

Guideline for Special Food Licensing

Public Health Directorate

Nutrition Section

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Guideline for Special Food Licensing

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Nutrition Section

Public Health Directorate

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Introduction

The Nutrition Section in the Ministry of Health in the Kingdom of Bahrain frequently works on developing their procedures to make it efficient for agents and business holders to submit requests for licensing and importing special food in the kingdom of Bahrain.

This Guideline documents are meant to provide assistance to industries and professionals on how to comply with governing statutes and regulations. The purpose of this guideline is to provide clear instruction on the Nutrition Section-Public Health directorate procedures for licensing and update of Special Food.

Guideline Scope

This guideline is made for special food product which are defined as food or food ingredients that claim to give physiological benefits that gives a higher beneficial value in promoting health and protects or lowers chances from diseases. Special food comes in different forms.

Special Food Types

Special food	Definitions
1) Foods for infants and young children (0-36 months)	Breast milk substitute and complementary foods for infant and for young children (0-36 months).
2) Foods for use in weight control diets	Special food for weight loss, weight gain and products for diabetes.
3) Sport supplements	Special food for improving athletic performance and build muscle.
4) Energy drinks	Energy drinks promoted as raising the level of mental and physical activity. Contained a high percentage of caffeine, sugar or artificial sweeteners is a basic basics component and it contains additional ingredients that give stimulating properties such as taurine, guarana, ginseng, and glucuronolactone.
5) Vitamins and mineral supplements	Special food containing one or more vitamins or minerals.
6) Carbohydrates, protein, and fats supplements	Special food that contain fatty acids, amino acids, or carbohydrates.
7) Foods with health or nutritional claims	Special food that provides physiological benefits beyond basic nutritional functions.
8) Others	Other supplements for nutritional and health purposes.

Producers on Submitting for License Certificate

First: Before submission

Applicants should prepare a new application including all documents listed in special food checklist (appendix1). Application is collected from food control section (imported food unit – Khalifa Bin Salman Port in Al Hidd).

Second: Validation & submission

- ▶ Application is submitted along with all the required mandatory documents mentioned in the checklist to food control section (Imported food unite Khalifa Bin Salman Port in Al Hidd).
- ◆ Food control section will send the application along with the required documents
 to nutrition section in the public health directorate.
- ◆ The nutrition section will review the application along with all required documents. Any missing mandatory documents will result into returning the applicants' request back to food control section for re—submission.

Third: Assessment and Queries

- ♣ Product is assessed in accordance with Nutrition Section-public health standard operating procedures, accredited references and legislations.
- ▶ During the period of studying the product, if any queries are raised, a request for further information will be emailed to the applicant. The applicant will have a time limit of thirty days unless if the agent requests an extension through the email. The absence of any response will result in rejection of the application and will require resubmission.

Fourth: Licensing certificate

- ▶ Special food license decision will take a maximum of thirty working days to be proceeded, however in some cases the time limit may differ due to some products that may require further evaluation.
- ▶ Special Food license certificate (appendix2) decisions are the following:
 - 1) Approve: with the validity of five years
 - 2) Required Change: Applicant will have thirty days to apply with the changes. In case the importer needs an extension, an official email should be sent to the nutrition section or otherwise the applicant will need to request for a new submission.
 - 3) Disapprove: Applicant will have a maximum of thirty days to send an official letter to the Nutrition section in public health to re-consider the decision of the products with the reason.

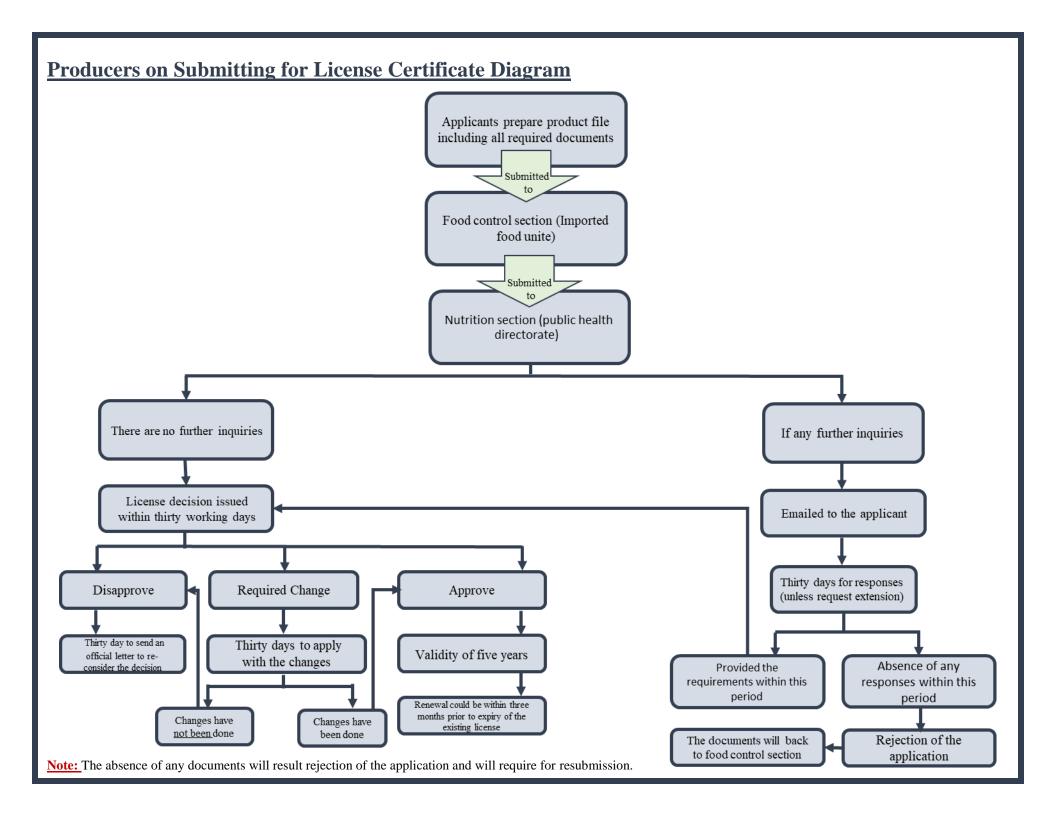
- ▶ Any changes accrued in the product composition/quantity or changes in the label, pack size or any other changes will require the agent to re-submit for a new registration application.
- ◆ The Safety, import and clearance of the product falls under food control department.

Five: Import and clearance

Food control section are responsible authority for the procedures and policy regarding the food safety, importation and clearance regulations.

Six: Renewal of special food licenses

Applicants are required to renew Special Food license every five years of its issuance. Nutrition Section-Public Health encourages the applicant to submit the renewal application within three months prior to expiry of the existing license. It is the responsibility of the applicant to adhere to these timelines.



General Restriction

- All products will be assessed by scientific guidelines by the nutrition section in the Ministry of Health. According to local regulations and laws, GCC standards, as well as national regulations and accreted references.
- All required documents must be legalized or have a declaration from issuing authority when submitting documents to the Ministry of health.
- It is mandatory to provide accredited lab analysis certificate for the product. Laboratory analysis dossier (lab documents) which should be issued by the manufacture company and not the importer.
- The product label must include the following:
 - The name of the product.
 - List of active and inactive ingredients
 - Nutritional data
 - Net contents
 - The name and the address of the manufacturer or the packing factory
 - Country of origin
 - Date marking and instructions for storage and use
 - Special food label must be subject to the GCC Standards /Technical regulations and equivalents.

- ❖ It is forbidden to market or claim that the product is licensed by the ministry of health or use the logo of the ministry of health on the package of the product.
- Any changes accrued in the product composition/quantity or changes in the label, pack size or any other changes will require the agent to re-submit for a new registration application.
- Marketing Special Food is not allowed unless approval is given from the Nutrition section –Public health directorate (appendix 3).
- The Safety, import and clearance of the product falls under food control section.
- In regards to energy drinks, it is prohibited to do any of the following actions:
- It is prohibited to sell it to persons under 18 years, all retail shops that sell energy drinks directly to consumers, should put in a prominent place a clear, legible statement in both Arabic and English language that it is not allowed to sell for persons under 18 years based on their regulations.
- It is prohibited to sell it in restaurants and canteens at health and educational institutions.

- ❖ Manufacturers and importers of energy drinks should add the following cautionary statement on the label of Energy Drinks in a prominent way in both Arabic and English language: "not suitable for pregnant or lactating women, persons under 18, years persons with sensitivity to caffeine or any other product components, or those who suffer from diseases that may affect their health especially Cardiovascular Disease patients, diabetics, and athletes during exercise"
- Resolution No. 13 of 2021 for issuing the executive regulation of Public Health Law has set a regulatory period not exceeding six months from the date of its implementation in order for the sellers, manufacturers and importers of energy drinks to adjust their positions in accordance with the provisions and requirements existed in the regulation. That is from the day following its publication in the Official Gazette, on 05/03/2021.
- Regarding the energy drinks products that currently offered in the market, the provisions of the regulation regarding energy drinks are not applied to them, and they will continue to be sold until the end of the regulatory period (six months).

Nutrition Section in the Public Health Directorate will provide technical support and assistance whenever sellers, manufacturers and importers faced any obstacles during the implementation or have inquiries in regard to energy drinks on the following contact details:

• Email: Phdnutrition@health.gov.bh

Contact No:17282218

Special Food Advertising Restriction

Marketing Special Food in any way of advertising whether it is (audible, visual, readable) is not allowed unless approval is given from the nutrition section according to the following:

- ❖ The content of the advertisement must be consistent with the products uses and the scientific evidence of its effectiveness.
- The advertisement should not include any exaggeration, deceptive, misleading messages.
- ❖ The advertisement should not encourage any unhealthy diet and lifestyle behaviors.

- ❖ The advertisement cannot be marketed directly or indirectly in a way that can cause harm to another product.
- ❖ The advertisement should not conflict with any cultural believes and behavior.
- After assuring that the marketing request compliant with the requirements of marketing Special foods. The period, layout and information in the advertisement must be mentioned in the license (appendix 3).
- ❖ In case the advertisement violated the given license, the nutrition section will take an action against the violated company.

Appendix

Appendix (1): Special food application and checklist template

	Date: من المنطلبات من المنطلبات من المنطلبات	Special Food Appl عصمة وماقي حكمها و قاة	licat آلخ	ion and checklis	PH/FC/ / NU <u>ال</u> تمارة تقديم طك		72021
	IMPORTANT: Failure to submit the necessary ite						d information.
	م حميع المعلومات المطلوبة.	إلغاء طليك. يدن عليك إكمال وتقدر Administrative			رم المواد / المعلومات	هام : عدم تقدر	
	Applicant name (company name an			2-1-2	-Z1 -E -	26.28	مقدم الطلب (
	address):	-			عبوانها).	اسم انسرته و	معدم انعبب ر
	Applicant contact number and email	:			نى لمقدم	والبريد الإلكتروة	رقم التواصل و
							الطلب:
	Manufacturer:						المصنع:
	Manufacture address :					:	عثوان المصنع :
	Marketing Authorization Holder :					:au	الشركة المسوة
		Product particula	rs 🖅	بيائات المند			
	Product name :						اسم المنتج :
	Form:	مسحوق Powder					شكل المنتج :
		oTablets افراص oOther	. آشریءَ				
++-	Product weight:						ممم العبوة:
	المعطليات الإلزاميية Mandatory Requirements						
	Copy of commercial registration					شهادة فيد الن	
	 Copy of certificate to practice co health surveillances import, exp 			لتجارية الخاضعة للرقابة	, لمزاولة الأنشطة ا	, شهادة لصريح	 نسخة من
	healthy food.	or in sale of functional		والصمية والمكملات	الأغذية الوظيضية	دستيراد وبيع	
		it does	_				الغذائية.
	Copy of the agent (applicant) ide				لمقدم الطلب.		
	 Two copies of colored clear Mod (artwork), inner label and packa 			نارجى والداخلي للمنتج			
	signature and stamp).	,,		برقة المنتجة).	نة ومختومة من السّ	لتتفيفية (موقع	والنشرة ال
	 Labelling and adjoining explanat 	,		ات الإيضاعية العصاعية	بواد الغذائية والبيانا	بون بطاقات الد	• يجب أن تك
	Arabic and, where another languation alongside the Arabic. All the info			أو اقتر إلى جانب اللغة	ستعمال لغة أخرى	العربية وعند ا	لها باللغة
	another language shall be identi			الثخرى مطابقة للبيانات	ميع البيانات باللغاث	عب أن تفون عه	العربية ، ي
	Arabic.					اللغة العربية.	المكثوبة ب
	 Products under NHRA classification letter 			نمدة (موقعة ومختومة)	ف نهرا: شهادة معن	الذاضعة لتصني	• للمنتيات
	issued from national health regu			نظيم المهن و الخدمات	ن الهيئة الوطنية لتن	لمنتج صادرة م	لتصنيف ا
		,, (,				.(NHRA	الصحية (۵



Date:

PH/FC/ / NU -

Special Food Application and checklist

استعارة طنيم طلب عرخيص الأغنيسة الخناصية وماثى حكمها وكالمة المعطلبات

•	Free sale certificate: with marketing date must be legalized or declaration from issuing authority and by the embassy of the Kingdom of Bahrain in the country of origin or embassy of any Arab country.	شهاده السعاج بالزرج (معتمده و مرفعته في يلد العشاء) تليت تاريخ تسرويق المنتو و يأنه معبو بإستعماله في يلد العشاء و يتم تداوله فيها.	•
	Lab analysis for product composition content (with exact composition per serving, source and function of each ingredient) from accredited lab. (Good laboratory practice could be required) Lab file must be provided from the company not external.	ملف التعلق المعتوى للعنتي لمعتوى تأوين المنتي (مع التركيب الدخرق لكل منصر. ومصدر ووظيفت كل مكون) من المنتور المعتمد (قد يتم طلب شهادة معارسة معتورية ويدة/ ملف التعاول يتم ترضيرها من قبل الشرك المنتية شقط	•
•	Valid legalized good manufacturing practice certificate/ manufacturing license of the manufacture from country of origin.	شهاده معارست التعنيج الريد في منتهيه العبلامية موقعة و منتوعة من ريه معتمدة و مرفعة في يلد العنشآ ، تأيت تيفرون التعنيج للمعنيج	•
•	Sample of the product should submitted if required.	إرغاق مرته من المنتج في عال طلب الزمارة المختصة.	
•	Any other required documents.	أية مستندات أو ريانات أو معلومات أخرى تطليها الزعارة المنتصة.	•

	Documents requirements If available	(=	المحتدات التي پچپ تواثر ها ()ن وجد	
	Certificate of alcohol free content.		شوادة هل المنتو من الكمول.	•
•	Certificate of pork free content.		شيادة هلن المنتي من لعيم الخنزين	•
	A previously issued certificate for the same product from nutrition section.		نسخه من شياده ترفوض سايفته هنادره للعنتج من غول عسيم التعديد	•
	Copy of licensed certificate issued by one of the GCC countries.		نسخه من شهاده ترفرون سايفه منادره للمنتو من إمدي دول الطور المريس	•

اگرار Declaration

- I declare that all the information supplied on the form and the documents attached are correct and I, under this
 declaration, grant the ministry of health (MOH) the right to verify the information included in my portfolio.
 - أقر يأن يمرع المعلومات المقدمة والمستندات المرفقة صحيحة و يمورب هذا الرقرار يحق لوزاره الصحة التحقق من صحتها إن لزم.
- I declare that the product is free of any banned hazardous substances that harm consumer health.
 - أقرارأن المنتح خال من أي مواد ممنوعة المحظورة تضر يصحة المستهلات
- For the products under NHRA calcification: I declare that I attached all the documents that I have submit to NHRH, attached artwork approved by NHRA.

للمنتوات الداضعة لتصنيف نهرا: أمر يأنني أرفقت ومرج المستندات التي تم تقديما اللهيئة الوطنية لتنظيم المهن و الخدمات الصحية(NHRA). ويأن غلاف المنتج مرخص من قبل الهيئة.

· All mentioned documents above will not be returned back to the agent once it have been submitted.

جمرع المستندات المذكورة أعلية ليدريتم إعادتها لمقدم الطليب

Impeter news & signature:	Head of imported fixed signature:	Food safety section (Imported food units) employee signature
اسج العوره وتوغيعه	الوقيع بالبيت الكوبية	
Page 2 of 2		

age .

Appendix (2): License for special food template

No.PHD / NS / /2021 Date: / /2021	icense For Special Fo	c: NS/()
<u></u>	رخيص الأغذية الخاصة و مافي حك	<u>شهادة ت</u>
P	نات المنتج roduct information	بيا
Product name اسم المنتج		
Brand name اسم العلامة التجارية		
Product dosage form / weight زن/الوزن		
Applicant name (اسم الشركة)		
	رار الترخيص License Decision	قـ
مرخص Approved ت	غیر مرخص Disapproved 🗅	يجب التغيرRequire change
DR. Buthaina Al-Ajlan - Chief of Nut توره بثينة العجلان-رئيس قسم التغذية		
The consumptions of the product is harmful to from the country of origin *This certificate has Safety, import and clearance of the product for food only after taking the written consent of the	human health . Any changes or write-off found in ; been issued based on the evaluation of the proc alls under food control section. Prohibiting the pu e Nutrition Section – Public Health Directorate .	the markets according to the following conditions: the certificate. Product was changed or withdrawn duct file (nutrition fact, claims and lab analysis). blication of any promotional advertising for special تعتبر الشهادة لاغية وللإدارة المعتمدة حق التصرف ب الشهادة تغيير من المنتج أو سحب المنتج من بلد المختبري" اسنيراد وتخليص المنتج وسلامته تخضع ت قسم التغذيه – إدارة الصحة العامة.
Page 1 of 1 This certificate is valid for	ن تاريخ الإصدار 5 years from the issued date	هذه الشهادة صالحة لمدة 5 سنوات مر
		CC: Dr. Najat Abu Alfateh/ Director, PHD

Appendix (3): Special food advertisement application template

Date: /		/
		إستمارة طلب ترخيص دعاية و إعلان الأغذية الخاصة ومافي حكمها
		Special food Advertisement Application Form
عها المادة (16) و	في حكة	وفقا للأئحة التنفدية لقانون الصحة العامة الصادرة بالقانون رقم (34) لسنة 2018 الفصل السادس (الأغدية الخاصة وما
وءه إلا بعد الحصول	ة أو مقرر	(17) فإنه لا يجوز الإعلان عن الأغدية الخاصة و مافي حكمها بأية طريقة من طرق الإعلان – سواء كانت مسموعة أو مرئية
		على ترخيص بدلك من الإدارة المختصة وفقا لشروط وإجراءات تم ذكرها في المادة (16) من القانون.
equivalent Article audible or visual	e (16) a or rea	c Health regulations which implementing in 2018 Law No. (34)Chapter Six (Special Foods and their and (17), it is prohibited to advertise special foods or their equivalent in any way of advertising - whether dable except after obtaining a license from the responsible legalized authority under the conditions and Article (16) of the Law.
		e to submit the necessary items/ information will delay the processing of your application. You must the requested information.

هام : عدم تقديم المواد / المعلومات الضرورية سوف يؤدي إلى تأخير أو إلغاء طليك. يجب عليك إكمال وتقديم جميع المعلومات المطلوبة . البيانات الإدارية Administrative data Applicant name (company name مقدم الطلب (اسم الشركة و عنوانها): and address): Applicant contact number and رقم التواصل و البريد الإلكترونى لعقدم بيانات المستميح المنتجات العراد الإعلان عنها Information about the product/(s) to be advertised Product name : اسم المنتج : Form: شفل المنتج : افراص Tablets أخرى a Others Required attached (Copy of the license along with the approved product label) A copy of valid issued certificate نسخة من شهادة الترخيص غير منتهية from nutrition section for the same الصلامية الصادره للمنتج من قبل قسم product. مرفق مطلوب (نسخة من الشهادة مع غلاف المنتخ المعتمد) بيانات الإعلان Advertisement details Advertising publishing channel: وسيلة نشر الإعلان _ الثانترنت (أدكر الموقع) (Internet (provide link : وسائل التواصل الإرتماعية (grovide account names) Social media _(أذكر أسم الحسان Brochures or posters (please provide details of where it will be ___ مطورات و ملصفات (إدثر مثان عرضها) (ocated _ أخرى (الرحاء تحديدة) (Others (please specify)

توقيع الدكتوره بثينة العجلان-رئيس قسم التغذية

LLPage

Advertising or marketing material if any such as: brochures, posters, bookletsetc.	Required attached عرفق مطلوب	المواد المستخدمة فى الإعلان أو التسويق إن وجد مثل : المطويات أو الملصقات أو كثيبات لغ
Advertisement period of time:	(i-)From :(ull)to:	الفترة الزمنية لنشر الإعلان:
Please mention the target people for the advertisement:		الرجاء ذكر الخثة المستهدفة من الإعلان:
Please briefly describe the proposed adv	عدر artisement	الرجاء وصف محتوى الإعلان المقترح بطريقة مختد
	اقرار Declaration	
grant the ministry of health (N التحقق من صحتها إن لزم.	on supplied on the form and the documents attached a (IOH) the right to verify the information included in m ات المرفقة صحيحة و بموجب هذا الإفرار يحق لوزاره الصحة ا بال من قبل شعر التعنية فقط pr use by nutrition section only	y portfolio. أقر بأن جميع المعلومات المقدمة والمستند
Request Status:	مرفوض Rejected موافق Approved	حالة الطلب :
Comment:		التعليق:
ثينة العجلان-رئيس قسم التغذية DR. Buthaina Al-Ajlan - Chief of	•	
		توقيع مقدم الطلب
		Applicant sign

Appendix (4): Reference competent authorities in some countries

No.	Country	Authority
1.	Italy	Ministero Della Salute DGISAN
2.	Spain	AECOSAN & FSC from one of the notified bodies in the approved list
3.	Germany	BVL-notification & FSC from one of the notified bodies in the approved list
4.	Canada	Health Canada
5.	USA	Food and drug administration
6.	New Zealand	MEDSAFE
7.	UK	RURAL PAYMENT AGENCY
8.	France	Synadiet
9.	Switzerland	Swiss export control- competent authority
10.	India	1. Food safety & standards act
		2. Drug control dept
11.	Poland	Chief Sanitary Inspectorate of the state Sanitary Inspection
12.	Egypt	Ministry of health
13.	Turkey	Food Supplements- Republic of Turkey Ministry of Food, agriculture & Livestock
14.	Philippines	FDA of Philippines
15.	Korea	Ministry of food and drug safety
16.	Cyprus	Ministry of health
17.	Japan	ministry of health labour and welfare
18.	UAE	Registration certificate - Dubai municipality
19.	Romania	Ministry of agriculture for medicinal herbs
20.	Thailand	FDA of Thailand
21.	Portugal	directorate general for food & veterinary
22.	Slovenia	MOH of Slovenia
23.	Australia	Cosmetics- Victorian Chamber of commerce & industry Therapeutic Goods Administration (TGA)
24.	Jordan	Jordan food & drug administration
25.	Oman	Directorate General of Pharmaceutical Affairs and Drug Control (DGPA&DC) a the Ministry of Health (MOH)
26.	Saudi Arabia	Drug sector Saudi food & drug authority