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# Which International Guideline for Regulating the Composition of Formula Milk Can be Applied in Iraq?

**Ehab Mudher Mikhael***

Clinical Pharmacy Department, College of Pharmacy, Baghdad University
*Corresponding author: ehab_pharma84@yahoo.com

**Abstract** **Background:** Formula milk is commonly used for feeding infants in Iraq; yet, no specific Iraqi national guideline present to regulate the importing and marketing of such types of milks, so this study aimed to find out a best international guideline that can be adopt as the Iraqi national guideline for importing and marketing of safe and optimum formula milk. **Methods:** A web search for the available international guidelines that control and regulate the composition of formula milks was done using the following keywords: formula milk, nutritional, composition, and guideline, through pubmed and Google websites. Five major guidelines were found: the codex Alimentarius commission, Food and Drug Administration (FDA) guideline, The Life Sciences Research Office (LSRO) of the American Society for Nutritional Sciences guideline, the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) guideline and the European food safety authority (EFSA) guideline. A comparison between these guidelines was made and based upon the following criteria's: the date of release, the date of most recent update, the mandatory and optional ingredients, and the proposed minimum and maximum limit of each nutrient. **Results:** EFSA guideline is the most recent one, which mention both the minimum and maximum required level of all macro and micronutrients. Maximum limit for most of micronutrient is not mentioned by both the Codex and the FDA guidelines. There are many micronutrient contents are not mentioned by FDA guideline. The minimum required level for most of macro and micronutrients are similar between Codex Alimentarius and ESPGHAN guidelines, however the maximum limit of most of these contents are not stated by the codex guideline. LSRO guideline is the most different guideline with regard to minimum and maximum required level of both macro and micronutrients when compared to all other guidelines. DHA is a mandatory component by EFSA guideline only. The maximum limit for ALA is set only by EFSA guidelines. Furthermore the minimum requirement of Na, Cl, K, Se, I, Folic acid, Vitamin D, niacin and choline are higher in EFSA guideline than that in all other guidelines. The minimum requirement of vitamin C, Vitamin K, B2 and B6 are lower in EFSA guidelines than all other guidelines. The maximum accepted level of protein and niacin in EFSA guidelines is lower than that of all other guidelines, while the maximum accepted level for B6 in EFSA guideline is lower than that in all other guidelines except for LSRO guideline. **Conclusion:** EFSA guideline is the most suitable guideline to be applied in Iraq to ensure marketing of safe and nutritionally adequate formula milk.

***Keywords:*** *formula milk, composition, international guidelines, Iraq*

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## 1. Introduction

Breastfeeding is the best way for feeding infants through ensuring adequate and safe nutrition that result in optimum growth, health and development of infants [1]. Anyhow there are some rare cases at which breastfeeding is contraindicated or not suitable as in case of infants with metabolic disorders like galactosemia and phenylketonuria, or the mother suffering from active infectious diseases like tuberculosis, brucellosis or AIDS [1,2]. On the other hand some women prefer not to breast fed their infant due to their busy work time, milk insufficiency or breastfeeding difficulties [3]. In all of the above cases infant formula milk can be used as an alternative way for feeding infant, however, it is not as safe as breastfeeding [4] but it is the most common way for feeding infants in Iraq [5].

To ensure marketing of a safe and nutritionally adequate formula milk, there is international guidelines that regulate the composition of formula milk like Codex Alimentarius commission [6] but national guidelines is so necessary since nutritional requirement may vary from country to another [7].

Indeed there is different infant formula milk with different composition [8]. A significant difference in the composition among these formula milks is present in market of developing countries [9,10]. And since in Iraq there is no any implementation of a national guideline and lack of monitoring bodies to check the implementation of the international guidelines to the imported formula milks [11], so this study aimed to find out a best international guideline that can be adopted as the Iraqi national guideline for importing and marketing of safe and optimum formula milk.

## 2. Methods

A web search for the available international guidelines that control and regulate the composition of different formula milks was done using the following keywords: formula milk, nutritional, composition, and guideline, through pubmed and Google websites. Five major guidelines were found: the 1st one is the codex Alimentarius commission which is released by Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) at 1981 and then updated at 2007 and amended at 2011 [12].

The second one is prepared by Food and Drug Administration (FDA) at 1985 and revised lastly at 2014 [13].

The third one is prepared by The Life Sciences Research Office (LSRO) of the American Society for Nutritional Sciences at 1998 [14].

The 4th one is the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and released at 2005 [15].

The 5th one is prepared by the European food safety authority (EFSA) and released at 2014 [16].

A general comparison between these guidelines was made and based upon the following criteria's: the date of release, the date of most recent update, and the mandatory and optional ingredients. Specific comparison among the guidelines was made and based upon the proposed minimum and maximum limit of each nutrient in each guideline to find out the most safe and adequate range of the required nutrients in formula milk for infants who live in Iraq.

## 3. Results

Table 1 showed the difference among different guidelines regarding minimum and maximum requirement for essential and optional macro and micronutrient requirement. EFSA guideline is the most recent one, which mention both the minimum and maximum required level of all macro and micronutrients. Maximum limit for most of micronutrients is not mentioned by both the Codex and the FDA guidelines. There are many micronutrient contents which are not mentioned by FDA guideline.

**Table 1. Standard requirement for formula milk according to different guidelines**

| Parameter | Codex Alimentarius | FDA guideline | LSRO guideline | ESPGHAN guideline | EFSA guideline |
|---|---|---|---|---|---|
| Energy (kcal/100ml) | 60 – 70 | - | 63 – 71 | 60 – 70 | 60 – 70 |
| Protein (gm/100Kcal) | 1.8 – 3 | 1.8 – 4.5 | 1.7 – 3.4 | 1.8 -3 | 1.8 – 2.5 |
| Fat (gm/100Kcal) | 4.4 – 6 | 3.3 – 6 | 4.4 – 6.4 | 4.4 – 6 | 4.4 – 6 |
| Linoliec acid (LA) (gm/100Kcal) | 0.3 GUL 1.4 | 0.3 | 0.35 – 2.24 | 0.3 – 1.2 | 0.5 – 1.2 |
| Linolinec acid (ALA) (mg/100 Kcal) | 50 – NS | - | 77 – 256 | 50 – NS | 50 – 100 |
| Ratio of LA/ALA | 5:1 – 15:1 | - | 6:1 – 16:1 | 5:1 -15:1 | No need for specific ratio in the presence of long chain poly unsaturated fatty acids |
| AA | Should be at least equal to DHA content | - | Not recommended | Should be at least equal to DHA content | No specific minimum content or specific AA/DHA ratio |
| DHA | GUL 0.5% of total fatty acids (Optional ingredient) | - | Not recommended | 0 - 0.5% of total fat (Optional ingredient) | 20 – 50mg |
| Carbohydrate (gm/100Kcal) | 9 – 14 (avoid sucrose and fructose) | | 9 - 13<br>Glucose and sucrose are not recommended | 9 -14<br>Only lactose is acceptable<br>Starch can be added but should not exceed 30% of total carbohydrates<br>Glucose is not recommended<br>Fructose and sucrose are not safe | 9 – 14<br>At which lactose 4.5g or more<br>CHO should be free from gluten<br>Sucrose should not be added but if added not exceed 2g/dl<br>Maltose and maltodextrin there is no min or max limit but CHO content should not exceed max limit |
| Oligosaccharide (gm/dl) | Not mentioned | Not mentioned | Not mentioned | Not mentioned | Safe but not necessary<br>If added should not exceed 0.8 |
| Taurine (mg/100 Kcal) | 0 – 12<br>Optional ingredient | | 0 – 12<br>Optional | 0 – 12<br>Optional ingredient | Not necessary<br>But if added should not exceed 12 |
| Inositol (mg/100 Kcal) | 4<br>GUL 40 | 4 | 4 – 40 | 4 – 40 | 4 – 40 |
| L carnitine (gm/100 Kcal) | 1.2 – NS | | 1.2 – 2 | 1.2 – NS | 1.2 – NS |
| Minerals | | | | | |
| Ca (mg/100 Kcal) | 50<br>GUL 140 | 60 | 50 – 140 | 50 – 140 | 50 – 140 |
| Ph (mg/100 Kcal) | 25<br>GUL 100 | 30 | 20 – 70 | 25 – 90 | 25-90 |
| Mg (mg/100 Kcal) | 5<br>GUL 15 | 6 | 4 – 17 | 5-15 | 5-15 |
| Na (mg/100 Kcal) | 20 – 60 | 20 -60 | 25 – 50 | 20 – 60 | 25-60 |
| K (mg/100 Kcal) | 60 – 180 | 80 – 200 | 60 – 160 | 60 – 160 | 80-160 |
| Cl (mg/100 Kcal) | 50 – 160 | 55- 150 | 50 – 160 | 50 – 160 | 60 -160 |
| Zn (mg/100 Kcal) | 0.5<br>GUL 1.5 | 0.5 | 0.4 – 1 | 0.5 - 1.5 | 0.5-1.5 |

| | | | | | |
|---|---|---|---|---|---|
| Fe (mg/100 Kcal) | 0.45 | 0.15 – 3 | 0.2 – 1.65 | 0.3 – 1.3 | 0.3 – 1.3 |
| Cu (ug/100 Kcal) | 35<br>GUL 120 | 60 | 60 – 160 | 35-80 | 60 -100 |
| Mn (ug/100 Kcal) | 1 – 50 | 5 | 1 – 100 | 1 -50 | 1-100 |
| I (ug/100 Kcal) | 10<br>GUL 60 | 5 – 75 | 8 – 35 | 10 – 50 | 15-50 |
| Se (ug/100 Kcal) | 1<br>GUL 9 | | 1.5 – 5 | - 9 | 3 – 9 |
| Fluoride (ug/100 Kcal) | If added shouldn't exceed 100 | | 0 – 60 | NS - 60 | Not necessary to be added |
| Vitamins | | | | | |
| A (IU/100 Kcal) | 200 – 600 | 250 – 750 | 200 – 500 | 200 – 600 | 233- 600 |
| D (IU/100 Kcal) | 40 – 100 | 40 – 100 | 40 – 100 | 40 – 100 | 80 -100 |
| E (mg/100 Kcal) | 0.5 GUL 5 | 0.7 | 0.5 – 5<br>Based on the polyunsaturated fatty acid content. | 0.5 – 5 | 0.6 - 5 |
| K (ug/100 Kcal) | 4<br>GUL 27 | 4 | 1 – 25 | 4 – 25 | 1-25 |
| C (mg/100 Kcal) | 10<br>GUL 70 | 8 | 6 – 15 | 8 – 30 | 4 – 30 |
| B1 (ug/100 Kcal) | 60<br>GUL 300 | 40 | 30 – 200 | 60-300 | 40 – 300 |
| B2 (ug/100 Kcal) | 80<br>GUL 500 | 60 | 80 – 300 | 80 -400 | 60 – 400 |
| B6 (ug/100 Kcal) | 35<br>GUL175 | 35 | 30 – 130 | 35- 175 | 20 – 165 |
| B12 (ug/100 Kcal) | 0.1<br>GUL 1.5 | 0.15 | 0.08 – 0.7 | 0.1 – 0.5 | 0.1 – 0.5 |
| Niacin (ug/100 Kcal) | 300 GUL1500 | 250 | 550 – 2000 | 300 – 1500 | 400 – 1200 |
| Pantothenic acid (ug/100 Kcal) | 400<br>GUL 2000 | 300 | 300 - 1200 | 400 – 2000 | 400 – 2000 |
| Folic acid (ug/100 Kcal) | 10<br>GUL 50 | 4 | 11 – 40 | 10 – 50 | 15 – 50 |
| Biotin (ug/100 Kcal) | 1.5<br>GUL 10 | 1.5 | 1 – 15 | 1.5 – 7.5 | 1-7.5 |
| Choline (mg/100 Kcal) | 7<br>GUL 50 | 7 | 7 – 30 | 7 – 50 | 25 – 50 |
| Nucleotide equivalent | Levels may need to be determined by national authorities | | 0 – 16<br>Not necessary | 0 – 5 mg<br>(optional ingredient) | 0 – 5 accepted<br>But not necessary |

NS: not specified; GUL: Guidance upper limit.

The minimum required level for most of macro and micronutrients are similar between Codex Alimentarius and ESPGHAN guidelines, however the maximum limit of most of these contents are not stated by the codex guideline. LSRO guideline is the most different guideline with regard to minimum and maximum required level of both macro and micronutrients when compared to all other guidelines.

Minimum and maximum requirements to values of nutritional energy, fat, carbohydrate, taurine. Inositol, L carnitine, Ca, phosphate, Mg, Zn, Mn, and Pantothenic acid are similar between EFSA guideline and most other guidelines. Minimum and maximum requirement for Vitamin A, and E are nearly the same between EFSA guidelines and most other guidelines.

DHA which is not recommended by LSRO guidelines and considered as optional content in ESPGHAN and Codex guidelines become mandatory by EFSA guideline. Additionally maximum limit for ALA is set only by EFSA guidelines. Furthermore the minimum requirement of Na, Cl, K, Se, I, Folic acid, Vitamin D, niacin and choline are higher in EFSA guideline than that in all other guidelines. Copper requirement is low in ESPGHAN and Codex guidelines than that in the other 3 guidelines. The minimum requirement of vitamin C, Vitamin K, B2 and B6 are lower in EFSA guidelines than all other guidelines. The maximum accepted level of protein and niacin in EFSA guidelines is lower than that of all other guidelines, while the maximum accepted level for B6 in EFSA guideline is lower than that in all other guidelines except for LSRO guideline.

## 4. Discussion

Worldwide promotion of infant formula and other commercial baby foods is leading to increased use of these products, especially in Middle East countries like Iraq at which there is an increase in infant formula milk market [17]. Because the scientific evidence clearly shows that feeding with infant formula is worse for the health of infants than breastfeeding [17]. So marketing of formula milk should be regulated to ensure safety and nutritional adequacy [18]. In Iraq, formula milk regulation through Codex Alimentarius commission is still waiting approval from Iraqi Ministry of health (MOH) [19] and actually there is no substantial action to regulate the distribution and use of formula milk in Iraq [11], therefore there is a need to adopting a suitable guideline that regulates the import and marketing of formula milk in Iraq. At the global level, the primary agency concerned with food quality is the Codex Alimentarius Commission. Its code for regulating formula milk is generally accepted throughout the world; however some countries have adopted more stringent guidelines [20].

Although the codex Alimentarius principles for ensuring safety formula milk is well known , but its value

is now being questioned in European countries [21], this may further encourage us to find another guideline which is more suitable to be adopted in Iraq.

Both FDA and codex Alimentarius guidelines are somewhat old dated, at which the first release of Codex Alimentarius was in 1981 but its last revision was in 2007 [20]. Additionally as shown in this study, Both the Codex and FDA guidelines don't state the maximum limit for many micronutrients. So this means that it is acceptable by such guidelines for the manufacturer to fortify formula milk with huge amount of minerals and vitamins. But unfortunately it was found that fortifying formula milk with excess from vitamins can be linked with childhood obesity and a number of diseases later in the life of the child like DM and hypertension [22] and it may be also a risk factor for neurodevelopmental disorders [23]. So Both FDA and Codex Alimentarius guidelines are not suitable to be adopted as a national guideline that regulates the import, marketing and sale of formula milks in Iraq.

LSRO and ESPGHAN guidelines are better than Codex Alimentarius because they sets not only the minimum but also the maximum required level of all micro and macronutrient in formula milk, but both are also old dated and not updated guidelines [14,15] and there are a lot of research on new constituents of formula milk [24], so they can't be recommended to be applied for regulation of formula milk in Iraq. While EFSA guideline is the most recent guideline, it also states both the minimum and maximum required level of all macro and micronutrients [16]. Therefore it may be more interesting than other guidelines, but does its proposed values of macro and micronutrient more suitable for Iraqi infants than that of other guidelines?

Regarding macronutrients, the EFSA guidelines set a new maximum limit of protein, which is lower than all other guidelines. This change and new limit was based on some negative finding of high protein intakes in infants like impairing the water balance, especially when no other liquids are consumed and/or extrarenal water losses are increased, [25]. In this regard the hot weather and lack of electricity in Iraq during summer increase risk of further extrarenal fluid loss through sweating and thus leading to further water imbalance [26]. Furthermore, high protein intake can also contributes to higher insulin secretion, and to a higher release of insulin-like growth factor (IGF)-1 and IGF-binding protein (IGFBP)-1, which may be associated with increased growth and a higher BMI in childhood [27]. This can be confirmed by a recent study that found many of the obese and over weighted children below 2 years in Iraq are those who are being formula fed rather than being breast fed children [28]. Therefore EFSA guideline about protein maximum limit is so suitable to be applied in Iraq.

Regarding lipid contents, EFSA guidelines set a higher minimum requirement for LA, may be because its deficiency is associated with many problems like poor growth, fatty liver, skin lesions and reproductive failure [29], however there is some disadvantages with very high intake of LA, since some epidemiological studies link the high intake of LA with many ccardiovascular diseases, however there is some controversy in this regard [30], so lowering the maximum accepted level of LA is highly acceptable to ensure safety. Regarding ALA, studies of the effect of Alpha linolinic acid intake in adult patients showed that although its intake is useful to decrease risk of cardiovascular disease but the dose should be adjusted to specific limit to avoid increase in risk of cancer [31], So it may be reasonable to set a maximum limit for ALA in infant formula milk as done only by EFSA guidelines.

Regarding docosahexaenoic acid (DHA) and arachidonic acid (AA), they are the two major long chain polyunsaturated fatty acids (PUFAs) in human milk. DHA supplementation to term infants during the 1$^{st}$ years of life is necessary to ensure Neuro and cognitive development as shown in a randomized clinical trial, in one study it was found that supplementation of DHA at 0.32% of total fat is necessary for infant cognition development [32], this percent if multiplied by maximum accepted level of fat which is 6gm, it will be around 20mg of DHA which is the minimum required level by EFSA guideline

Regarding nucleotides, which are considered as optional ingredients by CODEX, LSRO and ESPGHAN guidelines and as not necessary ingredients by EFSA guideline. There is controversy regarding nucleotides benefits on infant gastrointestinal and immune systems (33), besides that safety of large doses is unknown (33) So the recommendation by LSRO guideline is not safe and that adopted by ESPGHAN and EFSA guidelines is more rational.

The second part of this study focus on the requirement of different micronutrients.

One of the major changes in EFSA guideline in comparison with other guidelines is the requirement of Vitamin D which is increased by EFSA guideline. Vitamin D can be synthesized in the skin under the influence of ultraviolet B light. Consequently, requirements of dietary vitamin D depend also on geographical area and lifestyle factors determining the exposure of skin to sunlight (16). Iraq is one of the sunny countries in the world but paradoxically a lot of children suffer from rickets, perhaps because parents fear exposing their children to extremely hot sun during most months of the year (34). So this means that the increase in Vitamin D requirement by EFSA guideline is more applicable in Iraq.

Although all guidelines except EFSA set a minimum limit for choline in formula milk to be as 7 mg/100kcal but researchers found that choline level was lower in formula fed infants than those who are breast fed infants [35,36], and since Choline has important roles in human metabolism, ranging from cell structure to neurotransmitter synthesis; so choline-deficiency may have a negative effects on brain development [37,38]. Therefore increasing choline minimum required level by EFSA guidelines is acceptable in order to avoid any neurological development problems to infants.

Regarding Selenium, which is an essential trace element that plays a key role in antioxidant and immune functions, besides its role in thyroid metabolism [39,40,41]. Selenium blood concentration in infants depend on the intake [42], it is well known that the use of formula milk can also cause selenium deficiency [43] this deficiency may cause reversible growth retardation and alopecia with pseudoalbinism [44]. Additionally selenium deficiency can cause modest asymptomatic hypothyroidism in infants but if it is accompanied by iodine deficiency it may cause thyroid gland destruction [45]. So it is reasonable to set a higher minimum and maximum limit for fortification of formula milk by selenium according to EFSA guideline.

Similarly Thompkinson *et al* referred in his review that the minimum selenium content should be 3 $\mu$g/100 kcal and the maximum selenium content should be 9 ug/100Kcal [46].

Regarding Folic acid micronutrient, the minimum required level of it by EFSA guideline is much higher than that in other guidelines. In one study it was that the level of folic acid in formula fed infants was significantly higher than breastfed infants., however that study was done in a developed country [47] while another study which was done in India (a low income developing country), it was found that the level of folate was higher in breastfed infants than non breastfed ones [48], this result may be expected to be found in Iraq since Iraq is a one of the low income developing countries. Thus it may be reasonable to use the recommendations of EFSA guideline for increasing the minimum required level of folic acid in formula milks that are marketed in Iraq to avoid deficiency in folic acid which may be associated with negative outcome to the development of infant nervous system [49].

Among electrolytes, potassium, sodium and chloride minimum required level is higher by EFSA guideline than that in all other guidelines. These increases in minimum required level is reasonable since most electrolyte requirement are increased during hot weather through excessive sweating as occur in Iraq especially during hot summer months [50,51].

Deficiency in potassium or insufficient formula milk fortification with K may result in infant hypokalemia [52] while sodium deficiency causes failure in infant growth [53].

Iodine is another important micronutrient in formula milk. Its most critical role is to ensure normal function of the thyroid gland. In a recent study in Boston, USA it was found that iodine level is not significantly different between breastfed and formula fed infants, but actually the mean level of iodine in that study is lower in formula fed infants and even there is a very wide range variation in iodine level in formula fed infants [54] which mean that setting a higher iodine level as minimum requirement for formula milk by EFSA guidelines is very important to prevent any iodine deficiency at which goiter is the most visible sequelae of iodine deficiency, and the major impact of such deficiency is impaired neurodevelopment, particularly early in life [49,55].

The minimum cupper requirement is high by FDA, LSRO and EFSA guidelines than that by ESPGHAN and Codex guidelines. It was found that Copper supply was low in the powdered milks (especially until 6 months old) [56], may be because most manufacturer of formula milk comply with the requirement of codex guideline; therefore EFSA recommendations to increase minimum required level of Copper is reasonable

The minimum requirement of Vitamin K is decreased by EFSA guideline when compared to all other guidelines. It was found in a study conducted at 1999 that the level of vitamin K in formula fed infants is around 100 fold higher than that for breast fed infants [57], so it may be reasonable to lower the minimum required level from 4 to 1 ug/100kcal.

Regarding water soluble vitamins, the minimum required level of vitamin C, B2 and B6 and the maximum required level of niacin and B6 are shifted to a lower range in EFSA guidelines than all other guidelines. In this regard it was found that excess of vitamin C and vitamin B specially niacin may be associated with infant obesity [22] which may associated with harmful consequences later in life, besides that excess of vitamin B6 may cause neurotoxicity [16]. Additionally high doses of vitamin B6 may cause neurotoxicity [16].

In conclusion EFSA guideline is the most suitable guideline to be applied in hot developing countries like Iraq to ensure marketing of safe and nutritionally adequate formula milk; therefore it is recommended to evaluate all available formula milks in Iraqi market according to this guideline with special focus on Gold S26 which was shown by a recent study to be better than many other formula milks according to ESPGHAN guideline [58].

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## Conflict of Interest

None.

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