



Nutrient Assessment and Potential Renal Load of Solutes in Infant Powder Formulas Available on the Honduran Market

Adriana Beatriz Di Iorio*, Erika Yomalli Mera Cruz, Aquileo Daniel González De León Gómez and Adriana Hernandez Santana

Department of Food Sciences, Zamorano University, Municipality of San Antonio de Oriente, Francisco Morazan, Honduras

*Corresponding Author: Adriana Beatriz Di Iorio, Department of Food Sciences, Zamorano University, Municipality of San Antonio de Oriente, Francisco Morazan, Honduras

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Abstract

Introduction: Infant formulas (FIP) are food products that have been modified to partially or totally satisfy the physiological needs of the baby, manufactured under the rules of the Alimentarius Codex.

Objective: To evaluate whether the FIP available in the Honduran market comply with the international regulations European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGAN) and the European Technical Regulation (RTS), regarding the potential renal load of solutes (CRPS) and the content of vitamins, minerals and proteins.

Methods: The sample was 39 FIP, descriptive statistics was used, a review of the nutritional labeling was performed and the CRPS of each FIP was estimated. Statistical correlation was established between minerals, proteins and CRPS using the SPSS 25.0 program.

Results: 55% of FIP come from Mexico, the estimated CRPS is correlated with their protein content; FIP CRPS for > 1 year was 237.28 mOsm/L and 130.36 mOsm/L on average. A higher caloric and micronutrient concentration was observed in FIP for premature infants. In all FIP, the macronutrient content was in accordance with the recommendations of ESPGAN and RTS. .

Conclusion: FIPs of 0 - 12 months do not comply with the CRPS recommendation for the age of 0 - 6 months. The fat-soluble vitamins were located in the minimum limits established by the RTS. 5% of the FIP evaluated contained trans fatty acids and for over a year were above the maximum limit established for vitamin B3.

Keywords: CRPS; Infant Formulas; Water-Soluble Vitamins; Iron; Premature

Introduction

The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF), recommend exclusive breastfeeding (LME) for the first 6 months of life, thanks to its protection against gastrointestinal infections, respiratory diseases, allergies and obesity, both for developing countries (where these problems are greatest) and in industrialized countries. Globally, 40% of infants in 0 - 6 months benefit from LME, and Honduras, representing 31% thereafter, 71% of infants receive complementary feeding [1-3].

The conditions for the success of the LME are strictly linked to: the degree of maternal schooling, their prior knowledge, access to

information, their socioeconomic status, the counseling received from health personnel the support family, work, maternal health status and emotional state [3-5].

The geographical area of residence of nursing mothers has been identified as an influential factor in the success of the LME. In rural areas with lower educational level, little access to information on the benefits of LME, increased social and commercial pressure added to a growth promotion; positive influence on the selection of infant powder formulas (FIP) [6]. Likewise, if working conditions do not provide it, you can compromise the abandon mentor the LME earlier than planned [7].

Las FIP are products based on cow's milk (LV) or other animals and/or other components of animal origin, including fish or, should be nutritionally suitable to promote normal growth and proper development of infants [8]. They are not sterile and can be contaminated or contaminated through various means and environments, from hospitals and in the same home, so they must be handled with extreme care to reduce infections [9,10]. They seek to resemble in the composition of both macro and micronutrients of maternal milk (LM) [11,12] adapting to the physiology of the digestion and absorption of nutrients of the infant [13].

Renal load of solutes (CRS) is defined to the amount of solutes that must be excreted by the kidney, including proteins and electrolytes (potassium, calcium, phosphorus and sodium) [14]; and potential solute load (CRPS) as the sum of solutes that would be eliminated by urine if none of them were diverted to the synthesis of new tissues or lost by extra-renal routes renales. IVF FIP should be administered according con to the infant's age, reconstitution shall be adjusted to the concentrations stipulated on the labels of the infants in order not to expose the infant to renal overload of solutes [13,15,16].

IVF is classified into starter formulas ranging from birth to 6 months of birth and formulas are followed to replace infant feeding from 6 to 12 months, respectively [16]. The FIP are regulated within the margins established by CODEX Alimentarius allowing to meet the needs of most children, without nutritional deficiencies or excesses [17].

This study is intended to know whether the FIPs available on the Honduran market comply with the standards established by the Nutrition Committee of the European Society of Gastroenterology, Pediatric Hepatology and Nutrition (ESPGHAN) and the Technical-Health Regulations of Royal Decree 867/2008 of the European Commission Directive, (RTS) on the potential renal load of solutes (CRPS), caloric content, macronutrients, water-soluble vitamins, fat-soluble and minerals of interest.

Materials and Methods

A descriptive and exploratory study was conducted based on the review of the nutritional labelling of IPC for children aged 0 to 12 months (n=39). For each of the formulas was evaluated, the count of calories, and macronutrients, CRPS, essential fatty acids,

the presence of water-soluble and fat-soluble vitamins, iron and taurine according to the specification of FIPs classified for pre-mature, onset, follow-up, children over 1 year and special cases.

The study was carried out at the Zamorano Human Nutrition Laboratory (LNHZ), Francisco Morazán, Honduras between May and November 2018, the packaging of the purchased FIPs was photographed, its forehead as the nutritional label, to obtain the data necessary for its evaluation. The sampling was non-probabilistic. Like inclusion criterion determined the provision of the formula in acquired pharmacies and supermarkets in the capital, in order to assess its availability in the Honduran market. FIP was not considered repeated with different pack size, FIP with pack size of 450g were used. The IBM SPSS version 25.0 program was used to perform the descriptive statistic and its correlations.

CRPS was determined by a formula that considers proteins and some minerals such as sodium, chloride, potassium and phosphorus [18]. CRPS units are son expressed in millimoles/L (mOsm/L).

Equation 1. Equation for calculating the Renal Load of Potential Solutes (CRSP) [16]:

$$CRSP (mOsm/L) = \frac{gr \text{ de proteína por litro}}{0.175} + (Na + Cl + K + P)$$

Where 0.175 is constant of the formula and the acronym represent minerals such as sodium (Na), chlorine (Cl), potassium (K) and phosphorus (P).

The Technical-Health Regalement of Royal Decree 867/2008 of the European Commission's Address of the European Commission expressed in table 6 was used to determine compliance with the composition of the IVF studied; and parameters established by the European Society for Nutrition, Hepatology and Pediatrics (ESPGHAN) [19,20]. The ESPGHAN criteria [19] were used in PREps for preterms). For formulas for children over one year, special and from 0 to 12 months, was taken as a reference the regulation of FIP tracking, for there is no specific parameters for this type of FIP [19,20].

Mexico, despite its large market share of FIP, does not present regulations regarding nutritional content. There are only recommendations by regulations such as ESPGAN and RTS European Commission and these only cover preterm FIPs, start and follow-up, not for the other classifications mentioned.

Table 1 represents the minimum and maximum limits of energy, macro and micronutrients per 100 ml of formula set by the RTS for FIP of start and follow section.

Nutritious	IPF at the beginning		Follow-up IPF	
	ETR por 100 ml		ETR por 100 ml	
	Min.	Max.	Min.	Max.
Energy (kcal)	60	70	60	70
Proteins (g)	1,08	2,1	1,08	2,45
Glycides (g)	5,4	9,8	5,4	9,8
Lipids (g)	2,64	4,2	2,4	4,2
Ca (mg)	30	98	30	98
Retinol (µg)	36	126	36	126
Vit D (g)	0,6	1,75	0,6	2,1
Vit E (mg)	0,3	3,5	0,3	3,5
Vit C (mg)	6	21	6	21
Thiamine (g)	36	210	36	210
Riboflavin (µg)	48	280	48	280
Niacin (mg)	0,18	1,05	0,18	1,05
Vit B6 (g)	21	122,5	21	122,5
Vit B12 (g)	0,06	0,35	0,06	0,35
Folates (g)	6	35	6	35

Table 1: Minimum and maximum limits for start and follow-up formulas.

ETR: Technical-Health Regulations of Royal Decree 867/2008 of the European Commission Directive.

Results

39 FIPs were evaluated acquired at different points of sale in the Honduran market and classified according to criteria of the population to which they are addressed (Figure 1). 3% (1) for pre-term, 8% (3) infant formulas from 0 to 12 months, 18% (8) follow-up, 21% (7) for children older than one year, 26% (10) are onset and 26% (10) special formulas (lactose-free FIP, soy hydrolysate, etc).

Figure 2 shows that 55% of the FIPs offered come from Mexico, 33% from Europe (Denmark, Holland, Ireland) and 12% from South America (Colombia, Venezuela) and Central America (Costa Rica).

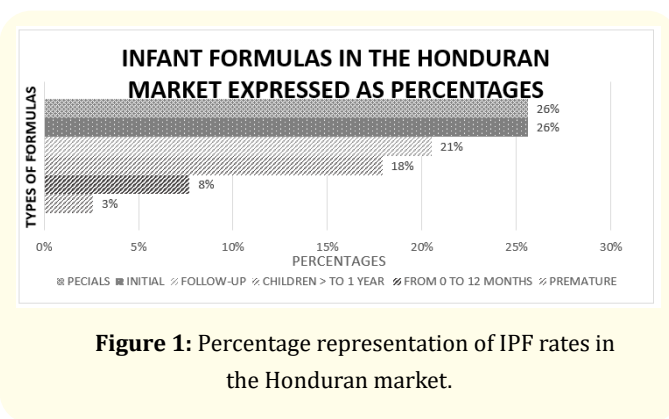


Figure 1: Percentage representation of IPF rates in the Honduran market.

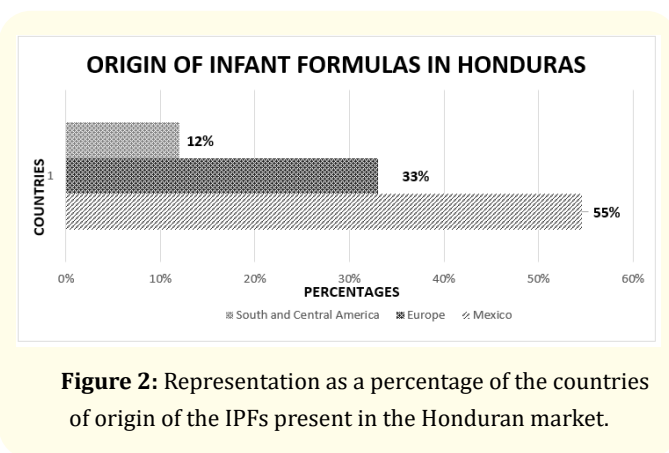


Figure 2: Representation as a percentage of the countries of origin of the IPFs present in the Honduran market.

Table 2 shows the calorie averages, and macronutrients of FIP under study. FiP for preterms have the highest concentration of energy and fats (80 kcal and 4.17g respectively), 40 - 60% of the energy supply is advised to come from lipids.

Table 3 shows the CRSP values and the components needed for its calculation: protein, sodium, potassium, chloride and phosphorus. The renal load (mOsm/L) of the iVF were located between (126.46 x 9.45 mOsm/L; the tracking FIPs ranged from 183.01 to 25.2 million 00; for infants older is a year between 237.28 x 53.38 mOsm/L and special FIPs between 141.23 x 12.39 mOsm/L.

Table 4 shows water-soluble vitamins and folic acid in FIP. The FIP for preterms had the highest concentrations of these micronutrients.

Type	Calories (kcal) [Average - DE]	Protein (g) [Average - DE]	Carbohydrates (g) [Average - DE]	Fat (g) [Average - DE]
Premature	80.00 ± 0.00	2.32 ± 0.00	6.60 ± 0.00	4.17 ± 0.00
From the beginning	65.74 ± 2.31	1.29 ± 0.06	7.35 ± 0.39	3.53 ± 1.25
Follow-up	67.62 ± 2.90	2.01 ± 0.29	7.93 ± 0.38	3.11 ± 0.24
Children > 1 year	75.39 ± 6.62	2.79 ± 0.39	8.74 ± 1.52	3.19 ± 0.61
Special	65.29 ± 2.91	1.56 ± 0.19	7.02 ± 0.45	3.41 ± 0.18
0 to 12 months	67.33 ± 1.15	1.51 ± 0.22	7.05 ± 0.07	3.55 ± 0.22

Table 2: IPF calories and macronutrients IPF in the Honduran market per 100 ml of prepared IPF.

The values represent the average - standard deviation.

Type	Folic acid [Average - DE]	B1 [Average - DE]	B2 [Average - DE]	B3 [Average - DE]	B6 [Average - DE]	B7 [Average - DE]	B12 [Average - DE]	C [Average - DE]
Premature	48.00 ± 0.00	0.14 ± 0.00	0.20 ± 0.00	2.40 ± 0.00	0.12 ± 0.00	4.00 ± 0.00	0.39 ± 0.00	20.00 ± 0.00
From the beginning	10.34 ± 2.87	0.07 ± 0.02	0.11 ± 0.01	0.62 ± 0.15	0.05 ± 0.01	1.91 ± 0.47	0.22 ± 0.05	10.53 ± 1.62
Follow-up	14.39 ± 4.06	0.09 ± 0.03	0.14 ± 0.03	0.60 ± 0.13	0.05 ± 0.01	2.41 ± 1.01	0.21 ± 0.09	10.41 ± 2.01
Children > 1 year	19.94 ± 5.07	0.11 ± 0.03	0.13 ± 0.04	1.11 ± 0.61	0.10 ± 0.58	3.96 ± 2.60	0.23 ± 0.15	8.77 ± 1.56
Special	10.17 ± 3.52	0.08 ± 0.03	0.10 ± 0.05	0.61 ± 0.15	0.05 ± 0.02	2.23 ± 0.70	0.19 ± 0.05	10.06 ± 2.17
0 to 12 months	10.16 ± 0.29	0.06 ± 0.01	0.11 ± 0.05	0.66 ± 0.03	0.05 ± 0.01	2.30 ± 0.81	0.20 ± 0.08	8.06 ± 1.28

Table 4: Water-soluble vitamins present in the IPFs of the Honduran market in 100 ml of prepared IPF.

The values represent the average - standard deviation. Vitamin B1, B2, B3, B6, and vitamin C are expressed in milligrams (mg), while folic acid and vitamin B7 and B12 are represented in micrograms (mcg).

In the table 5 shows the content of fat-soluble vitamins present in FIPs. In all cases, IVF for premature children had the highest concentrations for vitamins A, D and E.

Table 6 shows the content of essential fatty acids, iron and taurine in FIPs. Premature FIPs have the highest amount of taurine, linoleic acid, DHA and ARA. However, formulas for children older than one year have higher amounts of iron (1.16 mg).

Discussion

Calories and macronutrients

Calories: Consumption of 60 - 70 kcal per 100 ml (European Commission) [11] and 60 - 80 kcal per 100 ml (ESPGAN) [19] for START and follow-up FIP is recommended. All FIPs are within the set range reseating the caloric content of the LM [14]. FiP for preterms had mayor caloric density (80 kcal per 100 ml) however, embargo, they were located within the established range.

Type	CRSP* [Average - DE]	Protein [Average - DE]	Sodium Ω [Average - DE]	Potassium [Average - DE]	Chloride [Average - DE]	Phosphorus [Average - DE]
Premature	218.80 ± 0.00	2.32 ± 0.00	43.00 ± 0.00	97.00 ± 0.00	69.00 ± 0.00	72.00 ± 0.00
From the beginning	126.36 ± 9.45	1.29 ± 0.06	21.08 ± 4.43	78.40 ± 14.19	49.27 ± 10.44	29.28 ± 8.85
Follow-up	183.01 ± 25.00	2.01 ± 0.29	28.97 ± 5.41	90.17 ± 9.60	56.88 ± 13.64	50.13 ± 8.54
Children > 1 year	237.28 ± 53.38	2.79 ± 0.39	42.62 ± 4.87	147.83 ± 40.74	88.70 ± 44.70	75.80 ± 24.47
Special	141.23 ± 12.39	1.56 ± 0.19	21.02 ± 3.03	73.36 ± 10.48	45.38 ± 3.89	35.53 ± 8.04
0 to 12 months	149.32 ± 21.75	1.50 ± 0.22	29.60 ± 3.61	82.83 ± 13.25	54.60 ± 5.12	42.60 ± 14.54

Table 3: Renal Load of Potential Solutes (RLPS) and content of components related to it in 100 ml of prepared IPF.

The values represent the average - standard deviation. CRSP is expressed in mOsm/L, protein in grams, sodium, potassium chloride and phosphorus in milligrams (mg). * Renal Load of Potential Solutes.

Type	A [Average - DE]	D ₃ [Average - DE]	And [Average - DE]	K [Average - DE]
Premature	720.00 ± 0.00	3.00 ± 0.00	4.80 ± 0.00	6.40 ± 0.00
From the beginning	203.59 ± 21.21	1.00 ± 0.13	1.61 ± 0.56	6.50 ± 1.65
Follow-up	221.14 ± 29.09	1.30 ± 0.27	1.60 ± 0.77	6.09 ± 2.03
Children > 1 year	226.32 ± 34.42	1.09 ± 0.37	1.76 ± 0.97	4.77 ± 1.37
Special	211.78 ± 29.95	1.06 ± 0.18	1.55 ± 0.54	6.62 ± 2.69
0-12 months	216.11 ± 39.31	0.94 ± 0.14	1.94 ± 0.65	5.96 ± 0.55

Table 5: Fat-soluble vitamins present in the IPFs of the Honduran market in 100 ml of prepared IPF.

The values represent the average standard deviation. Vitamins A are expressed in IU (International Units) and vitamin D, E K in mcg (micrograms).

Type	Taurine [Average - DE]	DHA* [Average - DE]	CALL** [Average - DE]	Linoleic acid [Average - DE]	Iron [Medium - DE]
Premature	6.40 ± 0.00	15.80 ± 0.00	15.80 ± 0.00	0.66 ± 0.00	0.17 ± 0.00
From the beginning	4.41 ± 0.62	8.34 ± 2.52	12.55 ± 6.95	0.55 ± 0.60	0.71 ± 0.17
Follow-up	5.08 ± 0.33	6.96 ± 3.82	12.47 ± 9.22	0.47 ± 0.77	0.97 ± 0.18
Children > 1 year	5.97 ± 2.04	6.75 ± 4.94	1.80 ± 1.13	0.62 ± 0.18	1.16 ± 0.22
Special	4.43 ± 1.24	7.74 ± 1.33	12.39 ± 5.36	0.54 ± 0.08	0.76 ± 0.18
0 to 12 months	4.20 ± 0.52	7.16 ± 0.56	11.73 ± 3.41	0.58 ± 0.06	0.84 ± 0.15

Table 6: Essential fatty acids, iron and taurine present in the IPFs of the Honduran market in 100 ml of prepared IPF.

The values represent the average - standard deviation. Taurine, DHA, ARA and iron are expressed in mg (mylilig bouquets)and linoleic acid in g (grams). *Docohexanoicacid. ** Arachidonic acid.

Proteins (Pr): The containing means of protein of the IVF of initiation was 1.29 g/dL, 2.01g/dL for THE FIPs being monitored and the FIPs for infants greater than one year, had a value of 2.79 g/dL, complying in all cases with ESPGAN regulations [19,20].

Carbohydrates (Hc): The starting FIPs had average values of 7.35 g/dL, placing at the highest limit of the range established in compliance with ESPGAN and European Commission regulations. Tracking FIPs reported 7.05 g/dL being within the limits set by the RTS. Para FIP special was found a value of 7.02 g/dL and in FIPs for children over one year the value was 8.74 g/dL, being the maximum allowed FIP content according to ESPGAN ESPGAN [19,20]. The use of glucose and sucrose is discouraged due to its osmolar potential, glomerular filtering and caloric power; the latter should not exceed 20% [20] of the total HC expressed in the formulation.

Fats (Gr): Dietary lipids will provide energy, fat-soluble vitamins [25], LM has a mixture of monounsaturated, polyunsaturated and saturated fats with a value of 3.9 g/dL [34]. The Initial FIP de reported a fat value of 3.53 g/dL, tracking value of 3.11 g/dL, special FIPs of 3.41 g/dL and FIP from 0 to 12 months 3.55 g/dL, with all FIPs within THE regulations being found by ESPGAN [26]. The energy content of fats re represents 40 - 50% of the total ingested by an infant feeds formula, necessary to meet the requirements for the growth of the first 12 months of life, the other 50% is divided between Hc and Pr. The total gr should be divided into en:50% unsaturated fats and 50% saturated fats (34.35). 5% of the FIP studied presents trans ribgrass in its nutritional composition. The WHO states that trans fats must be absent in the FIP content, because they are causal for cardiovascular disease [35].

Potential renal solute load (CRPS)

Lto CRPS for start FIPs should be located around 130 mOsm/L in order to resemble the CRPS of the LM; the follow-up FIPs weigh a higher CRPS, since the infant acquires renal maturity at the end of the year of life [36]. The CRPS of the LM (93 mOsm/L) and the entire LV (308 mOsm/L) differ. Consumption of LV without dilution and FIP with CRPS not in accordance with renal maturity, affects the renal subject of the infant [37-39]. Renal causes anemia due to iron loss [38].

Homeostasis maintains the osmolality of the intracellular and extracellular fluid between 280 and 300 mOsm/L [39]. The intake of hyperosmolar fluids creates an osmotic gradient, leading to the extraction of water in the gastrointestinal tract leading to osmotic diarrhea. In order to minimize the potential risk in infants with normal gastrointestinal function, a *una* osmolality of infant formula not exceeding 500 mOsm kg⁻¹ is recommended if exist malabsorption is advised 400 mOsm/L1.

The FIP evaluated onset and follow-up were located within established regulations, FIPs for preterms showed a high CRPS for their poor renal maturity [25,26] renal In the absence of a regulation for FIPs from 0 to 12 months, it is risky to use in infants 0 - 6 months of age because the CRPS does not adapt to the established recommendations of 130 mOsm/L.

Fat-soluble vitamins

The FIPs evaluated meet the ranges established by the RTS and ESPGHAN however, their values were at the lower limits of that range, indispensable for growth, timely development, combat, infections, among others. Stressing that the maximum limits ingested can cause hypervitaminosis [36,38].

Water-soluble vitamins

Compliance in water-soluble vitamins of the IVF evaluated was determined with the use of RTS (Table 5). The mean of the range was taken as a reference and was expressed by percentage.

Low folic acid consumption is a cause of alloblastic anemia in its forms and defects in tubal or neural. Its deficiency, in addition to the low consumption of vitamins B6 (Vit B6) and Vitamin B12 (Vit B12), could be associated with cardiovascular diseases, increases in the concentration of the amino acid homocysteine favoring coagulation and deterioration of the arterial wall. The FIPs evaluated were within the range established by the RTS (Table 1) ranking in a range between 48% and 97% compliance.

VitB12 deficiency promotes pernicious anemia in infants, deterioration and/or neuron damage, cell reduction of hematopoietic cells of the bone marrow. To all of the FIPs evaluated, present 100% compliance taking as reference the mean of the range for this classification.

Thiamine or vitamin B1 (Vit B1) and riboflavin or vitamin B2 (Vit B2) represent low requirements according to the RTS. Vit B1 in association with CoA acts on the oxidative decarboxylation of aceto-acetate, while VitB2 is involved in oxidation-reduction reactions needed in various metabolic pathways, including energy production. The required amount is associated with the caloric power of the diet. The IVF evaluated were within the range established by the RTS (Table 1), in a range of 49% to 89% compliance for Vit B1 and in a range between 67% to 85% compliance, complying for the Vit B2.

Niacin or vitamin B3 (Vit B3), exerts action in the metabolism of carbohydrates, fatty acids and amino acids, acting in the synthesis of active forms of vitamin B6, riboflavin and folic acid. All IPOs evaluated were within the range set by the RTS (Table 1), presenting 100% compliance, for this category except for FIPs for children older than one year exceeding the maximum limit of the established % range by 5%.

The biotin or vitamin B7 (Vit B7) intervenes as an enzyme in the metabolism of macronutrients; specifically in gluconeogenesis, leucine catabolism, propionate metabolism and fatty acid synthesis gross. The IVF evaluated were in a range of 1.91 mcg for 4.0 mcg, however, embargo, there are no regulations for their regulation [25,26].

Ascorbic acid or vitamin C (Vit C) acts on collagen synthesis and in the functioning of renal glands by increasing the absorption of iron. All of the FIPs evaluated were within the range established by the RTS (Table 1). They are located between 64% and 78% of compliance.

Taurine content, unsaturated fatty acids and iron

Taurine is a key amino acid such as: neurotransmitter in the development of the nervous system, in maintaining the function of retinal receptors, in the conjugation of bile salts, favoring the absorption of fats. All FIPs were 36% to 54% of compliance. In premature infants it is essential because of its inability to synthesize it, their addiction should not exceed 12 mg/100 kcal for its possible cardiovascular complications among others.

Linolenic and linoleic fatty acids act in the development of the central and cognitive nervous system. FAO-WHO recommends a

fatty acid intake between 0.5% and 5%, respectively, of the total kcal consumed by the infant. The starting and monitoring FIPs were between 0.5 - 0.8% and 7 - 8% respectively of compliance. FIP for children older than one year have lower concentrations of DHA and ARA, perhaps associated with complementary feeding income and lower demand for this micronutrient.

Iron, is a priority in mental, motor and behavioral development, present in all cells of the body mainly attached to hemoglobin, its deficiency generates hypoxia. All IVF evaluated met the range set by ESPGHAN, FIPs for preterms had an average content of 0.17 mg not meeting THE ESPGHAN.

Conclusion

All FIPs complied with ESPGHAN and RTS regulations for macronutrients, CRSP, taurine and essential acids, fat-soluble vitamins were located in the minimum ranges established by the RTS. FIPs 0 - 12 months do not meet CRPS for infants 0 - 6 months. PREPs for preterms did not meet iron standards and FIPs for children older than one year exceeded the ceiling for vitamin B3. 5% [2] of FIP had trans fatty acids, it is advised to regulate their use in the production of FIP.

Conflict of Interest

The authors express that there are no conflicts of interest when writing the manuscript.

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