



SFDA FD. 2233:2018

اشتراطات البيانات التغذوية على البطاقة

Requirements of nutritional labeling

ICS: 67.040

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority



SFDA.FD 2233 /2018

اشتراطات البيانات التغذوية على البطاقة

Requirements of nutritional labeling

ICS: 67.040.00

الهيئة العامة للغذاء والدواء **Saudi Food & Drug Authority**

تقديم

الهيئة جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة الطبية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواء كانت مستوردة أو مصنعة محلياً، وقد قام قطاع الغذاء بالهيئة بتحديث اللائحة (اشتراطات البيانات التغذوية على البطاقة) بعد استعراض المواصفات ذات الصلة، وقد اعتمدت اللائحة الفنية في اجتماع مجلس إدارة الهيئة (17) والذي عقد بتاريخ (16/ 09 /1439هـ) الموافق (31/ 05 /2018م).

الهيئة العامة للغذاء والدواء **Saudi Food & Drug Authority**

Requirements of Nutritional Labelling

1. Scope:

- 1.1 The purpose of this Regulation is to control the nutritional labelling data.
- 1.2 This Regulation shall apply to all packaged food products, with the exception of the following products:
 - 1.2.1 Food containing very low level of calories, protein, carbohydrate, fat and saturated fat, salt or sodium and total sugars (which can be represented with “Zero”), such as spices and seasonings.
 - 1.2.2 Fresh vegetables and fruits, including any mix of fresh vegetables or fruits, whether whole or cut, without any additions (such as salads without toast bread), excluding dried vegetables and fruits.
 - 1.2.3 Fresh and chilled meat, poultry, and fish, excluding meat, poultry and fish with spices or water or cooked.
 - 1.2.4 Food served directly to the consumer from the place of preparation, such as salads, bakeries, desserts and takeaway food.
 - 1.2.5 Food products made of one nutrient, such as rice, tea, coffee and sugar.
 - 1.2.6 Bottled drinking water and mineral water, but the percentage of its mineral content must be clarified.
 - 1.2.7 Food products in small packs (pack size is less than 25 cm²)
 - 1.2.8 Food additives
 - 1.2.9 Food that need packing or more processing and not sold directly to the consumer.
 - 1.2.10 External packages of food sold through self-service, with separate nutritional label or printed on the original package.

الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority

2. Complementary References:

2.1 SFDA.FD/ GSO 9 “Packaged Food Product Label”

2.2 SFDA.FD/ GSO 2333 “Requirements of Food Products with Nutritional and Health Claims”

2.3 SFDA.FD/ GSO 2539 “Vitamins and minerals permitted for use in foodstuff”.

3. Definitions:

3.1 Nutrition Data: illustrative description to inform consumers on the nutritional characteristics of a certain food product, consisting of two aspects:

3.1.1 Nutrient Declarations

3.1.2 Additional Nutrition Information

3.2 Nutrient Declaration: uniform declaration or list of nutrients the food product contains.

3.3 Nutrition Claim: any offer stating, suggesting or claiming that the food product has special nutritional values, including but not limited to, the energy value or contents of protein, fats, carbohydrates in addition to vitamins and mineral substances. The following declarations shall not be considered as nutrition claims:

3.3.1 Mentioning the substances in the list of ingredients or contents.

3.3.2 Mentioning the nutrients, which is mandatory in nutrition declarations.

3.3.3 Information on the quantity and type of certain nutrients or ingredients on the label if so required under national legislations.

3.4 Nutrient: a material consumed as part of the food product for any of the following reasons:

3.4.1 Providing energy to the body.

الهيئة العامة للغذاء والدواء

Saudi Food & Drug Authority

3.4.2 Needed for growth, development and maintaining life.

3.4.3 Lack of such material results in change in the biochemical and physiological characteristics of the body.

3.5 Sugars: means all mono-saccharides and di-saccharides present in food.

3.5.1 Added sugars: include sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type.

3.6 Dietary fibers: : compound or complex carbohydrates consisting of 10 sugar units or more, which are indigestible by the micro-enzymes of the human intestine, and which belong to the following categories:

3.6.1 Compound or complex edible carbohydrates, naturally existent in food.

3.6.2 Compound or complex carbohydrates extracted from raw food through physical or chemical methods or enzymes, which are found to have physiological effect of a health benefit as shown in the scientific evidence approved by the authorities.

3.6.3 Compound or complex processed carbohydrates, which are found to have a physiological effect of health benefit as shown in the scientific evidence approved by the authorities.

3.7 Polyunsaturated fatty acids: means fatty acids with cis-cis methylene interrupted double bonds.

3.8 Trans Fatty Acids: all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration.

3.9 Nutrient Reference Value (NRV): a series of numerical values based on scientific data, used for the purpose of setting the relevant nutrition marks. There are two types of national NRVs as follows:

الهيئة العامة للغذاء والدواء

Saudi Food & Drug Authority

3.9.1 NRV-Needs: refers to the NRV based on nutrient level.

3.9.2 NRV- chronic diseases: refers to the nutrient levels linked to the control of the risk of chronic diseases associated with diet, excluding malnutrition and nutritional disorder diseases.

4. General Requirements

4.1 Nutrient declarations shall be mandatory for all packaged food products, save the products mentioned in clause 1.2. above.

4.2 List of Nutrients:

4.2.1 Upon using a nutrient declaration, the following information shall be provided:

4.2.1.1 Amount of energy.

4.2.1.2 Amount of protein and carbohydrate available (e.g. dietary carbohydrate and dietary fibers) fats, saturated fats, trans fats, cholesterol, sodium, total sugars and added sugar.

4.2.1.3 Amount of any other nutrient of a claimed nutritional or health effect.

4.2.2 In case of an elective declaration of a certain nutrient, in addition to what is mentioned in clause 4.2.1, the national regulations may make it mandatory to indicate the amount of any other relevant nutrient needed to maintain a good nutritional condition.

4.2.3 When applying a certain nutritional or health claim, it shall be mandatory under the national legislations or the national nutrition guidelines to indicate the amount of any other relevant nutrient needed to maintain a good nutritional condition.

4.2.4 The amounts and / or type of saturated fatty acids, unsaturated monounsaturated fatty acids, polyunsaturated fatty acids, cholesterol and trans fatty acids shall be declared addition to the requirements in section 1/2/4 and in line with 7.4.4.

4.2.5 In addition to the mandatory declarations referred to in clauses 4.2.1, 4.2.3 and 4.2.4, vitamins and minerals may be listed as per the following criteria:

الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority

4.2.5.1 The vitamins and minerals that identified by the relevant authorities shall be declared on the requirement to add them based on the health or nutritional needs of a particular country or region. /Or that listed as requirements in the food product specification.

4.2.5.2 In application of the nutrient declaration requirement, vitamins and mineral elements shall not be indicated if they represent less than 5% of the NRV or the official guidelines issued by the national authority for values per 100g or 100 ml, or quantities per serving on the label.

4.3 Calculation of Nutrients:

4.3.1 Energy Calculation:

The amount of energy indicated on the label is calculated using the conversion factors as shown in the below table (Table 1):

Carbohydrates	4 kcal/ g-17 kJ
Protein	4 kcal/g- 17 kJ
Fats	9 kcal/g- 37 kJ
Organic acid	3 kcal/g- 13 kJ

The amount of energy per gram of food is calculated

4.3.2 Calculation of Protein

To calculate protein quantity, the following equation shall be used:

Protein = total nitrogen (Kjeldahl method) x 6.25, unless another conversion factor is mentioned in Saudi Standards or analysis methods of the food product in question.

4.4 Declaration of contents of nutrients

4.4.1 Nutrient contents shall be declared as shown in the below table (Table 2):

الهيئة العامة للغذاء والدواء

Saudi Food & Drug Authority .

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
<small>* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.</small>	

- 4.4.2 Information of energy quantity shall be expressed in kcal per 100 g or 100 ml or per pack, if the pack contains one piece. Information shall be declared for each food serving as per the quantities shown on the label, or per each piece in the pack, while indicating the number of pieces in the pack.
- 4.4.3 Information related to the quantities of protein, carbohydrate and fats in g per 100 g or 100 ml, or per pack, if the pack contains one piece. Information shall be declared for each serving of the food product as per the quantities shown on the label, or for each piece in the pack, while indicating the number of pieces contained in the pack.
- 4.4.4 Numeric information of vitamins and minerals shall be expressed in metric units, per each 100 g, 100 ml, or per pack, if the pack contains one piece. Information shall be declared for each serving of the food product as per the quantities shown on the label, or for each piece in the pack, while indicating the number of pieces contained in the pack.
- 4.4.5 Information related to the daily need values shall be expressed in percentage, for all the information on the label as shown in table 2.

الهيئة العامة للغذاء والدواء

Saudi Food & Drug Authority

The following NRVs shall be used for the purposes of the label data in accordance with the international standards (Table 3):

Ingredient	NRV	Unit
Energy	2000	kcal
Protein	50	g
Total fat	70	g
Saturates	20	g
Cholesterol	300	Mg
Total carbohydrate	260	g
Dietary fibers	28	g
Sugar	50	g
Salt	6	g
Vitamin A	800	Mcg
Vitamin D	5-15	Mcg
Vitamin C	100	Mg
Vitamin K	60	Mcg
Vitamin E	9	Mg
Thiamine	1.2	Mg
Riboflavin	1.2	Mg
Niacin	15	Mg
Vitamin B6	1.3	Mg
Folate	400	Mcg
Vitamin B12	2.4	Mcg
Pantothenate	5	Mg
Biotin	30	Mcg
Calcium	1000	Mg
Magnesium	310	Mg
Iron	14 (15% dietary absorption; Diversified diets, rich in meat fish, poultry, and/or rich in fruit and vegetables) 22 (10% dietary absorption; Diets rich in cereals, roots or tubers, with some meat, fish, poultry and/or containing some fruit and vegetables)	Mg
Zink	11 (30% dietary absorption; Mixed diets, and lacto-ovo vegetarian diets that are not based on unrefined cereal	Mg

الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority

	grains or high extraction rate (>90%) flours)	
	14 (22% dietary absorption; Cereal-based diets, with >50% energy intake from cereal grains or legumes and negligible intake of animal protein)	
Iodine	150	Mcg
Potassium	2000	Mg
Phosphorus	700	Mg
Copper	900	Mcg
Selenium	60	Mcg
Manganese	3	Mg
Molybdenum	45	Mcg

- 4.4.6 Carbohydrates shall be indicated on the label. In case of clarifying the type of carbohydrate, the total carbohydrate components shall be declared as follows:

“Carbohydrates G, and sugars G”

The above may be followed with: (x) G.

(x) represents the name of any other carbohydrate element.

- 4.4.7 The amount and / or type of fatty acids or the amount of cholesterol must be stated following the statement of total fat content according to clause 4.4.3

Declaration shall be made as follows (Table 4):

Total Fats	...	G
Saturated fat acids	...	G
Trans fat acids	...	G
Monounsaturated fat acids	...	G
Polyunsaturated fat acids	...	G
Cholesterol	...	Mg

- 4.4.8 Conversion to calories may be electively added for each nutrient (carbohydrates, protein, fats) at the bottom of the label (fats 9 g, carbohydrates 4 g, protein 4 g).

الهيئة العامة للغذاء والدواء

Saudi Food & Drug Authority

4.4.9 Calculation of the daily consumption percentage based on a 2000-calorie diet for an ordinary person, while adding the statement (Percent daily values are based on a 2000-calorie diet). Therefore, the bottom part of the nutrition label must contain the percentage of daily need for the nutrients per serving.

4.4.10 Quantities of nutrients that can be considered negligible and can therefore be declared as "0" or as " $\times <$ " as indicated in table 5 giving values to the "x" for the specific nutrients, alternatively "the phrase" contains negligible amounts of can be labelled.

4.4.11 Rounding guidelines for the nutrient declaration in nutrition labelling of foods (table 5):

Nutritional element	Amount	Rounding
Energy		to nearest 1 kJ/kcal (no decimals)
Fat*, Carbohydrate*, sugars*, Protein*, fibre*, polyols*, starch*	≥ 10 g per 100 g or ml	to nearest 1 g (no decimals)
	< 10 g and > 0.5 g per 100 g or ml	to nearest 0.1 g
	no detectable amounts is present or concentration is ≤ 0.5 g per 100 g or ml	"0 g" or " < 0.5 g" may be declared
Saturates*, Mono-unsaturates*, Polyunsaturates*	≥ 10 g per 100 g or ml	to nearest 1 g (no decimals)
	< 10 and > 0.1 g per 100 g or ml	to nearest 0.1 g
	no detectable amounts is present or concentration is ≤ 0.1 g per 100 g or ml	"0 g" or " < 0.1 g" may be declared
Sodium	≥ 1 g per 100 g or ml	to nearest 0.1 g
	< 1 g and > 0.005 g per 100 g or ml	to nearest 0.01 g
	no detectable amounts is present or concentration is ≤ 0.005 g per 100 g or ml	"0 g" or " < 0.005 g" may be declared
Salt	≥ 1 g per 100 g or ml	to nearest 0.1 g
	< 1 g and > 0.0125 g per 100 g or ml	to nearest 0.01 g
	no detectable amounts is present or concentration is ≤ 0.0125 g per 100 g or ml	"0 g" or " < 0.01 g" may be declared
Vitamins and minerals	vitamin A, folic acid, chloride, calcium, phosphorus, magnesium, iodine, potassium	3 significant figures
	All other vitamins and minerals	2 significant figures

*Not applicable to sub-categories

4.5 Accepted Tolerance Levels

4.5.1 Levels of accepted tolerance shall be determined as per the requirements of public health, product lifespan, accuracy of analyses and intrinsic variations in the nutrient

الهيئة العامة للغذاء والدواء

Saudi Food & Drug Authority

contained in the product, and whether the nutrient is added to or naturally exists in the product.

4.5.2 The values used in the nutrient declaration shall be the average value extracted from the values concluded from the product analysis and which represent such product.

4.5.3 The tolerance limits of nutrient declarations on the label must be consistent with the following table (Table 6):

Nutrient	Nutrient declaration accepted tolerance limits	
Vitamins	-35%	+50%**
Minerals	-35%	+45%
Carbohydrates	If the product content per 100g:	
Sugars	>10g:	± 2g
Proteins	10-40g:	± 20%
Fibers	<40g:	± 8g
Fats	If the product content per 100g:	
	>10g:	± 1.5g
	10-40g:	± 20 %
	<40g:	± 8g
Saturated fats, monounsaturated fatty acids	If the product content per 100g:	
	> 4g:	± 8g
Polyunsaturated fatty acids	≤ 4g:	± 20%
Sodium	If the product content per 100g:	
	> 0.5g:	± 8 0.15g
	≤ 0.5g:	± 20%
Salt	If the product content per 100g:	
	> 1.25g:	± 0.375g
	≤ 1.25g:	± 20%

** The tolerance limit above can be accepted for vitamin c in liquids.

5. Principles and Criteria for Clarity of Nutrient Declarations on the Label:

الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority

5.1 General Principles: the principles indicated in clauses 7.1.1, 7.1.2, 7.1.3, and 7.2 of the specification referred to in item 2.1 shall be complied with.

5.2 Authority concerned with declarations:

- 5.2.1 The purpose of the recommendations issued by the said authority is to enhance clarity of the nutrient declarations on the label. The competent authority may determine other methods for display of the nutrient declarations, taking into account the practical methods at the national level and the needs of the consumer.
- 5.2.2 Design: Nutrients must be listed in numbers in a form of a table. If no sufficient space is available to write down the information in a table, it may be written in linear lines.
- 5.2.3 Nutrients must be listed in the same order determined by the competent authority, which shall be consistent in all food products.
- 5.2.4 Font: the competent authority shall take into account the font type, pattern and minimum size. The font size of the (energy amount) and (Serving Size) must be enlarged, using bold font to highlight this information.
- 5.2.5 Contrast: a specific contrast shall be maintained between the fonts and the background to ensure clarity of the nutrient declarations.
- 5.2.6 Numeric declaration: numeric declaration of nutrients must be consistent with the provision of clause 4.4. above.

6. Supplementary (additional) Nutrition Information:

- 6.1 The purpose of the supplementary nutrition information is to raise the consumer's awareness as to the nutrition value in the food products, to help them understand the nutrient declarations. There are many ways to provide such information, which can be added on the product labels.
- 6.2 The use of supplementary nutrition information on the food product labels shall be elective, and such information may be added to, yet may not replace, the nutrient declaration. However, if the targeted category of people has a high percentage of illiteracy or little information about nutrition, the symbols of nutrition groups or colors and photos can be used without the nutrient declaration.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

6.3 The supplementary nutrition information on the food product label must be accompanied with programs aimed at raising the consumer's awareness as to consumption and the use of the said information.

1395
mkhan

الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority

Technical Terms

Polyunsaturated fatty acids	أحماض دهنية متعددة غير مشبعة
Nutrition claim	ادعاء تغذوي
Monounsaturated fatty acids	أحماض دهنية أحادية غير مشبعة
Trans Fatty Acids	أحماض دهنية متحولة
Nutrition declaration	إيضاح تغذوي
Dietary fibers	الياف غذائية
Label	بطاقة
Nutrition labeling	بيانات تغذوية على البطاقة
Nutritional	تغذوي
Nutrition	تغذية
Fats	دهون
Sugars	سكريات
Energy	طاقة
Nutrient	عنصر مغذي
Unsaturated	غير مشبع
Carbohydrates	كربوهيدرات
Saturated	مشبع
Added sugar	السكر المضاف
Nutrient reference value	القيمة المرجعية للعنصر التغذوي

الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority

References:

- Codex Standard No. CAC/GL 2:2017- Nutrition Labelling Guidelines
- Food Labelling: Revision of the Nutrition and Supplement Facts Labels, CFR: 21 CFR Part 101, Federal Register Number: 2016-11861.
<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm385663.htm#highlights>
- Guidance document for competent authorities, tolerances for the control of compliance of nutrient values declared on a label with EU legislation No. 1169/2011.
https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition_vitamins_minerals-guidance_tolerances_1212_en.pdf
- EU Regulation, No 1169/2011
<https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32011R1169>
- A food labeling guide, guidance for industry, FDA
<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM265446.pdf>