

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEx ALIMENTARIUS COMMISSION**

**Forty-seventh Session**

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#### **PART 1:**

### **NEW WORK PROPOSAL ON THE DEVELOPMENT OF STANDARDS FOR HEALTH SUPPLEMENTS/ DIETARY SUPPLEMENTS/ FUNCTIONAL FOODS AND NUTRACEUTICALS**

(Prepared by India)

#### **I. BACKGROUND**

1. In the late 1980's, consumers in USA began to represent to the government that they should have a freedom to take products to supplement their diet to take care of their health, maintain health and may be to also use certain products in case of day-to-day problems of wellness. Many of them questioned "the reason for everything they need to consume was required to be prescribed by a doctor and approved by Food and Drug Administration of US". This emanated from the feeling that drugs have their own side effects and difficulties in accessing their physician easily for their day-to-day health problems. In effect the scenario was changing from illness-centric approach to wellness-centric approach. Business leaders also had difficulty to get anything they want to market without prior approval from Food and Drug Administration which required high scientific data and effort including cost and time. Scientific developments in understanding nutrition, nutrients and other dietary ingredients and their role in maintenance of health providing certain health benefits began to emerge largely. Several scientists, business leaders and a group of progressive lawyers in Tennessee, Salt Lake City, came up with a draft regulation which later took the shape of Dietary Supplements and Health Education Act notified by United States Food and Drug Administration. Thus began a wellness-centric approach to health.

2. The health supplements and nutraceutical industry is currently a booming industry worth billions and is expected to experience rapid growth in the coming decade. Because consumers are becoming more aware of potential health benefits and the importance of wellness, there has been an increase in popularity of food products like Dietary supplements, Health Supplements and Nutraceuticals. Across the globe, this market is expanding quickly, with regulations constantly evolving. In some countries, these items are classified as pharmaceuticals, while in others they are considered dietary supplements. Hence, the regulatory provisions vary between countries. Other challenges include identifying authentic raw materials, ensuring purity, efficacy and safety, lack of evidence and testing methods, false advertising, heavy metal contamination and supplement-drug interactions. Therefore, it is imperative to explore the emerging regulatory landscape for Health supplement and Nutraceutical and similar product across the globe.

3. The term "nutraceuticals" was introduced by Dr. Stephen DeFelice in 1989 and came from two words "nutrition and "pharmaceutical" which means "it is food or part of a food which provides health benefits. However, there is no international accepted definition of nutraceutical. Many of these products are sold using the term "natural" and offering major therapeutic claims as a safe substitute to prescription medications. These products can also be easily bought from online retail stores without any regulations or controls. There is no uniform, consistent or standardized regulation governing the manufacturing, sales or marketing of any of these products. [1]

4. The scientific research on nutraceuticals and nutrition supplements is often misinterpreted or overstretched for commercial interests because of high consumer demands. [2] Within the last decade, consumers have increased their use of nutraceuticals to the point of intentionally avoiding pharmaceuticals and regarding prescription drugs as being unnecessary, too expensive, and sometimes unsafe. In addition to herbal remedies and nutraceuticals, DS offer patients a promising preventive treatment option. [3]

**II. GLOBAL MARKET POTENTIAL [4]**

5. Past few decades, it has been observed that there is significant increase in use of supplements. The global Dietary Supplements (DS) market is growing exponentially in most countries. According to data from the National Health and Nutrition Examination Survey (NHNES)[5], it has been gaining interest since the 1970s. The geographical distribution is highly variable and has been divided into six major regions (Figure 1)[6] The USA, Europe, and Japan account for the largest share of the market, followed by Asia, Australia, and Oceania, all of which demonstrate the expansion of the market. In contrast, the Middle East and Africa have seen a surge in DS sales, with South Africa remaining the most important market. In the Middle East, the demographics and socioeconomic status of consumers, particularly in Saudi Arabia, has led to the development of this market, which is estimated to reach SAR 875 million by 2024. Differences in these geographical distributions may be the result of several factors, such as socio-demographic and socio-cultural characteristics, consumer behavior, and ageing populations. Globally, the market size of DS increased from USD 82 billion to USD 149.50 billion in 2021 and this will supposedly rise to USD 308 billion in 2028, with a compound annual growth rate growth of 8.90% (Figure 2)[7].

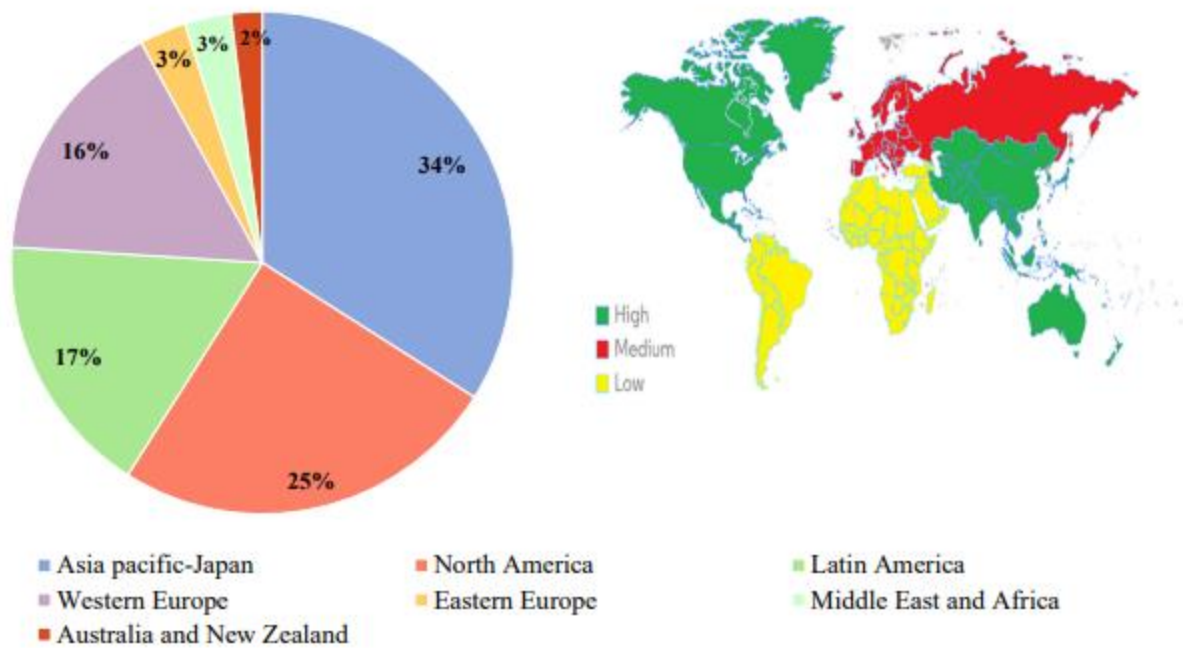


Figure 1: Geographical distribution of Diestary Supplements market and level of DS market Growth worldwide (High, Medium and Low)

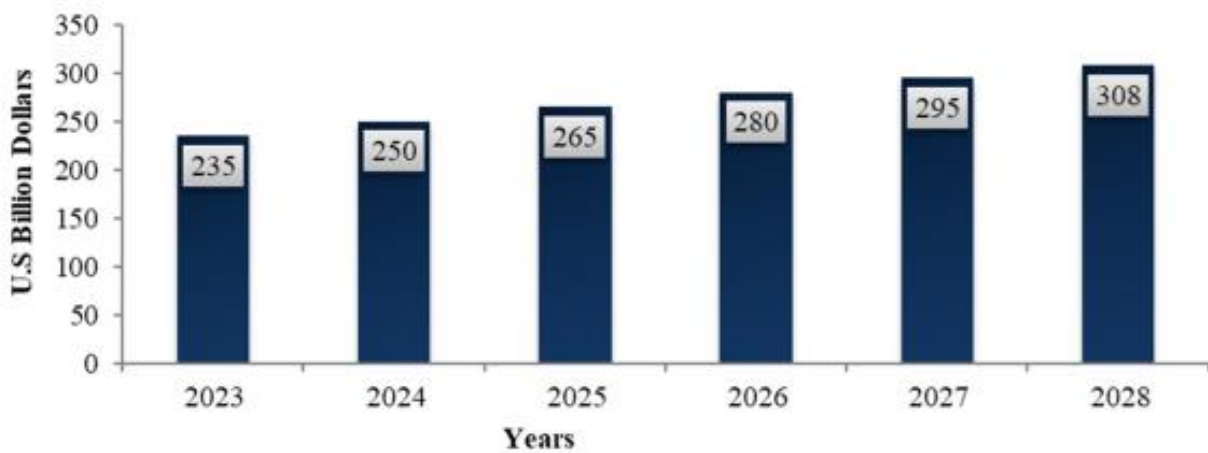


Figure 2: DS market size growth forecast for the period 2023

The import and export trade data is reflected in the **Table1** and **table 2** below.

**Table 1: EXPORT DATA OF HEALTH SUPPLEMENT /FOOD SUPPLEMENT/DIETARY SUPPLEMENT IN VARIOUS COUNTRIES**

EXPORT DATA								
Countries	2020		2021		2022		2023	
	Trade Value (US \$ Million)	Net Quantity (MT)	Trade Value (US \$ Million)	Net Quantity (MT)	Trade Value (US \$ Million)	Net Quantity (MT)	Trade Value (US \$ Million)	Net Quantity (MT)
Argentina	64.48	10317.30	77.24	29255.14	96.99	39877.01	97.15	42479.88
Australia	1176.55	98841.03	1070.77	86742.43	1154.38	106319.24	1346.90	107088.99
Brazil	400.58	96147.56	423.83	95273.44	520.11	105649.74	516.89	91019.47
Canada	1286.60	210455.00	1522.55	281887.87	1603.07	313572.33	1526.86	314933.28
Chile	184.17	18444.96	140.15	15089.93	138.26	15357.94	150.66	16089.93
China	5571.50	1058956.20	6463.37	1137228.89	6634.95	1134255.54	6661.29	1270989.10
Colombia	85.14	16615.47	110.21	19006.08	109.54	20071.88	121.78	22116.63
Dominican Rep.	56.82	22699.59	29.04	17754.78	33.49	17894.96	35.35	16183.85
Egypt	102.90	17481.67	261.09	39851.36	158.77	25249.17	168.91	22103.17
France	2081.19	391895.92	2527.04	409572.27	2364.19	405138.81	2547.79	391999.83
Germany	4647.69	750942.78	5194.29	798308.35	5341.67	833724.95	5724.45	761031.48
India	704.86	173705.61	865.01	194915.68	890.96	208303.06	943.28	243578.22
Indonesia	493.12	276317.46	605.44	314506.01	688.51	331091.47	Not reported	Not reported
Israel	207.77	28944.44	270.69	39099.59	271.95	40511.44	328.07	41490.83
Italy	1538.93	301674.77	1858.25	338954.44	1961.66	335153.75	2204.88	323084.43
Japan	1338.42	37797.69	1296.70	46092.73	1013.73	46203.21	902.06	44331.02
Jordan	60.64	9248.33	61.53	9385.09	76.93	12225.79	140.43	18322.81
Malaysia	709.61	302433.67	850.11	4319.56	959.25	331417.11	934.86	328197.37
Mexico	257.91	41991.10	290.61	43457.93	347.11	53947.44	351.08	45274.20
Morocco	46.53	7607.40	60.88	9010.74	72.84	9845.54	90.12	10102.24
Netherlands	3949.28	693781.60	4485.18	768018.70	5090.43	934965.36	5205.33	865145.67

Nigeria	3.94	431.74	7.10	20670.34	14.00	8570.29	23.66	30046.50
Rep. of Korea	651.85	11761.98	806.18	203952.43	804.86	193402.72	Not reported	Not reported
Saudi Arabia	27.94	6416.32	31.75	8888.47	Not reported	Not reported	Not reported	Not reported
Spain	892.92	183377.77	1102.22	214459.27	1217.52	228201.82	1603.83	220646.46
Thailand	1374.90	758134.31	1380.51	729012.24	1488.19	784979.45	1355.61	660860.15
Tunisia	29.31	8779.24	37.65	11472.80	28.69	8390.06	678.07	0.00
Türkiye	415.03	104105.71	453.96	117444.76	551.15	125500.23	678.07	136982.54
United Arab Emirates	304.56	99227.31	279.17	99149.38	338.25	105870.39	389.51	49400.46
United Kingdom	1900.22	187419.18	1757.29	200295.55	1720.59	199922.40	1836.22	189829.58
USA	6211.98	744128.94	8125.62	899439.78	7963.71	827666.09	7394.06	780064.97

Table 2: IMPORT DATA OF HEALTH SUPPLEMENT /FOOD SUPPLEMENT/DIETARY SUPPLEMENT IN VARIOUS COUNTRIES

IMPORT DATA								
Countries	2020		2021		2022		2023	
	Trade Value (US \$ Million)	Net Quantity (MT)	Trade Value (US \$ Million)	Net Quantity (MT)	Trade Value (US \$ Million)	Net Quantity (MT)	Trade Value (US \$ Million)	Net Quantity (MT)
Argentina	171.83	29113.73	210.25	33027.00	230.13	36937.17	222.92	34119.69
Australia	1584.15	302915.58	1784.79	247524.47	1842.78	239685.05	1648.15	210782.77
Brazil	506.80	68171.11	597.47	75018.96	629.78	72548.65	608.97	73915.62
Canada	1944.89	293720.15	2143.38	331645.48	2281.10	351795.66	2338.30	351742.28
Chile	336.82	161224.10	438.91	183689.22	477.52	156548.38	387.79	161944.90
China	4172.37	345748.93	4346.91	376732.50	4915.30	366813.77	5601.05	356223.11
Colombia	316.42	43310.94	366.43	48380.64	428.89	50889.91	376.97	47310.79
Dominican Rep.	175.34	21195.72	185.87	2828.24	233.00	3393.00	230.33	25899.54
Egypt	306.70	1858.27	366.72	1634.41	423.99	1391.66	330.60	1062.25
France	1660.63	295466.64	2027.34	391358.08	1968.89	356802.35	2054.91	324177.13
Germany	2790.38	515968.46	3175.45	553488.57	3222.20	593665.64	3535.77	535574.43
India	298.18	30690.16	386.67	47764.73	341.97	48570.81	308.00	27151.22
Indonesia	718.32	137689.57	900.46	158974.20	1024.79	215567.44	Not reported	Not reported
Israel	286.09	38034.43	289.40	2098.69	311.85	2782.31	266.07	1670.95
Italy	1015.43	158155.32	1175.87	172661.96	1136.99	195721.41	1321.74	201768.73
Japan	1185.50	396136.70	1215.83	398122.63	1270.87	412673.81	1099.62	365992.55
Jordan	170.89	22721.08	204.36	768.59	241.45	1250.81	252.19	801.43
Malaysia	854.92	194456.20	1143.42	231168.19	1160.78	237223.71	941.71	225314.09
Mexico	737.78	14801.75	832.45	22837.30	857.64	23637.30	846.09	29670.88
Morocco	111.22	23527.51	139.45	26246.45	146.75	27437.68	143.95	22703.08
Netherlands	2305.55	473858.24	2677.68	541479.59	2578.96	502076.27	3068.51	559828.96
Nigeria	364.66	94250.36	231.12	79617.15	210.73	50704.52	214.76	67426.53

Rep. of Korea	2182.54	154588.23	2469.32	172507.01	2608.18	180616.94	Not reported	Not reported
Saudi Arabia	810.43	108833.62	910.89	117690.74	Not reported	Not reported	Not reported	Not reported
Spain	1150.54	199203.22	1334.38	240654.82	1351.64	226551.78	1426.71	234067.97
Thailand	985.31	173934.18	1061.35	179124.42	1041.99	173589.13	937.99	158346.54
Tunisia	48.64	6174.91	47.67	6545.73	53.65	7475.37	0.00	0.00
Türkiye	621.84	141039.10	673.96	155102.06	632.43	143745.67	666.26	136190.51
United Arab Emirates	589.32	119099.95	663.21	140473.70	825.31	192926.42	893.96	9707.82
United Kingdom	2288.54	526601.33	1832.55	55843.50	2112.78	455678.20	2185.45	43850.18
USA	8055.48	832678.77	9014.51	927681.68	10028.30	1011822.01	8273.90	951893.42

## NOTE:-

1) The above data is for available HSN codes

- 2936-provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent
- 210610-Protein concentrates and textured protein substances
- 210690-Food preparation, not elsewhere specified or included

Reference: UN Comtrade Database

<https://comtradeplus.un.org/TradeFlow?Frequency=A&Flows=X&CommodityCodes=TOTAL&Partners=0&Reporters=all&period=all&AggregateBy=none&BreakdownMode=plus>

### III. OBJECTIVE

6. The proposal is to develop codex standards for health supplements/dietary supplements/ functional foods and nutraceuticals.

### IV. NECESSITY TO DEVELOP CODEX STANDARDS

#### 7. Lack of Harmonization/ Diverse Regulatory Framework

- **Different classifications:** Dietary supplements are classified differently across countries—some classify as food, others as drugs, or as a separate category altogether (e.g., Natural Health Products in Canada). Such a situation creates difficulties to cross-border trade and commerce leading to extensive registration processes of a product in one nation under entirely different category in another nation. However, there is a need to recognize national regulations as they cater to the socio-economic as well as cultural and concern related aspects.
- **Diverse definitions:** The definition of a dietary supplement varies widely. For example, in the U.S., a dietary supplement can include vitamins, minerals, herbs, amino acids, and other substances, whereas other countries may have narrower or broader definitions.
- **Different approval processes:** Some countries, like the U.S., allow dietary supplements to be marketed without pre-approval, while others, like Japan (for FOSHU products) or Canada, require rigorous pre-market approval. This inconsistency can lead to the same product being available in one market but not in another.
- **Varying standards for evidence:** The scientific evidence required to support health claims varies greatly. In the EU, claims must be backed by substantial evidence and be pre-approved, while in other regions, less stringent standards may apply. This can lead to discrepancies in the quality and reliability of claims made on similar products in different markets.
- **Misleading claims:** The lack of harmonization can lead to products being marketed with claims in one country that would not be allowed in another. This can mislead consumers about the safety and efficacy of the products they purchase, especially in a global marketplace where consumers may buy products online.
- **Safety concerns:** Supplements that are considered safe and are readily available in one country might be restricted or banned in another due to safety concerns or different interpretations of the available evidence. This results in safety risks for consumers. There is a need to develop a mechanism of consultation between nations before such restrictions or banning of nutraceutical/ supplements are undertaken with a view to obtain expert opinion from other nations. The mechanism to exchange available history of use documents/ safety profile data and quality data from other nations need to be evolved.
- **Regulatory barriers:** Manufacturers looking to export dietary supplements face regulatory hurdles as they are required to comply with the regulations of each target market. This can involve significant costs for re-labelling, reformulating, or conducting additional studies to meet different national standards.
- **Inconsistent labelling requirements:** Countries have different requirements for labelling dietary supplements, including how ingredients are listed, the health claims allowed, and required warnings or disclaimers. These differences complicate the process of creating a unified product for international markets.

8. The lack of a global consensus on health supplements may be due to differences between countries in the regulatory definition and categorization of Health supplements products. The permitted ingredients and the types of products covered by the term DS vary widely and are referred to by different names in different countries (Table 3). Differences in terminology can result in a product being classified entirely differently, leading to discrepancies in regulatory decisions that vary significantly from country to country.

Table 3 Terminology and definition of dietary supplements in different countries[8]

Country	Category Name	Definition
USA	Dietary supplements (DS)	DS are dietary supplements that contain one ingredient or multiple ingredients, such as vitamins, minerals, herbs or other botanicals, amino acids, and enzymes, to supplement one's total dietary intake. They are sold in forms such as tablets, capsules, softgels, gel capsules, powders, and liquids. Unlike medicines, dietary supplements are not intended to treat, diagnose, prevent, or cure disease.

<b>EU</b>	Food supplements (FS)	FS are concentrated sources of nutrients or other substances containing a wide range of ingredients, including vitamins, minerals, amino acids, essential fatty acids, fibre, and various plant and herbal extracts, that have a nutritional or physiological effect and are available in specific dosage forms (pills, tablets, capsules, liquids) to supplement one's normal diet.
<b>Canada</b>	Natural health products (NHP)	NHP is a category of naturally derived products such as vitamins, minerals, amino acids, probiotics, herbal and homeopathic medicines, and traditional medicines intended to improve human health (diagnosis; treatment; alleviation or prevention of a disease, disorder, or abnormal physical condition or its symptoms; restoration; modification or correction of organic functions).
<b>Australia</b>	Complementary medicine (CM)	CMs are therapeutic products consisting of one or more designated active ingredients, each of which has an established identity and a traditional use that is not of the conventional healthcare practices of a country.
<b>Malaysia</b>	Health Supplement (HS)	Health Supplement (HS) where HS refers to any product used to supplement a diet and to maintain, enhance and improve the health function of human body.
<b>China</b>	Health food (HF)	HF refers to foods that claim to have specific health functions or provide vitamins and minerals. It is specific to certain groups and modifies organic functions in humans, but is not intended to treat disease and does not cause acute, sub-acute, or chronic harm to the human body.
<b>India</b>	Health Supplement (HS)	Health Supplement (HS) is a category of foods, which consists of a concentrated source of nutrients (like proteins, minerals, vitamins, amino acids) and/or other ingredients with nutritional or physiological effects, singly or in combination, whose purpose is to supplement the normal diet.
<b>FAO</b>	<i>Functional food*</i>	A foodstuff that provides a health benefit beyond basic nutrition, demonstrating specific health or medical benefits, including the prevention and treatment of disease.

\*Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Twenty-seventh Session, FAO/WHO (J2928).

9. In the agenda item 12, Section 4.12 related to Food safety in personalized nutrition: a focus on food supplements and functional foods specifies that since the field of personalized nutrition continues to evolve and expand, ensuring the safety of these products becomes increasingly important, given their perceived safety by consumers and the varying regulatory frameworks across jurisdictions. As part of the food safety foresight programme, FAO is working on a report on this topic that will be published in the coming months. The report will provide a comprehensive analysis of the food safety and regulatory implications associated with personalized nutrition, focusing specifically on food supplements and functional foods.

10. In view of the above particularly the table 1 and 2 current export and import value/quantity and the fact that different countries have varying regulations and definitions for food supplements, leading to inconsistency in quality, safety, and labeling, developing standards for health supplements/dietary supplements/ functional foods and nutraceuticals is essential in the codex. Further;

- Codex standards help harmonize these regulations, allowing for a unified framework that countries can adopt or reference. This harmonization reduces regulatory divergence, making it easier for the compliance across multiple jurisdictions.
- Many countries, particularly developing ones, lack comprehensive regulations for supplements and nutraceuticals. Codex standards can provide a valuable reference that these countries can adopt or adapt, improving consumer safety and supporting their participation in the international market. These standards would particularly helpful for countries building regulatory capacity in food safety.



- Standards for food supplements within Codex can help reduce trade barriers by providing a commonly accepted reference point, enabling smoother cross-border trade and reducing risks of non-compliance with import and export regulations.

## V. APPROACH

11. The GSFA has already categorized these type of products for the purpose of using food additives under the category 13.0 “**Foodstuffs intended for particular nutritional uses**” and subcategorized as

- 13.3 Dietetic foods intended for special medical purposes (excluding products of food category 13.1).
- 13.4 Dietetic formulae for slimming purposes and weight reduction.
- 13.5 Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6
- 13.6 Food supplements.

12. The available Codex texts related to these categories are;

1. Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) established under Codex Committee on Food Labelling.
2. Standard for Formula Foods for Use in Weight Control Diets (CODEX STAN 181-1991) established under CCNFDU.
3. Standard for Formula Foods for use in Very Low Energy Diets for Weight Reduction (CODEX STAN 203-1995) established under CCNFDU.
4. General Standard for Labelling of and Claims for Prepackaged Foods for Special Dietary Use (CODEX STAN 146-1985) established under Codex Committee on Food Labelling.
5. Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005) established under CCNFSDU.

13. The nearest available standards for health supplements/dietary supplements/ functional foods and nutraceuticals is Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005). The scope and the definition of this standards are mainly for singly or combination of vitamins and minerals only. Since the field of personalized nutrition particularly health supplements/dietary supplements/ functional foods and nutraceuticals continues to evolve and expand, various terminology and definition along with the inconsistent labelling requirements are being used by the country’s leading to varying regulatory frameworks across jurisdictions.

14. Hence, it proposed to develop harmonized definition, labelling and claims requirement for health supplements/dietary supplements/ functional foods and nutraceuticals in similar way as per the framework of the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and General Standard for Labelling of and Claims for Prepackaged Foods for Special Dietary Use (CODEX STAN 146-1985). A new work proposal will be submitted to Codex Committee on Food Labelling for take up this work.

15. It is also proposed to develop standards for health supplements/dietary supplements/ functional foods and nutraceuticals having the essential composition, quality factors, ingredients, contaminants and hygiene as was done in case of Standard for Formula Foods for Use in Weight Control Diets (CODEX STAN 181-1991) and Standard for Formula Foods for use in Very Low Energy Diets for Weight Reduction (CODEX STAN 203-1995). A new work proposal will be submitted to CCNFDU for take up this work.

## RECOMMENDATION

16. The CAC47 is requested to consider and approve the proposal for developing the standards for health supplements/dietary supplements/ functional foods and nutraceuticals as proposed above at para 14 and 15. Accordingly, further works including submission of project document and development of draft standards will be initiated in the respective codex committee.

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**PART 2:****THE DEVELOPMENT OF THE STANDARDS FOR CASHEW KERNELS**

1. CAC40 (2017) approved the new work proposals on cashew kernels (submitted by India) and dried sweet potatoes (submitted by the Republic of Korea). The Coordinator for Asia at CCEXEC79 (2020) highlighted the interest in commencing work on developing a standard for cashew kernels and on dried sweet potato.
2. However, CCEXEC79 (2020) recommended that upon completion of its current session, CCPFV be adjourned sine die with the understanding that the Committee may be reactivated in the future based on needs identified by Members and a sufficient workload. The Codex Committee on Processed Fruits and Vegetables (CCPFV) was adjourned sine die by CAC43 in 2020.
3. Further, the CAC43 (2020), when adjourning CCPFV sine die, requested CCFFV to consider the feasibility of taking up the task related to the development of a standard for cashew kernels. Ghana, Kenya, Senegal and Uganda stressed the importance of cashew kernels in Africa and supported commencing work on developing a standard for this product.
4. It may be noted that the CCEXEC77 had noted the interest in the work on cashew kernels and that Codex members were encouraged to participate in the work of CCPFV and that this could be further discussed in the upcoming RCCs. Accordingly, all RCCs discussed the same. It is important to note that CCASIA21 and CCAFRICA23 supported commencing work on cashew kernels, while support in CCNE10 was also noted with respect to ongoing work by CCPFV. The same was highlighted in the CCEXEC79 by Coordinator for Asia.
5. Further, we would like to inform the Commission that the Cashew kernel is highly traded commodity internationally and its consumption has been growing worldwide at approximately 7% per year. Africa, Brazil, India, Vietnam, and Cambodia are the major producer of the cashew kernels while US and EU are major importer for the cashew kernels in the world.
6. Considering the fact that work proposal on cashew kernel has already been approved by CAC, globally traded commodity and has received support from three Codex regions, it is proposed that the work on cashew kernel should be taken up by Codex.

**CONCLUSION:**

In this regard, the commission is requested to reactivate the CCPFV working by correspondence to take up the work on development of standard for Cashew kernel and other proposals. There has been precedence in Codex, where a committee remained active for taking up only one or two agenda items and worked through correspondence viz, Committees like CCMMP (Dairy permeate powders), CCCPL (Quinoa), CCS (Dehydrated centrifuged sugarcane juice) and recently CCFFP has been re-activated for inclusion of on species in the standards.