the Food Supplements (Commodities Act) Decree.

Mandatory particulars, labelling and presentation

The legal names “toddler formula” and “toddler milk” (“peuterdrank” and “peutermelk”) suggest that the nature, identity, composition and other characteristics of the food are specifically tailored to contribute to the diet of young children aged between 1 and 3 years. This is not the case.

As noted above, 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 polyunsaturated fatty acids (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.

However, further to the draft Decree it would be permitted to place a “toddler formula” or “toddler milk” on the market with only one added vitamin, mineral or other substance. The composition of such a product and thus the compositional criteria in the draft Decree are **not specifically tailored to contribute to the diet of young children**.

The VNFKD also notes that the legal name of a product does not qualify as a ‘claim’ within the meaning of Regulation (EC) No 1924/2006 since the message or representation is mandatory under national legislation. That means that the conditions of Article 10(3) of Article 10(3) of Regulation (EC) No 1924/2006 do not apply. Therefore depending on the particular circumstances of the case and the composition of the particular food, **the legal name “peuterdrank” or “peutermelk” could be misleading as to the characteristics of the food and, in particular, as to its nature, identity, properties and composition**.

The VNFKD furthermore notes that further to Article 7(c) of the draft Decree, the following mandatory particular should be used in the marketing of YCF: “**a statement that the product is not a substitute for vitamin D supplementation**”. Such a statement **would likely be confusing and/or misleading to consumers**, since Article 4 of the draft Decree allows the voluntary addition of vitamin D. In such cases the amount shall be within the minimum and maximum thresholds set by Regulation (EU) No 2016/127. Such a mandatory statement is therefore likely to be misleading if the toddler formula or toddler milk does contain vitamin D. Also, the average consumer may not fully understand what is meant by “vitamin D supplementation” (“*vitamine D suppletie*”). Moreover, based on this mandatory particular consumers may think that they will have to use additional vitamin D supplements for their young children, even in cases where the product *does* contain vitamin D. Such a statement is therefore not only misleading, but also not accurate, clear and easy to understand for the consumer.

The VNFKD therefore considers that **the mandatory requirements set by the draft Decree would have the opposite effect** of what is intended by Article 7 of Regulation (EC) No 1925/2006 and the **general objectives of food information and fair information practices**, in particular Articles 3, 4 and 7 of Regulation (EU) No 1169/2011.

With regard to Article 8 of the draft Decree the VNFKD notes that the restrictions concerning the use of text, pictures and colours used in the labelling and presentation of toddler formula/drink is very broadly worded. This causes serious concern to the VNFKD. The text of the draft Decree suggests that manufacturers would no longer be allowed to use an umbrella brand and would have to change the brand names of the products. Such **restrictions on the use of umbrella brands** would be disproportionate, especially since the distinction between infant formulae and follow-on formulae on

the one hand, and YCF on the other hand is already ensured by the product denomination ("peuterdrank" or "peutermelk").

Draft Decree hinders innovation

Traditionally, The Netherlands have had a strong position in the area of research and development (R&D) of nutrition for infants and young children. The Dutch R&D Centres of Nutricia/Danone, DSM, FrieslandCampina, Mead Johnson/RB and Ausnutria collaborate with universities, research institutes and small and medium-sized businesses.

The VNFKD notes that **the draft Decree is too restrictive, and does not allow for product innovation**.

As noted above, Article 3 of the draft Decree establishes by means of a dynamic reference to the certain parts of Annex II of Regulation (EU) No 2016/127 a list of other substances that may be added voluntarily to YCF, as well as the respective conditions under which these substances may be used in the manufacture of YCF. Because of the reference to Article 2 of Annex II of Regulation (EU) No 2016/127 only protein isolates from cows' milk or goats' milk and soya protein isolates shall be used in of YCF. It is **not allowed to use other innovative sources of protein isolates**, such as rice or cereals.

The VNFKD also notes that because the addition of more than one vitamins, minerals and other substances is not mandatory, it remains to be seen which composition(s) of organic YCF will be allowed in practice in the Netherlands further to Regulation (EU) 2018/848. This could also **hinder the development of organic YCF**.

Uncertainties with regard to organic YCF

Further to point 2.2.2 of Part IV of Annex II to Regulation (EU) 2018/848, in the processing of food, minerals (trace elements included), vitamins, amino acids and micronutrients, may be used, provided that:

"(i) their use in food for normal consumption is 'directly legally required', in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if those minerals, vitamins, amino acids or micronutrients are not added; or
(ii) as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers:
- in products referred to in points (a) and (b) of Article 1(1) of Regulation (EU) No 609/2013 of the European Parliament and of the Council (7) their use is authorised by that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned, or
- in products regulated by Commission Directive 2006/125/EC, their use is authorised by that Directive." (emphasis added, VNFKD)

It is still **unclear how organic toddler formula/drink will be reviewed under Regulation (EU) 2018/848** where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the Dutch market. Further to the legal definitions of "peuterdrank" and "peutermelk", and Articles 3 and 4 of the draft Decree, it is possible that The Netherlands will allow organic toddler formula/drink on the market with just only one (1) added vitamin, mineral or other substance. The VNFKD is concerned that this might be **confusing and misleading to consumers** as regards the true nature of the product. This could also seriously **impact the worldwide export** of organic YCF (see below).

Mutual recognition

Further to the **principle of mutual recognition** member states may not restrict or forbid trade in foods which are lawfully produced or marketed according to standards applicable in another EU member state or are not subject to any such rules in that Member State, and are made available to end users in that Member State (see also Regulation (EU) 2019/515). Toddler formula/milk that comply with the provisions and requirements of the draft Decree can therefore not only be marketed in the Netherlands, but can in principle also be marketed in other EU member states. It also means that foods and drinks that have been designated as toddler formula or toddler milk and are lawfully marketed in another EU member state, can be marketed in the Netherlands.

Therefore under the current rules and in the absence of harmonisation, toddler formula/milk (YCF) with **essential compositional differences** can be sold in the member states. Since all of these products can bear the legal name “peuterdrank” or “peutermelk”, this could be **confusing for consumers and could mislead consumers**, not only in the Netherlands but also in other member states, in particular in those countries where different rules (will) apply to YCF and/or where it is reviewed if the foods are suitable for a particular group of consumers (in this case: healthy young children 1 - 3 years). For example, in Germany the compliance with the recommendations for composition of YCF, as published by the DGKJ (the German Society of Paediatrics and Adolescent Medicine) will be reviewed before placing on the market. In the view of the VNFKD this only further underlines the **need for regulation of YCF and harmonisation of the compositional requirements** to avoid inappropriate composition, as also noted by ESPGHAN CoN.

Export

Organic food products to be exported from the EU for placing on the market in China have to be certified in accordance with both Chinese and European rules on organic products. This is possible because of an overlap between EU and Chinese regulations. For food products, **bearing an EU organic logo is a unique selling point**. Chinese consumers will be inclined to choose a product bearing an EU organic logo over products that have only been certified as organic under Chinese regulations, because they tend to attach great value to the proven quality and health effects of the product.

As mentioned above, it is currently **unclear how organic YCF will be reviewed under Regulation (EU) 2018/848**. It is possible that organic YCF with just only one (1) added vitamin, mineral or other substance will be allowed on the market. This could be **confusing and misleading to Dutch and European consumers** as regards the true nature of the product, but could also **seriously impact worldwide exports** of organic YCF, especially to China.

Conclusion

In light of these observations, the VNFKD 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.