

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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NFSDU/40 CRD/4
Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME **CODEx COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

Fortieth Session
Berlin, Germany
26 - 30 November 2018

PROPOSAL FOR NEW WORK ON INTERNATIONAL PREBIOTIC GUIDELINES FOR USE IN FOODS AND DIETARY SUPPLEMENTS

(Prepared by Sudan)

BACKGROUND:

1. At the 50th session of the Codex Committee on Food Additives (CCFA), 26 – 30 March 2018, Sudan submitted a request to the CCFA upon (Priority List of Substances Proposed for Evaluation by JECFA) The Committee agreed to remove the request for the addition of the functional class “prebiotic” for gum Arabic from the Priority List, noting that it was not consistent with a food-additive function. In response to a proposal for the Committee to refer the matter to CCNFSDU, the Committee noted that such an action was out its competence.

Upon request from Dar Savanna Ltd., a Sudanese Natural Prebiotic producer, Sudan Government support its request to generalize prebiotic guidelines for use in food and dietary supplements as follows.

The justification for establishing international guideline for prebiotic is provided in the Annex of this document.

SCOPE:

- a. The purpose of the work is to establish guidance to assist competent national authorities in their evaluation of prebiotics' in order to authorize product as prebiotic or as a source of prebiotic.
- b. The scope of the proposal , applies exclusively on the development of standard/guidelines on prebiotics used as food ingredient, including dietary/food supplements.
- c. The scope of this document will include natural prebiotic recognized to convey a health benefit to humans in appropriate, efficacious amounts. Only prebiotic intended to be added to food or used to supplement the diet where scientific data has demonstrated a health benefit will be discussed.
- d. This document is not intended for use in any aspects of production of biologics or pharmaceutical products or animal feeds.
- e. The proposal includes definitions of prebiotics' and "food with prebiotics", requirements for the evaluation of a prebiotics as a food ingredient, requirements for the evaluation of a food with prebiotics, aspects of production, contaminants, hygiene, labeling and methods of analysis and sampling.
- f. The scope of this proposal only refers to prebiotics and food with prebiotics that are produced in food manufacturing facilities and traded internationally.

INTRODUCTION:

2. Recognizing the possible beneficial effect of prebiotics in food, the Food and Agriculture Organization of the United Nations (FAO) convened a Technical meeting to start work on the evaluation of the functional and health properties of prebiotics. A group of international experts agreed on guidelines, recommended criteria, and methodology for conducting a systematic approach for the evaluation of prebiotics leading to its safe use in food. It was recommended that a full expert consultation be convened under the auspices of FAO. This work provides governments, industry, and consumers with scientific advice in relation to functional and health aspects of prebiotics and general guidance for the assessment of prebiotics in relation to their nutritional properties or safety. These guidelines may also be used by Member Countries and Codex Alimentarius to identify and define what data need to be available to accurately substantiate health and nutrition claims.

“ The attached references 3, 4 , 5 , 6 , 7 , 8 , 9 , 10, 11 demonstrate in vivo and in vitro studies done Gum Arabic as a natural source of Prebiotic , but was not included in the list of prebiotic products mentioned in the FAO report on Prebiotic (2007) (1) “

3. Despite the recognized FAO/WHO definition of prebiotics (2007, Gibson et al 1995), there is global occurrence of products sold as prebiotics' that do not meet this definition. As such, the countries recognize the need and opportunity for development of a Codex Alimentarius guidance or standard to more clearly define the required characteristics of safe and efficacious prebiotics, and to ensure the same level of quality and manufacturing requirements for all operators on the market. The ultimate goal is to establish eligibility criteria to ensure consistent application at national and international levels by Codex member countries, available to promote human health and well-being.

4. The establishment of eligibility criteria and an organized framework fo prebiotic products will provide a guideline for global regulatory agencies to build prebiotics-focused regulations. The establishment of global requirements will satisfy authorities, consumers and industry, and will certainly lead to better consumer satisfaction, health and well-being.

PREBIOTIC PRODUCTION:

5. At present, according to a market report (2018) prepared for Dar Savanna Ltd., there are about 18 companies producing & selling natural and synthetic prebiotics globally.

INGREDIENTS MARKET:

6. According to the study, the prebiotic market stand at 680,000 MT in 2017, and is growing by 7%, to reach 1,500,000 MT by 2025.

INGREDIENT MARKET REVENUE:

7. The global prebiotics ingredient market was valued at 5 billion USD in 2017, and is expected to be valued at 15 billion USD by the year 2025 (Dar Savanna Ltd.).

PREBIOTICS TRADE EXCHANGE:

8. Data and information for this item will be request to Codex member countries.

NEED FOR PREBIOTICS STANDARD/GUIDELINES:

9. Given the wide acceptance of the importance of prebiotic to the health of the human population in addition to the growth of prebiotic food and drinks that market health benefits, governments have raised questions about appropriate regulatory framework to apply to prebiotics and foods with prebiotics, to facilitate its appropriate regulation on their national market.

10. The proposed work is to address the current lack of harmonization through the development of a Codex Standard or Guidelines in order to harmonize framework that includes essential requirements for probiotics', as justified in paragraph 3.

PRODUCTS APPLICABLE FOR THE CODEX STANDARD/GUIDELINES:

11. There are two kinds of products, natural prebiotic and synthetic prebiotics. Both kinds of products are applicable for the proposed Codex Standard/Guidelines.

12. Prebiotic are used as a food ingredient in a wide range of products, including dietary/food supplements.

REQUIREMENTS FOR THE EVALUATION OF A PREBIOTIC:

13. The following minimum requirements should be accomplished in order to authorize a prebiotic as a food ingredient, including dietary/food supplements: taxonomic characterization of the microorganism; characterization of the strain (in vivo e in vitro), demonstration of functional properties of the prebiotic, and demonstration of safety of the prebiotic for the intended use.

14. The food with prebiotic should accomplish the following minimum requirements; amount of prebiotic, the prebiotic demonstration of health benefits of the food. Additionally, it should be proved that the prebiotic keeps its functional properties in the food by in vivo or in vitro tests, and by at least one human clinical study with the aim of getting scientific support to establish the health effects of the prebiotic.

SAFETY:

15. Establishment of safety criteria is essential for public health. A safety assessment specific for prebiotic will be proposed.

ASPECTS OF PRODUCTION:

16. The main aspects of production would be addressed to indicate the most appropriate phases of prebiotic production within a closed, controlled system to provide utmost purity, quality and efficacy. Quality control and quality assurance will be addressed in addition to stability program.

CONTAMINANTS:

17. The products covered by the standard/guidelines shall comply with the maximum levels for contaminants that are specified by the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

HYGIENE:

18. The products covered by the provisions of the standard/guidelines should be prepared and handled in accordance with the *General Principles of Food Hygiene* (CXC 1-1969), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

LABELING:

19. It is proposed that, in addition to the General Standard for Labeling of Prepackaged Foods (CXS 1-1985), of the food, serving size and storage conditions.

METHODS OF ANALYSIS AND SAMPLING:

20. The analysis should be carried out by laboratories recognized by competent national authorities or by internationally recognized laboratories. Methods used for determinations should be validated and calibrated against a certified reference material, if available.

CONCLUSIONS:

21. Development of a standard or guidelines, and a harmonized framework for prebiotics, including general specifications and considerations is necessary to ensure and sustain quality prebiotic products on a global scale. This objective is in line with the Core Values of Codex, promoting collaboration, inclusiveness, consensus building and transparency, and follows the principles set as the Scientific Basis of Codex. Listed within the Codex Alimentarius Commission Strategic Plan 2014-2019, Goal 1: To establish international food standards that address current and emerging food issues and its corresponding objectives.

22. Development of a Codex standard will provide:

- a) A harmonized definition of prebiotic among Codex member countries.
- b) Agreed essential requirements and specifications for prebiotic that contribute to protecting the health of consumers, and ensuring fair practices in food trade.

23. The term prebiotic should be used only on products that feed probiotic strains residing in human or animal gut, with a reasonable expectation of delivering benefits for the wellbeing of the host.

RECOMMENDATION:

24. The Committee is invited to consider development of a standard or guidelines for prebiotics. A project document is presented in Appendix 5 and a proposal for a standard/guideline is attached in Appendix 6.

Appendix 1**Applicable Codex Standards:**

- i. General Principles of Food Hygiene (CXC 1–1969)
- ii. General Methods of Analysis for Contaminants (CXS 228-2001)
- iii. Recommended Methods of Analysis and Sampling (CXS 234-1999)
- iv. General Standard for contaminants and Toxins in Food and Feed (CXS 193-1995)
- v. General Standard for the Labeling of Pre-packaged Foods (CXS 1-1985)
- vi. Guidelines for Use of Nutrition and Health Claims (CXG 23-1997)

Appendix 2**Biography:**

1. FAO Report on Prebiotic (2007)
2. Minutes of the 50th Meeting of CCFA, Beijing, China 19-23 March 2018

Appendix 3

Glossary of terms:

Active Fluorescent Units	AFU
Codex Alimentarius Commission	CAC
Codex Committee on Nutrition and Foods for Special Dietary uses	CCNFSDU
Colony forming unit	CFU
Conference room document	CRD
Food and Agricultural Organization	FAO
International Code of nomenclature	ICNB
International Committee on Systematics of Prokaryotes	ICSP
International probiotic Association	IPA
List of Prokaryotic names with Standing in nomenclature	LPSN
World Health Organization	WHO

PROJECT DOCUMENT

1. PURPOSE AND SCOPE OF THE STANDARD / GUIDELINES:

At the present time, there is no internationally adopted definition for "prebiotic" although some countries have included regulations on "prebiotics" in their food legislation as an intervention to fill a legal gap in this area.

The proposed work is to address the current lack of harmonization which leads to issues and concerns for the regulators, prebiotics industry, and even consumers, with regard to quality, safety and labeling of "prebiotics" through the development of a standard or guidelines for prebiotics and food with prebiotics in order to harmonize framework that includes essential requirements for "prebiotics"

In accordance with the Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO) guidelines, the scope of the standard/guidelines is limited to the use of prebiotics in food, including dietary/food supplements. Drug applications and animal feeds are excluded from the scope of this work.

Therefore, it is essential that the industry have specifications for prebiotics in foods, in order to ensure the proper use of the term without contradicting national requirements or health claim provisions.

2. RELEVANCE AND TIMELINESS:

There has been growing interest in the concept of prebiotics and its role in human nutrition. Prebiotics are used in a variety of foods, the main category being dairy products, but they are also present as dietary/food supplements. Also they are found in other foods for infants, young children and adults. By definition, prebiotics should convey physiological and/or nutritional benefits for consumers. The general population is increasingly interested in maintenance of health and self-care and this may explain the consumers' interest in prebiotics. The establishment of a prebiotic guideline is supporting the United Nations sustainable development goal 3: "Good health and well-being", ensure health lives and promote well-being for all at all ages.

The scientific and clinical evidence have progressed rapidly, as has the development of a number of prebiotic foods. Unfortunately, misuse of the term prebiotic and confusion with Probiotic has also become an important issue, with many foods using the term without meeting the requirements criteria. At the same time, prebiotic foods have received the legitimate attention of regulatory authorities with an interest in protecting consumers from misleading claims.

Regulations on "prebiotics" are now under discussion in some countries while other countries have already established criteria and an organized framework for "prebiotics". With no international guideline, standard or reference harmonized, many different approaches would be taken.

Currently, prebiotics are distributed in 63 countries and prebiotic dairy-based powder milk are distributed in many Asian, Middle East & African countries (Dar Savanna Market Study 2017).

3. MAIN ASPECTS TO BE COVERED:

- i. The main aspect to be covered is the establishment of a harmonized definition of "prebiotics". It will be necessary to ensure that the definition is sufficiently broad to cover both natural & synthetic prebiotics.
- ii Establishment of a definition of "food with prebiotics".
- iii. Requirements for the evaluation of a "prebiotic" as a food ingredient.

The requirements should include the following aspects:

- a) Taxonomic characterization of the prebiotic.
- b) Demonstration of functional properties of the prebiotic, the functional properties of the prebiotic must be demonstrated by in vivo or in vitro tests, and by at least one human clinical study with the aim of getting scientific support to establish the health effects of the prebiotic.
- c) Safety of the prebiotic for the intended use: Establishment of safety criteria is essential for public health.
- d) Requirements for the evaluation of a "food with prebiotics".

The requirements should include the following aspects:

- a) Demonstration of health benefits of the food, the health benefit of the food must be documented by scientific substantiation by at least one human clinical study according to generally accepted scientific standards.
- b) Provisions for hygienic practice for production, handling, processing, storage and distribution of prebiotics and foods with prebiotics with reference to the General Principles of food Hygiene and other relevant codex tests.
- c) Provisions for chemical contaminants with reference to the General Standard for contaminants and Toxins in food and Feed.
- d) Provisions for labeling in accordance with the General Standard for Labeling of Prepackaged Foods (CXS 1-1985).
- e) Reference Methods of Analysis and Sampling.

Nutrition Fact Table parameters to include polysaccharide oligosaccharide.

All work will be coordinated with the applicable general subject Codex Committee to ensure the appropriate application of codex expertise and resources.

4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

General criteria

The codex Alimentarius Commission has a mandate of protecting consumer's health and ensuring fair practices in food trade. The proposed new standard/guidelines will meet this criterion by promoting consumer protection from the point of view of health, food safety and ensuring fair practices in the food trade and in particular:

i. Fair practices in food trade:

In the absence of an internationally accepted standard and guidelines, trading practices can become disordered and non-compliant.

ii. Food safety:

Establishment of safety criteria is essential for public health. It will be proposed that the safety of prebiotic as food for probiotic be demonstrated. In first place, a scientific approach for those prebiotics with an established safe history of use in foods, and for those newly recognized as prebiotics, an in-vitro evidence-based approach, shall all be utilized to demonstrate safety.

Criteria applicable to general subjects:

- (a) Diversification of national legislations and apparent result or potential impediments to international trade.

The lack of a harmonized definition for prebiotics and prebiotics food could result in many different definitions being developed for the purposes of inclusion in national regulations. The lack of a harmonized could result in unnecessary barriers to trade.

Also there could be misuse by manufactures of the "prebiotic" denomination and the misinterpretation of the prebiotic concept by consumers.

In addition, a harmonized definition for the term "prebiotics" could prevent its misuse on products label, communications or advertising.

- (b) Scope of work and establishment of priorities between the various sections of the work.

1. Definitions "prebiotics", food with prebiotics, "adequate amounts" and a health benefit on the host could be individually defined and addressed, as they are equally important requirements for all prebiotic products. It could be considered that health benefit refers to physiological and/or nutritional benefits.

2. Requirements for the evaluation of a prebiotics as a food ingredient.

- (c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

In 2007, scientific community and experts convened by FAO/WHO provided a scientific opinion on "prebiotics" agreed on its definition.

This report was followed by the "Guidelines for the Evaluation of Prebiotics in Food" where the FAO/WHO experts made several recommendations. One of these was to officially adopt the definition as well as more specific criteria as a prerequisite to qualify a product as a "prebiotic".

While the definition of prebiotics has been widely acknowledged by the scientific community and key players in the field of prebiotics, the FAO/WHO guidelines have not been implemented.

Only a few countries have regulations on prebiotics. Those countries that have developed legislation have different views on prebiotics in food, beverages and dietary/food supplements and their labeling.

In 2011, Sudan incorporated into its Gum Arabic Specification the application of Gum Arabic as having prebiotic activity.

(d) Amenability of the subject of the proposal to standardization:

The aspects that are essential for the identity of the product are: a harmonized definition, requirements for the evaluation of a prebiotic and the amount of prebiotic in the product.

(e) Consideration of the global magnitude of the problem or issue:

The establishment of eligibility criteria and an organized framework for the production of prebiotic products will provide proper guidance for global regulatory agencies, enabling them to prepare prebiotic specific regulations, and also will benefit consumers and industry.

5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES:

Development of guidelines and a harmonized framework for prebiotics, including general specifications and considerations is necessary to ensure and sustain quality prebiotic products on a global scale. The development of international standards, guidelines and other recommendations contributes to protect the health of consumers and to ensure fair practices in food trade.

This objective is in line with Core Values of Codex, promoting collaboration, inclusiveness, consensus building and transparency, and follows the principles set as the Scientific Basis of Codex, listed within the Codex Alimentarius commission Strategic plan 2014-2019.

The new work proposal will contribute to:

Strategic goal 1: "Establish international food standards that address current and emerging food issues"

1.2 Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.

The lack of harmonized regulations on prebiotics has been clearly identified as an emerging issue related to food safety, nutrition, and fair practices in the food trade.

1.3.2 Promote cooperation with other international governmental and non-governmental standard setting organizations to support development of relevant Codex standards and to enhance awareness, understanding and use of Codex standards.

In order to optimize the development of the standard/guidelines will be very important facilitate the effective participation of organizations and all Codex members.

Strategic goal 2: "Ensure the application of risk analysis principles in the development of Codex Standards:

6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS:

The standard/guidelines, once adopted, would be available for use as appropriate in future amendments of specific commodity standards and/or general standards.

The proposed work will make reference to relevant standards and related texts in particular of the following:

- General Principles of Food Hygiene (CXC 1:1969).
- General Standard for Labeling of Prepackaged Foods (CXS 1-1985)
- General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995)
- Guidelines for Use of Nutrition and Health Claims, which refer to the use of health claims in food labeling and, where required by the authorities having jurisdiction, in advertising of foods. The guidelines are applied with the aim of assisting competent national authorities in their evaluation of health claims in order to determine their acceptability for use by the industry (CAC/GL 23-1997).

7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE:

No expert advice other than which is to be found in the CCNFSDU is required at this time.

8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR:

No technical input other than which is to be found in the CCNFSDU is required at this time.

9. PROPOSED TIME-LINE FOR COMPLETION OF THE NEW WORK:

Subject to approval by the Codex Alimentarius commission in 2019. The draft standard/guidelines will be submitted for consideration by CCNFSDU in 2019 and the work is expected to take at least three sessions of the Committee.

PROPOSED DRAFT STANDARD/GUIDELINES ON PREBIOTICS**1. PURPOSE:**

To establish guidance to assist competent national authorities in their evaluation of "prebiotic" in order to authorize a product as a probiotic strain.

The recommendations focus on the criteria for substantiating that a microorganism addresses the minimum requirements to be considered probiotic microorganism and the general principles for the systematic review of the scientific evidence.

The recommendations include considerations of safety within the evaluation of a prebiotic product, but are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Codex Standards and Guidelines or general rules of existing national legislations.

2. SCOPE:

This standard applies exclusively to prebiotics used as ingredient in the manufacture of food, including dietary/food supplements. Drug applications and animal feeds are excluded from the scope of the standard/guidelines.

3. DESCRIPTION:

3.1. Prebiotic means food for probiotics that, when administered in adequate amounts, confer physiological and/or nutritional benefits on the host.

3.2. Food "with prebiotics" means a food which has a content of prebiotics.

4. REQUIREMENTS FOR THE EVALUATION OF A PREBIOTIC:

4.1.1: Minimum requirements:

4.1.1.1: Taxonomic characterization of the prebiotic.

4.1.1.2: Characterization of the prebiotic (in vivo e in vitro)

The characterization of a prebiotic should be demonstrated by in vivo or in vitro tests (human or animals studies) with the objective of getting scientific endorsement to demonstrate it increases the number of probiotic bacteria in the colon.

4.1.1.3: Demonstration of functional properties of the prebiotic:

The physiological and/or nutritional benefits of the prebiotic should be documented by scientific substantiation by at least one human clinical study, statistically supported, according to internationally recognized scientific standards.

All the studies to screen the potential prebiotics, including human trials, should be conducted by institutions accepted by competent national authorities or by institutions with wide international recognition, following international standards.

4.1.1.4: Safety of the prebiotic for the intended use:

The prebiotic should be safe for the intended use (i.e. for the targeted consumer and in the conditions of recommended use).

The safety of a prebiotic should be demonstrated by in vivo or in vitro tests with the objective of getting scientific endorsement to ensure the safety of the prebiotic.

4.2: FOOD WITH PREBIOTICS:

The manufacturer should prove that the prebiotic keeps its functional properties in the food by in vivo or in vitro tests, and by at least one human clinical study with the aim of getting scientific support to establish the benefits of the prebiotic. Then, the food can be authorized as a food "with prebiotics", and it should be labelled in accordance with the item 8.2

4.2.1: Minimum requirements:

4.2.1.1: Amount of prebiotic:

The content of polysaccharide or oligosaccharides in the food recommended for daily consumption should be 10g.

4.2.1.2: Demonstration of physiological and/or nutritional benefits of the food:

The benefit of the food should be documented by scientific substantiation by at least one human clinical study, statistically supported, according to internationally recognized scientific standards.

Animal and in vitro studies are considered supportive evidence. Supportive evidence refers to studies/data which, on their own, are not sufficient for the scientific substantiation of a benefit and that may be part of the totality of the evidence only if pertinent human studies showing an effect of the food/ingredient are available.

All the studies to screen the potential benefits, including human trials, should be carried out with the food as it is consumed. Those studies should be conducted by institutions accepted by competent national authorities or by institutions with wide international recognition.

4.2.2.1: Products with prebiotic activity demonstrated:

In case the prebiotic is already known to have prebiotic properties, it is safe for human consumption and, it has an established safe history of use in foods, it should only be demonstrated that the prebiotic keeps its functionality/efficacy in the food where it is added, within the proposed end use of the food.

Efficacy study refers to an intervention study (in humans, in animals) which investigates the relationship between the food/ingredient and the claimed effect.

4.2.1.2.2: A change in food matrix of an authorized "food with prebiotics"

When the food producer changes the composition of a food that has been already authorized as "food with prebiotics", he should demonstrate the adequate survival of the prebiotic in the food throughout its shelf life.

4.2.2: Mixture of two or more prebiotic with prebiotic activity:

If a combination of two or more prebiotic is added, each of the prebiotic in the mixture should be proved to have prebiotic activity and to meet the minimum requirements set out in 4.1.1.

In addition, it should be demonstrated that the combination of prebiotic maintains its functionality/efficacy in the food in which it is added, as it is to be consumed.

5. ASPECTS OF PRODUCTION:

Prebiotics and food with prebiotics should be prepared, processed, packaged, transported and stored within a closed and controlled system to provide utmost quality and purity, and to address quality control aspects and quality assurance aspects.

6. CONTAMINANTS:

The products covered by these Guidelines shall comply with the maximum levels of the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).

7. HYGIENE:

It is recommended that the products covered by the provisions of this standard/guidelines be prepared and handled in accordance with the General Principles of Food Hygiene (CXC 1-1969), and other relevant Codex tests such as Codes of Hygienic Practice and Codes of Practice.

8. LABELLING:

In addition to the General Standard for labeling of Prepackaged Foods (CXS 1-1995) the following specific provisions apply:

8.1: Name of the Prebiotic product.

8.2: name of the food

The product should be labeled as "Name of the food", the blank being filled in with the wording: "Contain prebiotics" or "With Prebiotics".

8.3: List of ingredients.

8.4: Serving size:

The serving size that needs to be consumed daily to obtain the documented physiological and/or nutritional effect, which should be equal to the daily amount tested in human studies, should be mentioned.

8.5: Storage conditions:

The storage conditions of the product to maintain its quality should be specified.

9. METHODS OF ANALYSIS AND SAMPLING:

The analyses should be carried out by laboratories recognized by competent national authorities or by internationally recognized laboratories. Methods used for determinations should be validated and calibrated against a certified reference material, if available.

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JUSTIFICATION FOR ESTABLISHING INTERNATIONAL GUIDELINE FOR PREBIOTIC

Background

In 1908 Dr Mitchen Cots won Noble price for discovering the friendly Probiotic bacteria and said , If adults maintains the same number of probiotics as those found in children who breast fed for two years , then they may live double his age (he was 70 years old when he made that statement),

Bogratt , the Gidfather of Medical doctors wrote in Doctor'Oath :

Let food be your Medicine and let Medicine be your food

However, in 1928 AntiBiotics which kills both bad and friendly bacteria , was discovered and was commercialized in 1942 . The last sixty years of the nineteenth century witnessed escalation of lifestyle diseases as well as use of AntiBiotic drugs . With absence of

The friendly probiotic bacteria and it's Prebiotic food from both clinical research and trading circles.

Recent clinical research has proven that most lifestyle diseases are caused by the deficiency of the friendly probiotic microbiota in the colon .

The WHO expert group (2001)defined probiotics as 'live microorganisms which when administered in adequate amounts confer a health benefit on the host'. The prebiotic which is food for probiotics is defined according to FAO working group (2007) as "A prebiotic is a non-viable food component that confers a health benefit on the host associated with modulation of the microbiota'

2)Nutritional Justification

New scientific and clinical research has proven that prebiotic and probiotic will play a leading preventive and Curative role in the fight against lifestyle diseases .

However Most Natural foods lack prebiotic nutrients and at the same time most people , being health professional s or non-professionals do not differentiate it from Probiotics. The two names have almost same letters and pronunciation. Since 2007 the market was flooded by Probiotic nutrients products , both as standAlone and as an ingredient . Probiotic products can not substitute Prebiotic products for many reasons as follows :-

- a) Technological challenges prevents production of high numbers of probiotic strains which are needed in trillion amounts to confer significant health benefits in the colon host
- b) There are between 500 to 1000 types of friendly probiotic strains in the colon and the maximum numbers of strains used in probiotic products has not yet exceeded 12 strains
- c) The feeding of the colon with few number of strains may cause imbalances in the total number of strains available in the colon
- d) The already low number of strains used is expected to loose their number having to pass through the acid medium of the stomach and the base medium of the small intestine

- [] Despite these challenges , the market has seen the release of so many unsuccessful probiotics

Products . In 2009 EFSA has disqualified over 183 probiotic products and recent research has shown that probiotics are not effective (,,)

As a result of this nutritional gap due to ineffective probiotics and unavailability of natural foods with rich levels of prebiotic nutrients many investors has

Managed to extract prebiotic Oligosaccharides from a non edible sources like chicory roots

Unfortunately Gum Arabic being the only edible plant with rich prebiotic Polysaccharides (over85%) is classified as food Additive by WHO/FAO , and is used like that for the last 60 years .

If an international Guideline for prebiotic is established then natural and non natural prebiotic could be recognized globally and have it differentiated from probiotics or additive use

3. Trade Justification Having separate International guidelines for probiotics and Prebiotics will will help fair trade and in particular open new investment opportunity to trade Gum Arabic as Prebiotic to increase both its use and prices compared to its current limited use as additive as well as its traded price . Being an additive Gum Arabic is not allowed to be used in baby foods , but if the Guideline recognize it as Prebiotic nutrients then it will be used in the baby food sector worth of \$600 billions.