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ORIGINAL ARTICLE

Nutritional composition of infant milk formulas. Level of compliance in their manufacture and adequacy of nutritional needs☆

C. Jardí Piñana, N. Aranda Pons, C. Bedmar Carretero, V. Arija Val*

Grupo de Investigación en Nutrición y Salud Mental (NUTRISAM), Institut d'Investigació Sanitària Pere Virgili (IISPV), Universitat Rovira i Virgili, Reus, Tarragona, Spain

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Abstract
Introduction: A high percentage of infants are fed with infant formulas. The aim of this study was to assess compliance with Technical Sanitary Regulations on the manufacture of Spanish infant formulas, and analyse their compliance with recommendations relating to nutritional composition and the Dietary Reference Intakes for infants.
Materials and methods: A total of 31 formulas were analysed, of which 18 were infant formulas, 10 follow-on formulas, and 3 growing-up milks. The European Technical Sanitary Regulations, the Spanish Dietary Reference Intakes and the Institute of Medicine of the United States and Canada were used for the assessment of compliance and adequacy.
Results: The energy and macronutrient content of analysed infant formulas is placed in the middle of the range indicated in the Technical Sanitary Regulations, and meets the recommended amounts. However, most micronutrients such as phosphorus, calcium, retinol, vitamins D, E, C, B_6, B_{12}, thiamin, riboflavin, and folate are at the lower limit of the Technical Sanitary Regulations. However, the recommended consumption of infant formulas exceeded the Dietary Reference Intakes for vitamins E, C, retinol, vitamin B and folate, and vitamin B_{12} for follow-on formulas.
Conclusions: Infant formulas are within the reference values of the European Technical Sanitary Regulations in terms of energy and macronutrients, but we believe that the level of micronutrients should be reviewed, based on current scientific data on infant requirements and possible adverse effects.

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* Corresponding author.
E-mail address: victoria.arija@urv.cat (V. Arija Val).

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Composición nutricional de las leches infantiles. Nivel de cumplimiento en su fabricación y adecuación a las necesidades nutricionales

Resumen
Introducción: Un porcentaje elevado de lactantes son alimentados con fórmulas infantiles. El objetivo fue valorar el cumplimiento de la Reglamentación Técnico-Sanitaria (RTS) en la fabricación de fórmulas infantiles españolas y analizar el grado de adecuación a las recomendaciones de composición nutricional y a las recomendaciones de ingesta diaria para lactantes.
Material y métodos: Se analizaron 31 fórmulas infantiles: 18 de inicio, 10 de continuación y 3 de crecimiento. Para la valoración de cumplimiento y su adecuación se utilizó la normativa europea de la RTS, las Ingestas Dietéticas Recomendadas (RDI) para la población española y las del *Institute of Medicine* de Estados Unidos y Canadá.
Resultados: El contenido de energía y macronutrientes de las leches infantiles analizadas se sitúa en el centro del margen indicado en la RTS y se adecua a las cantidades recomendadas. No obstante, la mayoría de los micronutrientes —tales como fósforo, calcio, retinol, vitamina D, E, C, B_6, B_{12}, tiamina, riboflavina y folatos— se sitúan en el límite bajo de la RTS. Sin embargo, la cantidad recomendada de leche de inicio superaba las RDI en vitamina E, C, retinol, vitaminas del grupo B y folatos, y de vitamina B_{12} para las de continuación.
Conclusiones: Las leches infantiles se encuentran dentro de los valores de referencia de la normativa europea de la RTS en cuanto a energía y macronutrientes; sin embargo, creemos que sería necesario hacer una revisión para los micronutrientes, basándose en datos científicos actuales de los requerimientos del lactante y sobre sus posibles efectos adversos.

Introduction

Scientific evidence gathered in recent years supports the nutritional quality of breast milk to feed newborns and infants, due to the specificity and bioavailability of its nutrients and the contribution of live cells, digestive enzymes, immunomodulators and growth factors.[1] However, a high percentage of 6-month (54.1%) and one-year-old infants (78.3%) are fed with infant formulas.[2] These milks attempt to reproduce the properties, composition and bioavailability of breast milk.[3]

Spain's Royal Decree 867/2008, of May 23, amending community directive (2006/141/EC), approves the Technical-Sanitary Regulation (TSR) that specifically deals with initiation and continuation infant formulas, establishing minimum and maximum values of nutritional content.[4] Its purpose is to provide values to establish the nutritionally adequate contributions of infant formulas. These values are independently established from scientific tests performed in human infants, taking breast milk composition as a reference.[5] There is no specific directive regarding the composition of growing-up milks, so manufacturers follow existing recommendations for continuation milks.[6] Notwithstanding, although the manufacture of artificial milks is assumed to comply with Royal Decree 867/2008 on the TSR[4], it would be interesting to find out whether they adhere to the maximum or minimum values allowed and their relationship with health.

It would also be interesting to analyse the degree to which the nutritional contribution of artificial milks complies with the recommended content, to verify that the artificial milks being prescribed to infants adequately meet their energy and nutritional needs.

In view of this situation, we intend to assess the degree to which infant formulas comply with the TSR and analyse whether the nutritional composition of these milks satisfies the daily recommended intake in infants.

Material and methods

Samples of initiation, continuation, growing-up and special artificial milks commercially available in Spain and related to the pharmaceutical environment have been selected. The nutritional composition figures were taken from the information provided by the manufacturer on the bottles and cartons available for sale and from the Parapharmacy Catalogue 2010.[7] Values are expressed in units/100 ml of milk reconstituted from dry extract.

The mean values of energy and nutrients contained in each milk group (initiation, continuation, growth and special) have been calculated.

Compliance of artificial milk with Technical-Sanitary Regulations

The mean composition of initiation and continuation artificial milks has been compared with the TSR from Royal Decree 867/2008.[4] In the case of growing up milks, since there is no regulation available, their nutritional composition has been compared with cow's milk.[8] The mean value between the minimum and maximum indicated in the TSR