

Evaluation of Current Standards and Proposed Rules for Special Nutritional Foods

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ABSTRACT

Special nutritional foods are one category of processed foods. In this category, 5 different food standards are defined in the current rule of the Korean Food Code ; that is, infant formulae, complementary foods for infants and young children, foods for nutrient supplementation, processed dietary fiber-based foods, and foods for special dietary uses. The major difference between the special nutritional foods and the other processed foods is that the special nutritional foods are characterized by their dietary uses for specific population groups rather than food ingredients or manufacturing and processing techniques which characterize and distinguish most of other processed foods. Although several countries establish similar standards for this type of foods, they use different legal names such as foods for special dietary uses(U.S.A., CODEX, Japan), foodstuffs intended for particular nutritional uses(EC), or special purpose foods(Australia). In addition, there are some other differences in the definitions for these food types and categorization of food types among countries. The major difference in the definitions is the description of 'special dietary uses' by specifying certain population groups whose nutrient requirements are different from those of ordinary men due to physiological or physical conditions and therefore may not be sufficiently met by consuming ordinary foods. The categorization of this type of foods is based on the type of dietary uses in the other countries, whereas we include foods simply supplemented with nutrients or foods having certain components such as dietary fibers even if these food types do not have special dietary uses. Recently, a revision of standards for special nutritional foods has been proposed. However, the description of 'special dietary uses' is not clearly indicated in the definition, and some food types which should not be categorized into the special nutritional foods still remain in this category. In order to correct these problems, the standard of food labeling in the Food Safety Law needs to be revised along with revision of food standards in the Food Code. (*Korean J Community Nutrition* 1(2) : 75~80, 1999)

KEY WORDS : special nutritional foods · special dietary uses · food standards.

According to the Food Safety Law(Department of Health and Human Services 1995), the Minister of Health and Human Service Department can establish and notify standards for processed foods if it is necessary for human health. Based on this law, the Food Code(Department of Health and Human Services 1996) has been notified to regulate safety and to standardize identity, manufacturing and processing, and essential composition of processed foods. In this Food Code, processed foods are largely categorized into 18 groups, and 149 food standards for identity as well as manufacturing and processing and essential composition are established. Special nutritional foods are one category of processed foods of which 5 food standards are defined in the Food Code :

that is, infant formulae, complementary foods for infants and young children, foods for nutrient supplementation, processed dietary fiber-based foods, and foods for special dietary uses. The major difference between the special nutritional foods and the other processed foods is that the special nutritional foods are characterized by their dietary uses for specific population groups rather than food ingredients or manufacturing and processing techniques which characterize and distinguish most of other processed foods. In this review, overall characteristics of standards of identity for special nutritional foods defined in the Food Code are discussed and compared with standards defined by food regulations in several other countries including CODEX, an international food code. In addition, since the proposed rules for the standards of special nutritional foods have been notified(Korean Food and Drug Administration 1999), major contents of the proposed revision are discussed by comparing the current

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rules. However, standards of each food group categorized into the special nutritional foods are not reviewed at this time because they need to be reviewed individually and in much detail.

Definitions of Special Nutritional Foods

1. Comparison of definitions described by food regulations established in several countries

Several different legal names for this type of food group are currently used (Table 1). The legal name defined in the Korean Food Code (Department of Health and Human Services 1996) is special nutritional foods, whereas the U.S.A. (Office of The Federal Register National Archives and Records Administration 1996), Japan (Department of Health in Japan 1994), and CODEX (CODEX Alimentarius Commission 1994) use the name, foods for special dietary uses. The name of foodstuffs intended for particular nutritional uses is used in European Community (EC) (European Commission 1989), and the name of special purpose foods is used in Australia (National Food Authority Australian Food Standards Code 1992). There is a major difference between ours and the others. The legal names used in the other countries emphasize 'special dietary uses', whereas ours stresses 'special nutrition' which may be misinterpreted by consumers or food manufacturers in such a way that nutritional qualities of foods in this food group are superior to those of any other food groups.

Although several different legal names are used, the definitions of this type of food group have a common characteristic. That is, these types of food are manufactured and processed for the purpose of special dietary uses for specific population groups with particular nutrient requirements. According to the definition described in the Korea Food Code, there are two major requirements which distinguish these types of food from the other types of processed foods. The first one is the requirement for specific population groups with particular nutrient requirements such as infants, young children, patients, the elderly, obese people, or pregnant and lactating women, and the second one is the requirement for manufacturing and processing techniques (Table 2). The first requirement for specific population groups is very much similar to the definitions established by other countries. For example, CODEX defines foods for special di-

etary uses as foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders. According to an EC Directive, foodstuffs for particular nutritional uses must fulfil the particular nutritional requirements of certain categories of persons whose digestive process or metabolism are disturbed or who are in a special physiological condition or infants and young children in good health. The code of federal regulations in U.S.A. defines the term of 'special dietary uses' as follows : 1) uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight ; 2) uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood. All these definitions describe the meanings of 'special dietary uses' or 'particular nutritional uses' by defining population groups whose nutrient requirements are distinct due to physiological and physical conditions and, therefore, may not be sufficiently met with ordinary diets.

Because these types of food are manufactured and processed for special dietary uses to fulfill the particular nutritional requirements of specific population groups, certain manufacturing and processing techniques may be required, which is the second requirement described in the definition established by the Korean Food Code ; that is, special nutritional foods are manufactured and processed by adding or reducing nutrients or combining nutrients and food ingredients. However, this requirement is only defined in our regulation. Instead, the definitions established by CODEX or EC Directive only describe that the composition of these types of food must be different from the others. For example, CODEX describes in the definition that the composition of foods for special dietary uses must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist. European Commission Directive describes that foodstuffs for particular nutritional uses must be clearly distinguishable from foodstuffs for normal consumption because of their special composition or manufacturing process.

Among the two requirements, the first one is more im-

Table 1. Comparison of legal names used in different countries for special nutritional foods and types of processed foods included in this food category

Legal names of special nutritional foods	Types of processed foods
Special nutritional foods(Korea)	<ul style="list-style-type: none"> • Infant formulae ; infant formula, follow-up formula • Complementary Foods for infants and young children : weaning foods, baby foods • Foods for Nutrient Supplementation • Processed dietary fiber-based foods • Foods for Special Dietary Uses : low-calorie foods, low-sodium foods, medical foods
Foods for special dietary uses(U.S.A)	<ul style="list-style-type: none"> • Hypoallergenic foods • Infant foods • Foods for reducing or maintaining body weight • Foods for use in the diet of diabetics • Foods used to regulate sodium intake
Foods for special dietary uses(Japan)	<ul style="list-style-type: none"> • Medical foods • Foods for pregnant and lactating women • Infant formulae • Foods for the elderly • Foods for special health uses
Special purpose foods(Australia)	<ul style="list-style-type: none"> • Foods for specific dietary uses ; gluten-free foods, low-lactose(or lactose reduced) foods • Low joule foods • Carbohydrate modified foods • Formula dietary foods • Canned foods for infants and young children • Cereal-based foods for infants and young children • Infant formula • Low sodium and low salt content foods • Supplementary foods
Foodstuffs intended for particular nutritional uses(EC)	<ul style="list-style-type: none"> • Infant formulae • Follow-up milk and other follow-up foods • Baby foods • Low-energy and energy-reduced foods for weight control • Dietary foods for special medical purposes • Low-sodium foods, including low-sodium or sodium-free dietary salts • Gluten-free foods • Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen • Foods for persons suffering from carbohydrate-metabolism disorders(diabetes)
Foods for special dietary uses(CODEX)	<ul style="list-style-type: none"> • Infant formula • Canned baby foods • Processed cereal-based foods for infants and children • Follow-up formula • Foods with low-sodium content • Gluten-free foods • Foods for special medical purposes • Formula foods for use in weight control diets

portant than the second one. Although the foods are manufactured and processed in such a way that the nutrient composition is greatly altered, the purpose of doing so must be suitable for supporting particular nutrient requirements of specific population groups. Therefore, the definition described in the Korea Food Code needs to be revised to describe that the special nutritional foods are characterized by being manufactured and processed for supplying particular dietary needs which exist by reason of a physical or physiological condition rather than by

just indicating dietary uses for certain population groups.

2. Comparison of the current rule and the proposed rule for definition of special nutritional foods

As shown in Table 2, the revision of the definition for special nutritional foods has been recently proposed(Korean Food and Drug Administration 1999). The proposed population groups for consuming these types of food are remained the same, but additional purposes of these types of food such as the purpose of meal replace-

Table 2. Proposed revision of standards for special nutritional foods

	Current rules	Proposed rules
Definition	<ul style="list-style-type: none"> • Foods for dietary uses for infants, young children, patients, the elderly, obese people, or pregnant and lactating women ; and • Foods manufactured and processed by addition or reduction of nutrients or by combination of nutrients and food ingredients 	<ul style="list-style-type: none"> • Foods for dietary uses for specific population groups requiring special nutritional management such as infants, young children, patients, the elderly, obese people, or pregnant and lactating women ; or • Foods for the purpose of meal replacement for part of daily diet ; or • Foods for the purpose of supplementation of nutrients inadequately supplied from ordinary diets ; and • Foods manufactured and processed by addition or reduction of nutrients or by combination of nutrients and food ingredients
Types of special nutritional foods	<ul style="list-style-type: none"> • Infant formulae : <ul style="list-style-type: none"> infant formula Follow-up formula • Complementary foods for infants and young children : <ul style="list-style-type: none"> Weaning foods Baby foods • Foods for nutrient supplementation • Processed dietary fiber-based foods • Foods for special dietary uses : <ul style="list-style-type: none"> Low-calorie foods Low-sodium foods Medical foods 	<ul style="list-style-type: none"> • Infant formulae • Follow-up formulae • Cereal-based foods for infants and young children • Other baby foods • Foods for nutrient supplementation • Medical foods • Foods for meal replacement

ment or nutrient supplementation are newly included in the definition. There are a few problems in the proposed definition. Firstly, the physiological and physical characteristics of those population groups are not described. Therefore, the reasons that this type of foods has characteristics of special dietary uses or particular nutritional purposes are still unclear. Secondly, even if the foods have dietary uses such as meal replacement or nutrient supplementation, the reasons for those uses must be based on facts that certain population groups may not be able to meet their particular nutrient requirements by consuming ordinary foods. Therefore, foods simply having characteristics of meal replacement or nutrient supplementation should not be categorized into the special nutritional foods.

Categorization of Special Nutritional Foods

1. Comparison of categorization of special nutritional foods established by several countries

As shown in Table 1, there are similarities and differences in the categorization of foods in this food group among several countries. Infant formulae, complement-

ary foods for infants and young children, and medical foods are common types of special nutritional foods in all the countries except the U.S.A., whereas processed dietary fiber-based foods are unique in Korea, and foods for special health uses are unique in Japan. Among the several standards established by different countries, CODEX (CODEX Alimentarius Commission 1994) and the EC Directive (European Commission 1989) strictly categorize foods only having characteristics described in the definition into this type of food group. According to the regulation of the U.S.A., however, infant formulae is not categorized into this type of food group even though they have special dietary uses. Instead, they are regulated by a different law called 'Infant Formula Act' (Office of The Federal Register National Archives and Records Administration 1996). The reason for establishing a separate law for infant formulae is mainly due to special needs for regulation of food manufacturing process, safety, composition etc. which may not be sufficiently regulated by the regulation for general processed foods as well as foods for special dietary uses. Similarly, a separate regulation for medical foods is also under the review by U.S. Food and Drug Administration (1996).

2. Comparison of the current rule and the proposed rule for categorization of special nutritional foods

The problematic characteristics of categorization for special nutritional foods in the current rule (Department of Health and Human Services 1996) are as follows : 1) some of the food types such as processed dietary fiber-based foods and foods for nutrient supplementation do not have special dietary uses other than supplying certain food components or nutrients ; 2) some of the food types with different dietary uses such as infant formulae and follow-up formulae are categorized into the same type of food ; 3) some food types characterized by a reduction of certain nutrients such as low-calorie or low-sodium foods may not be differentiated with other type of processed foods labeled 'low-calorie' or 'low-sodium'. Therefore, the categorization of foods must be based on the type of dietary uses of foods which are primarily characterized by the type of physiological and physical conditions influencing nutrient requirements.

Several changes in the categorization of special nutritional foods have been recently proposed (Korean Food and Drug Administration 1999). Some of them are improved by reflecting the problems in the current rule, and some of them still possess problems. Improvements of the categorization are as follows : 1) infant formulae having dietary uses of breast milk substitute and follow-up formulae having dietary uses of complementing breast milk for infants during the weaning period are separately categorized ; 2) complementary foods are categorized into the two types based on major food ingredients and nutrients supplemented to them, which is similar to CODEX standard ; 3) a new category of special nutritional foods, medical foods, is introduced for dietary uses for people with diseases or physiological or physical conditions resulting in alteration of nutrient requirements. However, there are still the same food types such as foods for nutrient supplementation and foods for meal replacement which should not be categorized into the special nutritional foods basically because they are not different from other types of processed foods supplemented with nutrients or replacing meals of general population groups. In some respects, most of special nutritional foods have dietary uses of meal replacement or nutrient supplementation. For example, infant formula substituting breast milk and some of the medical foods can replace even all meals of patients fed with a tube during certain periods of time

and are only sources for nutrients. However, the major differentiating factors of these food types from ordinary processed foods supplemented with nutrients or replacing meals should be based on rationale for the purpose of nutrient supplementation and amounts of nutrients supplementation which must be appropriate for supporting special nutrient requirements of certain population groups. Therefore, the principles for categorization of processed foods into special nutritional foods should be based on whether or not the foods have special dietary uses for certain population groups with special nutrient requirements, and those foods are manufactured and processed in such a way that they can support special nutrient requirements of a specific population group.

There are a number of reasons why food manufacturers want their foods to be categorized into the special nutritional foods even if they are not appropriate for this type. First, the legal name, 'special nutritional foods', may give an image to consumers that this type of foods is nutritionally superior to any other processed foods. Secondly, according to the Korea Food Safety Law (Department of Health and Human Services 1995), these types of food can claim nutrient functions on the label, whereas most other processed foods can not, and this is a big promoting factor for food manufacturers to advertise and differentiate their merchandise from the others. In order to prevent these problems, the legal name must be changed to 'foods for special dietary uses', and the definition must clearly describe what the term of special dietary uses mean. Additionally, the food labeling standards in the Food Safety Law must be revised in such a way that nutrient function claims should be made based on the amounts of nutrients present in the foods instead of types of foods. Once these are corrected, more appropriate categorization of special nutritional foods can be made automatically.

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